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D4.5 Service Portfolio for Sustainability

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0.1	First draft structure (EMPIRICA)
0.2	Case studies Belgium and Portugal (EHTEL)
0.3	Stakeholder and customer roles (IHD, EHTEL)
0.4	Chapter 2, Chapter 3, Annexes (EMPIRICA)
0.5	Revision and completion of Chapter 3, Chapter 4 (EHTEL)
0.6	Revision and completion of Chapter 3, Chapter 5 (IHD)
0.7	Chapter 6, Recommendations for sustainability (EMPIRICA, EHTEL, iHD)
0.8	Executive summary (EMPIRICA, EHTEL, IHD)
0.9	Update with the work related to adjusting the service portfolio and the business model in preparation for the transitional period
1.0	Finalisation and submission

Acronyms and abbreviations

Acronym / abbreviation	Meaning
AAL	Ageing Well in the Digital World
AHA	Active and Healthy Ageing
AOK	Allgemeine Ortskrankenkasse
API	Application Programming Interface
BHBM	Be Healthy Be Mobile
BM	Business model
BMC	Business Model Canvas
BMTF	Business Modelling Task Force
CBC	Capacity Building and Collaboration
CoP	Communities of Practice
COPD	Chronic obstructive pulmonary disease
DHI	WHO's Digital Health and Innovation Department
DIH	Digital Innovation Hub
DTA	Digital Therapeutics Alliance
EBP	Evidence-based practice
EC	European Commission
EEIG	European Economic Interest Grouping
EFPIA	European Federation of Pharmaceutical Industries and Associations
eHN	eHealth Network
EHR	Electronic Health Record
EIP on AHA (EIP-AHA)	European Innovation Partnership on Active and Healthy Ageing
EIT Health	European Institute of Innovation and Technology
EMR	Electronic Medical Record
ENISA	European Union Agency for Cybersecurity
EU	European Union
FAIR data	Data which is findable, accessible, interoperable and reusable
FHIR	Fast Healthcare Interoperability Resources
GA	Grant Agreement
GDPR	General Data Protection Regulation
GHI	Global Initiative for Interoperability
GPW	Thirteenth General Programme of Work
HCP	Healthcare professional
HIS	Health Information System
HIV	Human immunodeficiency virus
HTA	Health Technology Assessment
ICT	Information and Communication Technology

Acronym / abbreviation	Meaning
ICU	Intensive care unit
ISO	International Organization for Standardization
JASEHN	Joint Action to support the eHealth Network
JIC	Joint Initiative Council on Global Health Informatics Standards
KT	Knowledge tool
MDD	EU Medical Devices Directive
MoU	Memorandum of Understanding
MS	Member State
MVP	Minimum viable product
NCD	Non-communicable disease
NPO	Non-Profit Organization
NSCC	Norwegian Smart Care Cluster
OECD	Organisation for Economic Co-operation and Development
PCP	Pre-commercial procurement
PHR	Personal Health Record
PPI	Public procurement of innovation
R&D	Research and Development
RTTE	Radio Equipment and Telecommunications Terminal Equipment
SA	Service Area
SDG	Sustainable development goal
SDO	Standards Development Organisation
SDO	Standards Development Organisation
SLA	Service level agreement
SME	Small and medium sized enterprise
SOA	Service-oriented architecture
UMHAI	Unique Mobile Health Application Identifier
WHO	World Health Organization
WP	Work Package

Executive Summary

This report documents the work undertaken to develop a business model for the European Innovation and Knowledge mHealth Hub. The Hub is managed by WHO, ITU and the Andalusian Regional Ministry of Health (Spain), with the contributions from other 18 Hub partners, forming the Hub consortium. The Hub is funded by the European Commission as a project until February 2022 and will then enter a Transitional Period expected to work towards achieving financial sustainability beyond that period.

The report details the approach to developing a service portfolio for the Hub which will ensure service continuity and pave the way for sustainability of the Hub beyond the project duration.

The overall Hub service portfolio and business model is the result of applying various methods and ensuring dialogue with potential customers, partners and wider stakeholders in the field of mHealth and digital health. A needs-based approach has ensured there is demand for the services proposed and allows for prioritising the roll-out of services based on customer needs and project-related limitations.

Following a mid-term evaluation of the Hub project, it was recognised that the project outcomes in the form of project deliverables, the web hosted resources, the programme support of the piloted services to countries and the online community engaged through Hub Talks were valuable to sustain but would not have sufficient committed and investing organisations to finance the Hub immediately after the project. A Transitional Period was envisaged as a period of time when an assured budget would be available to cover the operating infrastructure, service development and business development costs whilst income streams from memberships, services and consultancy could grow.

Consequently, the report is updated with details about the consortium activities to plan and prepare the Transitional Period, planned activities and services during that period, the governance mechanism which will be followed, and contractual arrangements between the WHO, ITU, i~HD, EHTEL and OuluHealth that need to be in place, for all parties to actively involved in launching the Transitional Period after the lifetime of the Hub as an EU project ends.

1 Introduction and background

This report details the approach and work undertaken towards elaborating a service portfolio and a sustainable business model for the European mHealth Hub.

1.1 Objectives of the European mHealth Hub

The European mHealth Hub is an EU-funded project running in the period March 2017 – February 2022, whose main objectives are to:

- establish an EU mHealth Hub for **collecting and disseminating research and experience** relating to the large-scale implementation of mHealth programs and good practices.
    - produce Knowledge Tools (KTs) for health systems and services on non-communicable diseases (NCDs).
    - provide a code of ethics for mHealth
- **build capacity** for the Hub to be able to support Member States in implementing national mHealth programs.
- define a **business model** for the Hub activities which ensures its **service continuity and financial sustainability** beyond the project duration.

Further to the main objectives, the **long-term vision** of the Hub is to:

- Serve as a **focal point for expertise on mHealth** in the WHO European Region.
- Assist countries in **implementing mHealth practices**
- Act as **facilitator of innovation** in mHealth
- Act as an **accelerator** for the EU Digital Single Market
- Serve as an **example** for the creation of similar Hubs in other regions of the world

1.2 Sustainability-related objectives

From the main objectives above, this report focuses on defining a **business model** for the Hub activities which ensures its **service continuity and financial sustainability** beyond the project duration. The operational sub-objectives to achieve this include:

- Identifying the target stakeholders / customers who will benefit from the Hub services
- Developing value propositions for the different stakeholder / customers. This includes selecting appropriate channels and working towards lasting customer relationships.
- Defining the activities necessary to fulfil the value propositions (service portfolio)
- Identifying necessary knowledge holders and experts who can carry out the activities, as well as necessary infrastructure in place to enable service delivery.
- Establishing partnerships with stakeholders to support the service delivery
- Elaborating a revenue model to ensure future stakeholders / customers can benefit from the Hub services while ensuring the Hub financial sustainability.

1.3 Relation to the Hub workplan and mode of work

The key Hub activities linked to this report include:

- A4.1.3 Adapting governance structure and defining governance mechanisms. Lead: ITU, WHO and FPS
- A4.1.7 Establishing synergies with existing operational frameworks. Lead: EHTEL as subcontractor to FPS
- A4.1.8 Defining mechanisms for attracting additional funds. Lead: IHD as subcontractor to FPS
- A4.2 Establishing Hub's portfolio of services, which comprises:
    - A4.2.1 Defining the portfolio of services that will be offered to stakeholders interested in large-scale mHealth solutions implementation. Lead: EMPIRICA as a subcontractor to FPS
    - A4.2.2 Defining business models for advanced consultancy services. Lead: EMPIRICA as subcontractor to FPS

The key task leaders – EMPIRICA, IHD and EHTEL, subcontractors to FPS and forming the Hub's Business Model (BM) core team – have worked closely with the three beneficiaries – WHO, ITU and FPS – via dedicated regular meetings. For the business modelling activities in the project, the BM core team has established a Business Modelling Task Force (BMTF) comprising Hub subcontractors with more substantial effort contribution – SPMS, HL7, University of Agder, Technical University of Vienna, Ericcson NT, Estonian CHC and PCHA/HIMSS.

As the Hub service portfolio is a global topic for the Hub, several events have been organised with the entire Hub consortium of beneficiaries and subcontractors. The latter have all been involved in several requests for input and feedback to the ongoing work feeding into D4.5.

2 Summary of the approach

To elaborate the Hub's service portfolio and business model, the BM core team has applied a stepwise approach supported by the use of well-known business planning methods.

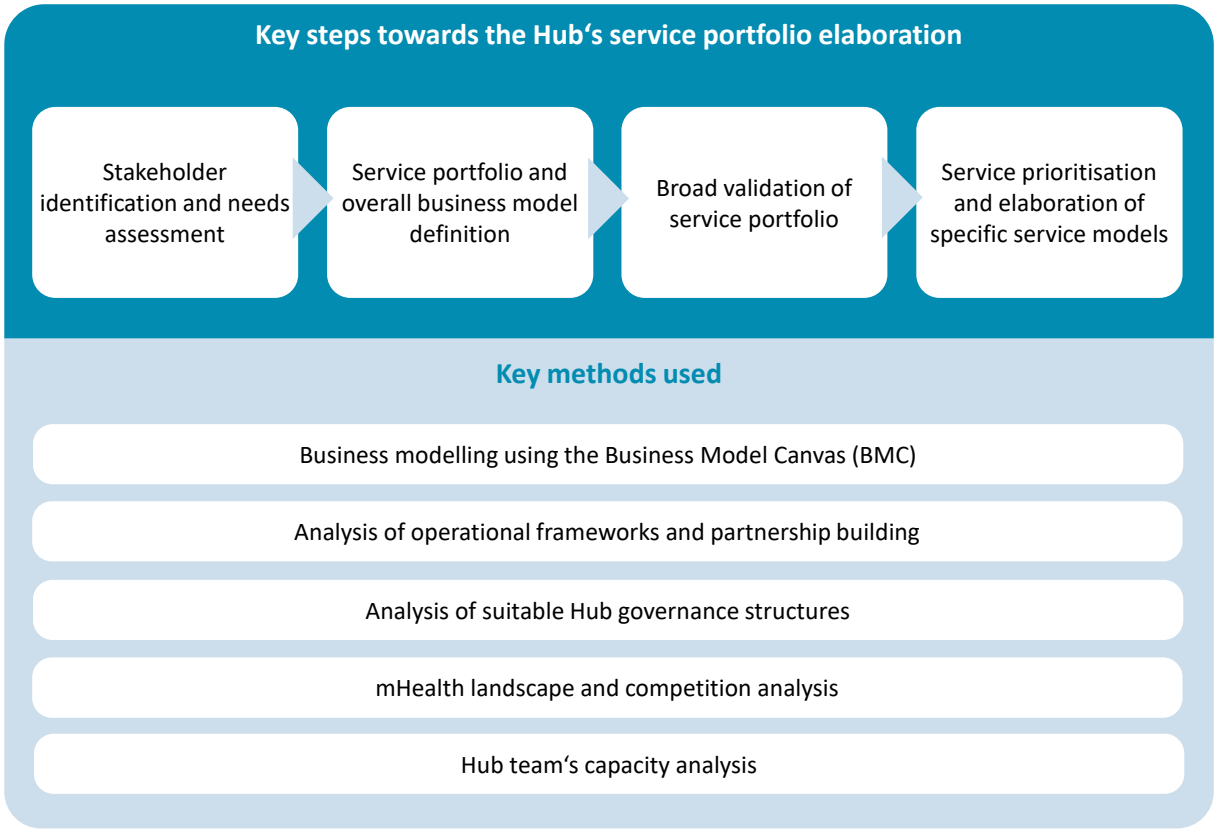


Figure 1. Overview of the approach

An **analysis of the different stakeholders** relevant to the Hub's activities was carried out, resulting in the identification of thirteen broad categories of stakeholders:

1. Patients and the public
2. Health and care professionals
3. Health and care provider organisations
4. Non-profit and charitable health organisations
5. Health and care payers
6. Public health agencies
7. Assessment and licensing bodies
8. eHealth competence centres
9. Policymakers
10. Innovation sponsors
11. Industry associations
12. Industry
13. eHealth ecosystem

The potential of each stakeholder group was analysed with regards to different roles they can assume when interacting with the Hub (user, partner, customer). The full stakeholder grouping and analysis can be found in Annex 1.

A **needs assessment** was performed in order to understand the main potential customers' needs around the use of mHealth knowledge and how the Hub can support this process by providing tailored services. Various sources were used of the assessment, including:

- Insights from the webinar "European mHealth Hub Support for Country-Level Implementation" held on 30 June 2020, with participating potential customers from Hungary, Belgium, Germany, Finland, Czech Republic, Republic of Croatia, Romania, Norway, Spain, Cyprus, Regional Cooperation Council for Western Balkans, North Macedonia, Poland, Turkey, Iceland, Republic of Montenegro, Moldova. Details can be found in deliverable D4.3.
- Results from a Hub survey addressed to the members of the eHealth Network (eHN). Respondents provided insights about the expected areas of support and the preferred delivery methods. More details can be found in deliverable D4.3.
- Feedback from the Hub's 2020 call for expressions of interest, answered by 10 countries from Croatia, Turkey, Romania, Poland, the Czech Republic, Hungary, Regional Cooperation Council + South Eastern Europe Health Network (covering 6 Western Balkans Economies: Albania, Bosnia and Herzegovina, Kosovo, Montenegro, North Macedonia and Serbia), Germany, Austria, and Finland. More details can be found in deliverable D4.3.

The full needs assessment can be found in *Annex 2*. It allowed the BM core team to derive a **first version of the service portfolio**, which can be found in *Annex 3*.

The first version of the service portfolio was introduced to potential customers in a dedicated webinar organised by the Hub on 23 October 2020. It brought together 18 representatives from governments, industry, associations, healthcare professionals / providers, insurers, innovation hubs, and developers. The webinar provided valuable insights, which are summarised in a webinar report, found under *Annex 4*.

The webinar helped to inform **a second version of the service portfolio**, as well as the emerging high-level business model of the Hub (see section 3).

The service portfolio was next **validated with stakeholders though an online survey** launched by the Hub in order to better understand what features of the proposed Hub are most attractive and likely to be most useful to each stakeholder group, and to discover what in-kind or financial contributions might be acceptable to them. Participants were asked to rate the usefulness of the services and features of the Hub, indicate what form of financial or non-financial contribution is acceptable (e.g., membership fee, paying for access to a specific service only, sponsorship, in-kind contribution, and promotion).

In total, 89 respondents completed the survey. Of these, 53 respondents were mHealth users, 14 were mHealth payers and decision makers, and 22 were providers and enablers of mHealth solutions. Most services presented were considered highly useful, where the agreement with the respective feature's usefulness ranged from 64% for personalised advice and consultancy to 84% for evidence of health

outcomes, costs-benefit and user acceptance assessment. On average, more than 30% of all survey respondents would be willing to pay for a mHealth Hub membership through an annual fee in order to access any one of the proposed features (accessing the Hub's network of experts was voted by 43% of the respondents). Even though there was a clear favour for membership, survey respondents expressed their willingness to pay for accessing a specific service when needed. Approximately half of the respondents expressed their willingness to contribute to and to promote the Hub's services. A detailed analysis of the survey responses can be found under *Annex 5.*

The survey also contributed to designing the **third version of the service portfolio** (see chapter 3). In a next, currently ongoing step of this process, the BM core team is elaborating details of the business model for each service with the support of the BMTF. Business modelling follows the Business Model Canvas (BMC) approach as a widely used technique for creating and describing business models (see *Annex 6* for more details about the BMC approach).

In parallel to this work strand, essential aspects required for the Hub to function have been explored.

The BM core team has **analysed different operational frameworks**, including Member State frameworks, private or collaborative frameworks, and networks and associations, in order to better position the Hub and at the same time analyse possible synergies and opportunities for partnerships. For more details, see chapter 4 and *Annex 12*.

As some of the analysed operational frameworks represent potential partners for the Hub, this aspect has also been addressed in the interviews. An important outcome of this process is the Hub's **collaboration with ORCHA**, an mHealth assessment organisation. In a series of discussions, the Hub and ORCHA have been and are exploring a potential partnership to strengthen the Hub's technical expertise and provide added value to the Hub network when it comes to assessment expertise.

An **analysis of the mHealth landscape** and organisations offering similar services to the Hub has helped to position the Hub within the mHealth domain as a unique initiative with a clear vision, mission and service offer. For more details about the landscape and competitor analysis, see *Annex 7*.

The Hub team has also identified several **governance options** which the Hub can adopt beyond the EU-funded project duration. The options were discussed in a first sustainability workshop in end May 2021 and will be further discussed with the Hub partners in the following months.

Another step towards sustainability was to **understand Hub partners'** (3 beneficiaries and 18 subcontractors) **strengths and capacities to support the future Hub services**. The partners were asked to elaborate on the services they could generally contribute to, based on realistic capacities of their organisation and give concrete examples. A detailed analysis of this mapping is found under *Annex 8*.

The process followed by the Hub team has allowed for explorations beyond the scope of services described in the current workplan and has ensured that the proposed Hub service portfolio is demand-driven and reflects well potential customers' needs. It has also revealed that the workplan and expected outcomes of the Hub as a funded project are not completely aligned with customers' expectations. This is not particularly surprising, considering the dynamic nature of the mHealth topics in recent years and the fact that as an EU project, the Hub has limited flexibility. This fact has, however, started an internal reflection between the report authors and the Hub beneficiaries, leading to a **common view of necessary strategic and operational adjustments and considerations** in order to ensure the post-project sustainability of the Hub. These considerations include:

- Distinguishing between the current period of the Hub operation, focusing on the project workplan as defined in the Grant Agreement (GA), and a transitional period which could accommodate the full service portfolio development.
- The need for the Hub to identify at this stage the most suitable future governance that would provide for agile decision making and operate more like an SME rather than an EU project in order to become self-sustainable.

In line with this reasoning, the Hub management team has initiated a consultation with the European Commission about a possible extension of the Hub project to accommodate a transition period.

3 The Hub service portfolio and business model

3.1 Hub mission and vision

At European level, there is a solid ground for mHealth, with an enormous wealth of apps that can serve multiple purposes and multiple stakeholders. Yet the integration into the healthcare systems, the adoption and use of the apps require that multiple complex dimensions needed to be brought together and harmonised at various levels. The desired future position of the European mHealthHub is to serve as …

Vision

… a thriving knowledge sharing and learning mHealth environment which promotes adoption and use of mHealth to provide better health and care to European citizens.

The Hub should aim to accelerate and promote the adoption and use of mobile health, to provide better health and care to European citizens.

Mission

Accelerating the adoption of mHealth in Europe's health systems

The Hub aims to achieve this via several operational goals:

O1. Raising awareness among stakeholders about mHealth's important role in supporting health and care systems

O2. Promoting knowledge exchange and sharing of mHealth practices, initiatives, evidence, incl. encouraging the capturing of undocumented practices

O3. Connecting relevant stakeholders who wish to collaborate on adopting and innovating in mHealth

O4. Offering personalised support and advice to stakeholders interested in advancing mHealth in their regions and countries

O5. Championing best practices in Europe, e.g., with regards to ensuring quality and transparency of mHealth solutions and services

O6. Fostering harmonisation of approaches, rules and standards across Europe towards cross-border mHealth synergies

3.2 Hub service portfolio

The portfolio of Hub services can be grouped into the following service areas (SAs):

- Service area 1: Education, networking and mHealth promotion
- Service area 2: Access to the Hub's knowledge resource library and expertise
- Service area 3: Personalised support in mHealth implementation

3.2.1 Education, networking and mHealth promotion (SA1)

Link to operational goals	O1, O3, O6
Short description	The Hub offers several activities for promoting the adoption and use of mHealth by raising awareness of mHealth benefits and good practices, facilitating collaboration and innovation, and encouraging collaboration towards common principles and standards for mHealth. The Hub organises regular events (Hub Talks) to enable a continuous discussion around mHealth topics which are of most interest to the community. The Hub is also working towards establishing a trusted community of practice for its members, which enables them to exchange knowledge, establish new partnerships and collaborate at international level.
Key services and value propositions	• Webinars, conferences, workshops, training courses offered by Hub experts • mHealth communities of practice • Matchmaking and twinning between mHealth initiatives

SA1-1: Webinars, conferences, workshops and training courses

mHealth programmes require multi-stakeholder engagement and collaboration, the field is rich with innovation at a technical level and also at usage and benefits levels. The experiences and insights vary across disease areas and across countries. For these reasons there is a huge opportunity for the Hub to stimulate and accelerate mobile health adoption through events and fora that brings stakeholders together to learn from each other, share experiences and to co-create solutions to challenges. There is a value opportunity and a business opportunity for the Hub to organise conferences that showcase success and disseminate learnings, as well as deeper dive workshops to explore specific topics and to develop strategies for them. The Hub should explore hosting its own annual conference, potentially at a European level, holding regional conferences and workshops, and contributing presentations and talks and exhibition stands at a wide range of other relevant events being held by other organisations. A variable business model may be required for these events, some attracting a participant fee, some being sponsored and some being funded from its core operating budget.

The many diverse organisations in this landscape inevitably experience a turnover of staff. Even existing staff may find themselves with a need to up skill in an area outside of their existing knowledge base, in order to play an appropriate role in designing or implementing or adopting or governing a new mHealth programme. There is therefore a business opportunity as well as a community need for training courses and education in the various knowledge and skills capabilities needed

within mHealth. Training courses are likely to be income generating through registration fees, although costs including tutor fees will need to be covered.

SA1-2: Communities of Practice

Communities of Practice (CoP) are primarily formed by people who engage in a process of collective learning in a domain of common interest where complementarity of skills, knowledge, perspectives and insights make for a sum that exceeds the result of their addition.

The mHealth Hub communities of practice will exchange knowledge but they also innovate, map knowledge and identify gaps, seeking ways to expand and improve their collective capacity to solve problems. Typical activities will include problem solving, requests for information, exchange of experiences, opinions and ideas, re-using of assets, collection of evidence and peer reviewing. Through these activities they can grow confidence in own decision making.

It is anticipated that in the future much of the current activity of the Hub for collecting information, analysing and drafting reports and recommendations and assessments by the Hub on key mHealth aspects, will leverage on these communities .

SA1-3: Twinning

A specific form of sharing and learning is the twinning of sites (countries, regions, cities or provider networks) that have a common ambition to deliver a successful mHealth programme for similar patient groups or leveraging a similar technological approach. These sites may be at different stages in their evolution, either one more advanced than the other or each having pursued steps in a different order. Typically, a twinning originator (the owner of a successful mHealth practice) would share their knowledge with one or more adopters following a pre-defined workplan. The Hub is not an owner of that knowledge and serves as i) a matchmaker between originators and adopters, ii) as a facilitator of the twinning, and iii) as a promoter of the documented outcomes which may be of interest to other Hub members (customers). Hub partners are very experienced in facilitating twinning activities across Europe, with empirica having supported 20 twinning activities in the ScaleAHA1 study and 24 twinning activities in the DigitalHealthEurope2 project.

[1] http://www.scale-aha.eu/home.html

[2] https://digitalhealtheurope.eu/

3.2.2 Access to the Hub's knowledge resource library and expertise (SA2)

Link to operational goals	O2, O5
Short description	Through its outreach in the WHO European Region, the Hub is continuously extending its mHealth knowledge resource library. It contains information on mHealth use and implementation, such as summaries of success factors, initiatives, solutions, and evaluation evidence. In addition, the Hub is producing own research, such as an overview of assessment frameworks for mHealth, documented mHealth policy initiatives, evidence of health outcomes of mHealth practices, a quick guide to ethics for mHealth, etc. The Hub's knowledge resource library and expertise is growing rapidly, but it is only as good as the community which contributes to it. mHealth stakeholders are invited to share their experiences and resources and be acknowledged as contributors to the Hub's library.
Key services and value propositions	To offer access to a structured repository of knowledge for various stakeholders on essential mHealth topics, such as: • Policy initiative areas • Evidence of health outcomes, cost-benefit and user acceptance assessments • Reimbursement and incentive models • App certification criteria, models and frameworks • Digital health literacy initiatives • mHealth programmes implementation support guidelines and roadmaps • Innovations and horizon scanning relevant to mHealth solutions • mHealth best practices on integration of mHealth into healthcare systems • Quick Guide to mHealth ethics

SA2-1: Policy initiatives areas

This service is meant to provide an overview of the policy areas in which Member States have been considering the extended use of mHealth solutions. This service will build on the outcomes delivered by WP5. The creation and maintenance of this catalogue of policy initiatives areas requires for the Hub to be in direct interaction with the right people in the different countries and to create the needed infrastructure to make the data capture both accurate and qualitative. The Hub will thus have to start with the countries which have already documented mHealth policies and develop a strategy to continuously identify the Member States (or Regions) which start developing policies. The areas in focus are not limited to those initially identified in WP5 and will also consider overarching policies which make the use of mobile solutions generically possible in the global eco-system (such as for example the focus on secured and binding mobile identification and authentication) or the policy developed to make mobile data FAIR compatible. The expected resources made available to the Hub members is a searchable catalogue of policy areas matched to a number of policy related criteria together with a link to the best

translated examples of the description of those implemented policies and links to the relevant documentation.

SA2-2: Evidence of health outcomes, cost-benefit and user acceptance assessments:

This service aims at collecting the documentation gathered by digital solutions, operational frameworks, official assessment frameworks or other bodies on the benefits mHealth solutions can provide for the citizen/patient (clinical outcome, quality of life), the healthcare providers and the health system in general (with a focus on quality, effectiveness and efficiency). This needs to be dealt both at individual solutions level but also considering the importance of external factors linked to the context, the culture and the organisation set up at the project or service level through independent competent assessment teams. The objective is here to identify with more clarity the external factors which have a major impact on the solution deployed and the possible risk mitigation strategies.

As for health outcomes and cost-benefit, the Hub proposes to privilege information validated by official public bodies or HTA agencies - usually in the context of reimbursement- but will also promote validated scientific documentation and conduct continuous literature review. The assessment reports of public bodies are for now not always in the public domain and this will require specific discussions with each partner body.

As for User Acceptance, the Hub envisages to rely on the methodology and criteria already established by a number of operational frameworks (See SA2.4).

SA2-3: Reimbursement and incentive models:

The service requires a close collaboration with the countries or regions, including health insurance bodies, which have already set up a reimbursement or incentive model for mHealth applications. The Hub proposes to take stock of the models developed, mapped them against a number of pertinent criteria and provide validated translation of the most advanced models. The Hub also proposes to reference and tag specifically the solutions which have been validated by those models in connexion with SA2.4. Finally, this service area will also feed one of the priority topics of the SA1.2 (Community of practice).

SA2-4: App certification criteria, models and frameworks:

KT1 has currently provided a document which provides a global overview of existing Assessment frameworks used by Member States and other bodies. Although useful for interested Hub clients to have a global idea of the existing situation, it is however not fit for purpose when considering concrete uses by the priority clients as access to the referenced resources of the different frameworks remains cumbersome, and non-actionable meaningful search action is currently possible. The progressive development of adapted search criteria, first simpler and progressively more complex (requiring thus more analysis and the adding of new data), is thus a preliminary condition for the attractivity and sustainability of this

service. The Hub thus enhances the intelligence of the customer in accessing and selecting the most appropriate information and resources based on their own needs. The KT1 guided assessment development is comprised of several steps, which include first identifying and accessing assessment criteria which would meet existing broad assessment categories and identifying the most rare and innovative resources and then progressively evolving towards a more semantic oriented search which would require the active use of tagging and the possible addition of supplementary metadata which would make the understanding of the information both more straightforward and precise. A structural partnership with the most prominent public and private frameworks will also need to be established and mutual updating notification protocols will need to be defined in order to guarantee the overall sustainability of the service. This service can be considered as an important enabler for other services such as the consultancy services (SA3) to be offered and a suitable user interface could be offered.

This service could possibly provide two sub-services:

The first outcome is to provide a validated and actionable (with a link to the native frameworks) catalogue of criteria- mapped against the active operational frameworks – and for each of the main criteria retained the functionalities which need to be evaluated in priority. In a second step, thanks to a semantic tagging of the criteria and functions, an operational search tool will be developed to allow the Hub clients to look after criteria which matches specific keywords. Here again continuous update of this catalogue is needed.

The second possible outcome is to provide an overview of the digital solutions themselves assessed by the different public and private partner frameworks which will accept to collaborate with the Hub, providing the clients with an access to a dedicated search tool which would make it possible to list the solutions against a pre-defined set of criteria (such as pathology/indication, key functions, gender, age, and language) and would refer to the frameworks which have assessed them through a dedicated visualisation.

A dedicated “push” communication channel could also be established in order to inform the clients of new adding's which would match their specific areas of interest.

Finally, this service is also very instrumental in developing SA3.1.

SA2-5: Digital health literacy initiatives

Although this can be considered as being part of SA2.1 and with also with a clear connexion with SA1, this service is mentioned undependably as it is considered as one service area which will require a dedicated investment by the Hub itself in order to connect to the stakeholders which have been developing such initiatives and are usually not always easy to identify as they can be initiated and supported by different type of actors (universities, NGOs, Ministries, operational frameworks, etc…). These initiatives are also often connected to very specific systems and environments and cannot always be generalized. The ambition of this service is here again to create a dedicated repository of the best practice and best documented (and translated) initiatives but should ideally be complemented by a transversal

analysis of those initiatives which would allow to derive practical and operational recommendations actionable by the Hub clients.

SA2-6: mHealth programmes implementation support guidelines and roadmaps:

The resources to be made available by this service are implementation methodologies adapted to the objective pursued (prevention versus care orientation, general population versus specific target groups). The methodology developed to support the WHO initiative "Be mobile be healthy" (BMBH) can be referenced and further developed to include supplementary EU based reference implementation schemes. It should be complemented by the methodologies developed by local, regional or national authorities, either independently or with the support of a separate operational framework to support usually more curative oriented use cases and for which usually the integration in the eHealth global ecosystem is an important requirement. Similar to other services areas, the repository of those methodologies should be easily searchable with –when available- a direct access to the original documentation.

The collection, selection and validation of KPIs to support those methodologies are a central focus point of this service. Those KPIs are expected to be made available through a dedicated and adapted search tool.

SA2-7: Innovations and horizon scanning relevant to mHealth solutions

This service is focusing on analysing the main trends and evolutions in the mHealth landscape (and more generally digital solutions including mHealth components). With the support of operational frameworks, research centres, Digital Innovation Hubs, industry associations, SDOs, patients and healthcare providers associations, the Hub will help documenting existing gaps (both at technology and clinical levels) in order to provide guidance to the key stakeholders of the value chain. This will be done through the selection and review of documentation submitted by the above-mentioned actors which can be complemented by regular consolidated reports produced either by the Hub team itself or by one of its structural partners. Here again a specific attention needs to be paid to the exploitation of those resources on the hub and the use of dedicated communication channels to pass over the most important messages. Obviously SA2.7 will also be used to support SA3.3.

SA2-8: mHealth best practices on integration of mHealth into healthcare systems

Like SA2.5, this service could be considered as being part of SA2.1 but is listed apart considering the growing importance of this objective in European countries and more globally to consider the possible contribution of the Hub to the creation of European Health Data Space(s). This service will document and make available successful integration strategies considering the different interoperability layers at stake (alignment of regulatory and legal constraints, collaboration agreements, alignment of care processes, semantic and technical (applications and infrastructure) and the strategies developed an open data-ecosystem inclusive of data produced via mHealth solutions. The different technical interoperability frameworks currently used will specifically be analysed and commented

(Telemedicine Interoperability Framework Model (TIFM), X73PHD-IHE framework, the mobile health (MH) clinical decision support system (CDSS) framework and Ambient Assisted Living (AAL) framework) with reference to implementation sites.

SA2-9 Quick Guide to mHealth ethics

This service is meant to capitalize on existing experience (questions raised by ethical committees and other official and non-official bodies involved in ethical questions) and initial documentation produced by the Hub. The Guide will be constantly updated to incorporate new findings as they arise and will also feed the community of expertise (SA1.2). It has to be understood as a commented check-list to support the different phases of a policy implementation.

3.2.3 Personalised support in mHealth implementation (SA3)

Link to operational goals	O3, O4
Short description	The Hub offers tailored support to client organisations from the WHO European Region interested in implementing mHealth practices into their local, regional, or national health systems. Over a period of several months up to a year, Hub experts work with the client to build their capacity for mHealth implementation and advise on key aspects of relevance. The aspects depend on the client's organisational and political ambition and can include, for example, support in mHealth policy development, support in conducting various analyses (stakeholder needs assessment, ecosystem analysis, legal and regulatory analysis), advise on technical aspects (e.g. requirements definition, interoperability considerations, setting up mHealth app repositories for quality assessment and certification), piloting aspects (testing and validation approaches and designs), business aspects (business model and reimbursement planning, governance), legal and ethical aspects, etc. A tailored support package is agreed and executed over several months, up to a year, depending on the desired scope of support.
Key services and value propositions	• Designing tailored mHealth implementation guidance for NCDs and other areas • Support in setting up assessment framework and certification processes • Support in mHealth interoperability and integration with EHR systems • Support in defining mHealth strategies and policies

SA3-1: Designing tailored mHealth implementation guidance for NCDs and other areas

The service is providing a top-down approach guidance to countries that aim to improve their current health and care delivery pathways for NCDs, by better

understanding the gaps and bottlenecks of the current systems and how mHealth could improve certain components of the pathways. The designated team of Hub experts will carry out a needs assessment with the country, to understand the pain-points of the current system. The team will make sure to involve the appropriate stakeholders for the specific care pathway since the beginning of the process, to make sure all voices are being considered. The team will co-create together with the country Personas, to specify the stakeholder groups for the health apps, it will define service scenarios to better illustrate the interactions of the personas with the health and care actors. The team will define process pathways and requirements of health apps. The team will help the country to identify appropriate solutions and/or support the country in defining PCPs or PPIs, as well as match-making processes with best practices of interest.

This service is currently being developed by the Country support task of WP4 and piloted with Hungary.

SA3-2: Support in setting up assessment framework and certification processes

The service is a bottom-up approach for providing assistance to countries and organizations to set-up an assessment framework for mHealth that in turn can support other decisions and strategies related to deeper inclusion of mHealth in the healthcare systems. The designated team of experts will guide stakeholders through key steps in setting up AF and evaluation processes, such as carrying out needs assessment and involving the stakeholders and experts needed, defining the scope of the assessment framework, deciding on the types of apps to be covered, deciding on assessment domains and criteria, defining workflows for the assessment process and funding/business modelling to ensure sustainability of the assessment process.

This service is currently being developed in different streams of the project (WP2 KT1 together with the Country support task of WP4) and is being piloted with the Czech Republic.

SA3-3: Support in mHealth interoperability and integration with EHR systems

The service aims to provide support on interoperability and integration with EHRs. There is a rich knowledge base developed in the WP2 KT3 stream of work and has the potential to be further operationalised and serve as personalised support for regions or countries that aim to touch on this subject. For example, the Hub has the capacity to provide technical support in terms of interoperability requirements etc.

SA3-4: Support in defining mHealth strategies and policies

There is a high demand for this service, as most countries do not have any mHealth specific strategy or reimbursement processes for health apps. The Hub has the capacity to provide this type of support, as the Hub built a rich knowledge base developed in WP5 around mHealth strategies and policies. Key activities could include support in defining reimbursement processes, guidance in identifying

relevant policies, stakeholder engagement and providing tailored information, such as good practices and lessons learned.

While the first two services are currently being developed in the project and piloted with two countries, the last two services have a rich knowledge base developed in the project and need to be further operationalised.

3.3 Business model for making the service portfolio sustainable

KEY PARTNERS

Apart from the Hub-internal consortium partners, this section refers also to partners which are currently external to the Hub, but with whom the Hub would like to establish a partnership. This partnership can be based on mutual non-financial benefits for both parties, such as content sharing, joint events organisation, etc., or financial benefits (e.g., ongoing discussions with ORCHA indicate that ORCHA could support the Hub customers wishing to have a technical implementation of a portal/library for mHealth accreditation directly, in exchange for a referral fee; more details can be found in chapter 4.1.2). A partner can assume multiple roles and be a content and a financial/business partner at the same time. The relationship can be formal (e.g., through a contract, or inclusion of the external partner into the current Hub consortium) or informal (e.g., mutual agreement to share content and promote each other's activities).

- EC, eHealth Network, eHealth Stakeholder Group, other multi-national policy groups and fora
- Academic and not for profit bodies engaged in supporting mHealth and eHealth
- ICT vendor associations
- SDOs
- Healthcare professional associations
- Patient and citizen advocacy groups
- Healthcare payer representative association

KEY RESOURCES

Key resources for maintaining the back-office, as well as key resources needed for developing each service area.

- Leadership to drive the Service Area
- Online platform to host resources and community interactions
- Experts and moderators who will provide peer input to our communities
- Guidelines and case study materials
- Educational resources, online tutorial materials
- Promotional materials and awareness raising channels
- Formal assessment reports of mHealth solutions and programmes

CUSTOMER RELATIONSHIPS

- Members from all stakeholder groups who participate in all online channels, optionally face to face events
- Fee paying participants and subscribers to particular channels and events
- Experts who interact and contribute through our channels, provide peer guidance
- Experts who develop and deliver learning resources
- Experts who synthesise emerging publications, produce or collate assessment evidence, guidance, find new experts

CHANNELS

- Web hosted resources
- Web hosted news and blogs
- Social media communities
- Online webinars and tutorials, panel discussions, interviews
- Face to face conferences
- Face to face workshops
- Online learning platform
- Participation in external events and stakeholder meetings

CUSTOMER SEGMENTS

- Health and public health policymakers, ministries
- Healthcare payers and associations
- mHealth programme leads and NGOs
- Health and care professionals and associations
- Patients, patient organisations, citizen organisations
- Health ICT and mHealth solutions developers
- MedTech
- Pharma

COST STRUCTURES

- Senior leadership to run the mHealth Hub (shared with other Service Areas)
- Office staff to manage memberships and fees, finance, expert networks and resources (shared with other Service Areas)
- Technical staff and ICT (possibly outsources) to host the online environments (shared with other Service Areas)
- Audio-visual costs for interviews, keynotes, some educational materials
- Expert fees for performing assessments of mHealth solutions and programmes
- Expert fees for contributing resources or community inputs (required for some experts)
- Face to face meeting costs
- Travel for key staff and experts to attend external meetings e.g., for advocacy, awareness-raising, fund-raising
- Invited speaker fees for face-to-face events, online courses and keynote videos
- Small budget for promotional materials and channels, exhibition booths at events (if not sponsored)

REVENUE STREAMS

- Grants from national health ministries and other policy-makers
- Grants from healthcare payers and associations
- Donations from sponsoring organisations e.g., industry
- Annual membership fees from participant organisations
- Single channel or event fees from individual participants
- Fees for performing assessments of mHealth ICT products and services
- R&D grants e.g. EC programmes

3.4 Roll-out considerations

The Hub service portfolio represents the desired scope of services which has been validated through the stakeholder survey. The scope goes beyond the current workplan of the Hub as a funded project. The service prioritisation can therefore be made on a temporal basis, distinguishing between the current project period and a transition period, as detailed in the table below.

SA1. Education, networking and mHealth promotion	SA2. Access to the Hub's resource library	SA3. Personalised support in mHealth implementation
Current services		
Series of webinars on various topics	• Overview of health apps repositories and assessment frameworks • mHealth Hub – Quick Guide to Ethics • mHealth Policy and Regulations • Collection of mHealth best practices for integration into healthcare systems	• Implementation support for Czech Republic with focus on mHealth strategies, certification, reimbursement, and best practices on mHealth • Implementation support for Hungary with focus on diabetes health applications
Future services		
Webinars, workshops, events Matchmaking and twinning between mHealth initiatives	mHealth evidence (health outcomes, cost-effectiveness, user acceptance)	Designing tailored mHealth implementation guidance for NCDs and other areas

mHealth communities of practice Training courses	Reimbursement and incentive models Digital health literacy initiatives	Support in setting up assessment framework and certification processes Support in mHealth interoperability and integration with EHR systems Support in defining mHealth strategies and policies

Table 1. Grouping of current and future services

4 Hub partnerships

Key partnerships are crucial to develop the service portfolio, amplify and support the value proposition, and help the mHealth Hub business model work. Through semi-structured interviews with potential Hub partners, both members and external to the Hub consortium, an exploration of possible synergies and partnerships was conducted in the first semester of 2021 (See Annex 12 for the complete list of interviews).

The interviews made a preliminary exploration covering the following topics: possible existing inputs for the mHealth Hub (without supplementary investment), current business model of the partner, type of relationship which could be privileged, possible common developments and initial requirements for partnership.

This exploratory work was structured around different types of mHealth operational frameworks: (1) Member State frameworks, (2) private or collaborative frameworks, (3) networks and associations.

Member State frameworks included DiGA (Germany), mHealth Belgium – Agoria (Belgium), SPMS (Portugal), Osakidetza – Kronikgune (Basque country, Spain), Oulu Health – Finnish Health Hub (Finland) and TicSalutSocial (Catalonia, Spain). Private or collaborative frameworks included ORCHA (United Kingdom), HL7 Europe and Personal Connected Health Alliance. Industry networks and associations included EIT Health, MedTech Europe.

Potential partnerships were analysed in a continuum from synergies and non-binding agreements to formal business partnerships. The consequences towards the governance structure of the mHealth Hub as a result of the formal business partnerships is out of the scope of this initial exploration.

4.1.1 Insights from interviews with operational frameworks

In this section, we summarise the key insights from the interviews conducted with the three types of operational frameworks presented before. Together, it forms a multidimensional view of the potential partnerships and synergies with the demand and supply side.

Member State operational frameworks

National and regional mHealth operational frameworks share common interests and concerns. They exchange bilaterally ad hoc knowledge and expertise about the development of the entire cycle of mHealth deployment, from assessment to reimbursement and integration with health systems. For instance, mHealth Belgium exchanges with DiGA in Germany, and the Portuguese Ministry of Health with the Andalusian Ministry of Health. Those that are not actively exchanging at present manifested their willingness to connect with other public frameworks.

All interviewed operational frameworks, frontrunners in the European context, expressed that the Hub is seen as a timely and ideal pan-European collaboration platform. They underscored the need to connect and network to share strategic experience on impact of mHealth programmes. They all convened that connecting

with other operational frameworks and the development of a European framework, and eventually a European standard, for the assessment of mHealth apps would provide many advantages in line with the EC Digital Single Market policy, creating mutual reliance in resources and outcomes. For instance, the cross-referencing and publication of mHealth apps that would bring to national mHealth app developers the opportunity to expand their business operations.

Partnership with a sharing platform represented by the mHealth Hub would enable cross-border discussion about the mHealth challenges in terms of data sovereignty, business models or assessment criteria for certification bodies. Therefore, a network of national and regional operational frameworks centred around the activities of the mHealth Hub is envisioned as an opportunity for multiple partnerships. This network would increase visibility at European and international level and would unleash contributions by the different national and regional hubs based on their hands-on expertise in implementing mHealth programmes, including sharing of domain experts, good practices, guidelines, twinning activities, etc.

Private and collaborative frameworks

Private and collaborative frameworks are represented by organisations which scope of practice is either European or global. Engaging with the mHealth Hub is seen differently depending on the framework interviewed. Most of them prefer to exploit the in-kind synergies of sharing knowledge and resources before a clear business model is presented.

The activities where private and collaborative frameworks could play a synergetic role are, for instance:

- Developing an mHealth maturity model inspired by the experience developed by HIMSS family of maturity models (Electronic Medical Record Adoption Model, Continuity of Care Maturity Model, Digital Health Maturity Model).
- Providing mutual access to knowledge resources between members of the Hub and partners' members.
- Signposting good practices in mHealth interoperability (IHE, HL7)
- Supporting the development of community of practices linked to the Hub by themes (i.e., maternal child health, nursing, hospitals, primary care, etc.) or technology-oriented communities of practice (privacy, security, interoperability).
- Providing expertise based on mHealth implementation projects and sharing domain experts for the mHealth Hub expert rooster.

In the case of ORCHA, a private UK company with a consolidated service offering in the field of mHealth, a strong synergy could be developed as a formal business partnership. The next subchapter explores the cooperative approach between ORCHA and the mHealth Hub.

Industry networks and associations

Overall, the mHealth Hub value proposition is attractive to the technology industry and is seen as a catalyser of regulatory progress. However, some concerns were raised by industry players regarding the scope of the mHealth Hub and the market approach. Hence, the terms digital health therapeutics is considered more appropriate as it include digital health market trends like telehealth and telemonitoring.

A key driver for the industry is the simplification of market access to the different European countries. The industry fears market fragmentation and therefore is keen to contribute to harmonisation through participation in roundtables. For instance, it is considered highly beneficial to align national and regional assessment frameworks and eventually develop a federated framework for assessing and certifying mHealth applications which would allow companies to expand their businesses in different countries without the need for reassessment. There is a need of alignment and mutual recognition on clinical evidence, effectiveness, cybersecurity, and interoperability of mHealth apps. Along this line, the industry expressed interest in supporting the mHealth Hub to facilitate advocacy and the development of a European-wide assessment framework.

Another area where the industry envisage potential partnership with the mHealth Hub is reimbursement and the connection with public and private healthcare payers. As with the federated assessment framework, streamlining reimbursement paths in Member States would provide faster access to national and regional markets.

Interviewed organizations expressed their willingness to provide feedback on how the mHealth Hub offering can be developed, especially in the service areas of networking and education. In exchange, the industry associations and networks would promote the mHealth Hub to their communities, enlarging the outreach of the Hub activities to a wide range of technology providers. It would also provide expertise in regulatory matters and in how to navigate the system. Some people however consider as very challenging for the Hub to position itself in such a way that it can both link together and add on the already many existing initiatives working both on interoperability and assessment methodologies, such as for example the new ISO/PRF TS 82304 standard in development .

At this stage, it is still soon to establish long-standing formal agreements with the industry networks and associations. Nonetheless, it exists willingness to provide financial support and sponsorship to develop activities related to harmonisation of assessment frameworks, reimbursement and evidence sharing. At individual company level, a subscription model could attract network and association members to obtain tangible services.

Preliminary conclusions

Considering the three visions provided by the type of operational framework analysed, the mHealth Hub can develop different synergies and partnerships. Member state frameworks are keen to engage with the Hub in a formal partnership that will be the foundation of a network of national and regional operational frameworks. Private and collaborative frameworks differ in their approach from in-kind synergies to formal business partnerships. Finally, industry networks and

associations are more inclined to develop a progressive relationship, starting from the sponsorship of key activities to further and more formal modes of partnership over time.

4.1.2 Competition versus partnership: The ORCHA example

Based on the results of the preliminary interviews conducted with several possible partners inside and outside the consortium (see section 4.1.1.), it appeared that the current offer of ORCHA was largely overlapping with the envisioned mHealth Hub services portfolio. It has thus been decided to push the analysis a bit further and to deepen the discussion considering the relationship and the future mHealth Hub both from a competition and structural partnership angles. Both parties have thus simultaneously produced and shared a first document which highlights the possible areas of cooperation but also the challenges to be met (see *Annex, 10*: SWOT analysis).

During the second meeting with ORCHA representatives, the following conclusions have been reached:

- ORCHA confirms its willingness to establish a structural partnership with the mHealth Hub. To facilitate this process, a Memorandum of Understanding (MoU) could be set forth on a short-term basis.
- As the current ORCHA offer covers –at least partially- the different services planned by the Hub, a more detailing mapping need to be done.
- ORCHA also confirms its flexibility to discuss possible business models, which would not always necessarily require financial flows.
    a. Referencing ORCHA consultancy services while making ORCHA resources available to its members.
    b. Ad hoc common developments for topics of common interest or specific contractual assignments.
- ORCHA has been supporting 9 European Member States in developing specific mHealth policies: This experience is per se an interesting element to capitalize upon. It has thus been proposed as a first collaboration step to organize a dedicated webinar focused on the analysis of the results achieved and on the process of "co-creation" of Member States with ORCHA.
- The possible reuse of ORCHA API development infrastructure to support mHealth hub specific objectives on the short/medium term before possibly complementing it with information coming from other national public Hubs.
- A third meeting will be organized to map more precisely the services proposed by ORCHA with the HUB portfolio.

The ORCHA example has also been instrumental in developing the Value Proposition for the second pillar of services.

ORCHA is not the only "private" initiative present on the market, but it is the current operational framework with the broadest geographical scope and the largest experience of cooperation with Member States as illustrated below.

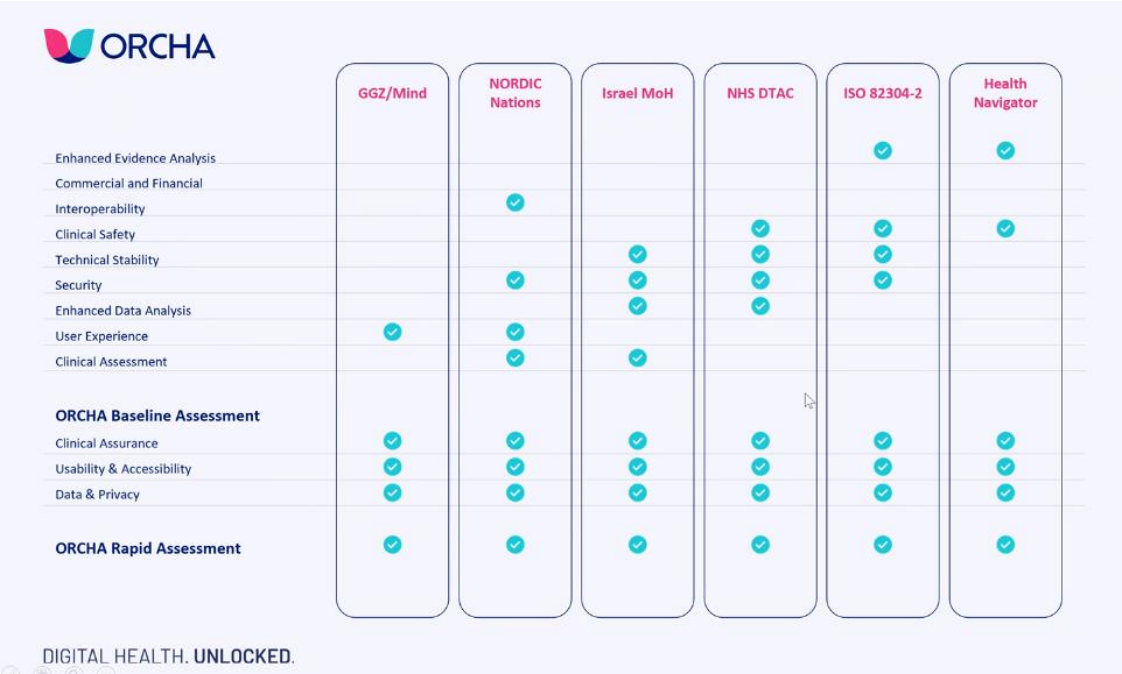


Figure 2. Overview of relevant standards included in the ORCHA framework

Some valuable other frameworks, more rooted in non-EU countries, such as Therappx in Canada, might also possibly be approached in a second step with the idea to compare results of the algorithms used by the different frameworks.

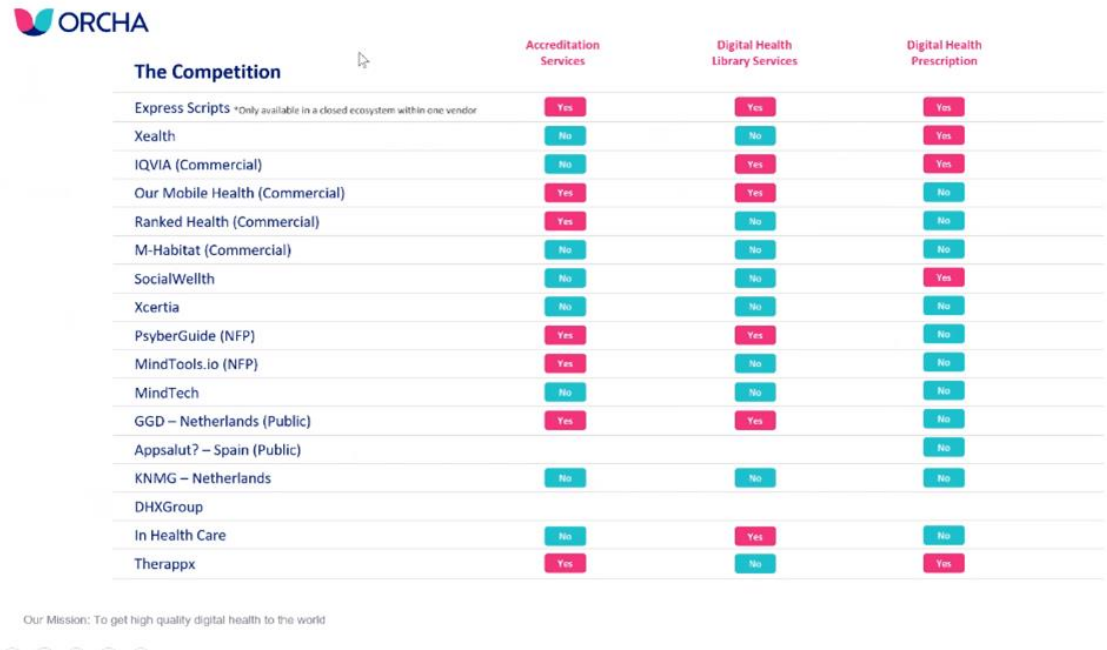


Figure 3. Overview of ORCHA's market positioning

Pending the signing of a Memorandum of Understanding (MoU) with ORCHA, the next version of this document will provide more details on the main areas of cooperation at short-, medium- and long-term levels, the possible implementation methods and the associated business model.

5 Hub governance options

This chapter provides an analysis of alternative schemes for the future governance of the European mHealth Hub (Hub), and an assessment of options against a set of criteria. It is however noted that it is not for the authors of the report to make a conclusive assessment of options but rather to provide a framework for further discussion within the Hub consortium and with external stakeholders and potential future "business" partners of a sustainable Hub.

5.1 Organisational models

The four models outlined in this sub-section of the deliverable (and referred to as Options 1, 2, 3 and 4) were considered, following consultation with the beneficiaries. They are presented below, together with a commentary on how they could likely manifest themselves in the overall Digital Health context.

It is also important to clarify that:

- These are not the only alternatives and additional or hybrid approaches may be relevant.
- A phased approach may be adopted, linked to the maturity of the mHealth Hub and the degree of four options with a phasing from the current project, through the transition phase to a fully sustainable status.
- As the primary objective of the Hub is to support national Health Authorities and other relevant public bodies, it is expected that all four options will always remain under a public or not-for-profit arrangement. However, the Hub may attract its own income e.g., value may be monetised by means of memberships and/or fees for certain services.

Option 1: Continue as-is – A follow up partnership of organisations

Option 1 implies a continuation of the current situation, where a renewed partnership of organisations that are considered most relevant for sustaining the Hub assets, delivering and promoting its minimum viable services is set up. The assets are handed over to this partnership.

Given the present and project level of maturity of the Hub assets and the fact that outcomes produced within the EU-funded projects are public goods, it is highly unlikely that by the end of the project the Hub will be in a position to generate sufficient income to fully sustain its operation and maintenance of its resources. The funding in this option may therefore be considered to come from three main sources: income generated by the Hub; partners' own investments (in-kind and/or financial) and potential external funding (see *Annex 11* prepared by the Hub beneficiaries).

The legal basis for the transition phase, may be to simply form a new consortium, bound by a Consortium Agreement, to implement the scope of a new (largely, continuation) EC funded project. As such, it may provide short-term sustainability solutions, e.g., in the form of an extension of the current work while preparing for the next phase, securing – amongst others – financing of the pre-launch activities

of the Hub and possibly support for its first one or two years of its business plan activities.

For longer term sustainability formalising the partnership could, for example, be that of a **European Economic Interest Grouping** (**EEIG**)[3]. Briefly, this scheme is designed to make it easier for natural persons, companies, firms and other bodies to co-operate across borders in different countries to do business together, or to form consortia to take part in EU programmes.

A **European Economic Interest Grouping** (**EEIG**) is a type of legal entity of the European corporate law created on 1985-07-25 under European Community (EC) Council Regulation 2137/85. It is designed to make it easier for companies in different countries to do business together, or to form consortia to take part in EU programmes.

Its activities must be ancillary to those of its members, and, as with a partnership, any profit or loss it makes is attributed to its members. Thus, although it is liable for VAT and employees' social insurance, it is not liable to corporation tax. It has unlimited liability"

One of the most famous examples of EEIG is the ARTE TV channel.

The instrument faces practical limitations when it needs to incorporate public bodies, but its members might be partially or totally supported by public funding. The management board is independent but can be extended to representatives of the different entities when needed.

Option 2: An international public organisation or a European Agency

For the Hub to support implementation of mHealth policies and strategies at national level, its continuing development could be through an EU level governance mechanism for maintaining the content and operating the portfolio of services. This could be achieved if handed over to a public entity with an international mandate such as WHO, ITU or an EU Agency.

At this stage, however, it is highly unlikely that any of the three international organisations that are beneficiaries of the mHealth Hub project will be in the position to take over the future operations of the Hub. They do, however, consider that their continuing commitment can be reflected through other mechanisms, as for example their participation and role in the management board or other suitable body in the future Hub governance.

3 A type of legal entity of the European corporate law created on 1985-07-25 under European Community (EC) Council Regulation 2137/85. Its activities must be ancillary to those of its members, and, as with a partnership, any profit or loss it makes is attributed to its members. Thus, although it is liable for VAT and employees' social insurance, it is not liable to corporation tax. It has unlimited liability.

A European Agency is a body governed by European law and set up by an act of secondary legislation (regulation/joint action/decision). It has its own legal personality and has financial and administrative autonomy and is independent in the execution of the assigned mission/tasks. The Agency usually receives financial contributions from the EC, and it is most often a permanent body which has its seat in one of the MS of the European Union.

In this option, the Hub would be adopted by an EU governance body chaired by the EC and the MS, such as the eHealth Network. There is a standing challenge for the eHealth Network to maximise visibility of its adopted policies and encourage their implementation at MS level through national Digital Health Networks; the latter are envisioned to support the alignment of those entities at national level that are likely to drive use and re-use of health data within the European Health Data Space, being a high priority area for EU policy co-ordination.

The Hub could be instrumental for establishing a consistent and highly accessible channel to support national Digital Health Networks implement their national objectives through successfully leveraging on mHealth good practices and common resources. The increased accessibility and visibility can have a multiplier effect towards national stakeholders especially when used by the National Digital Health Networks to increase awareness and promote alignment with the eHealth Network vision.

A European Agency (which has not been identified at this stage, but could emerge in the future) identified, would further take on the responsibility of the maintenance and growth of the Hub and would act as a Supervisory Authority for third parties' participation in the implementation and maintenance as well as those connecting to and benefiting from the exploitation of the Hub. A combination with Option 1 can be one way of incentivising the formation of consortia to deliver the priorities to the specifications defined by the Agency, together with the mHealth Hub stakeholders. The Agency would maintain financial and administrative autonomy and could be accountable to European level - MS representation digital health governance bodies such as the eHealth Network.

Option 3: A Network of national level mHealth Hubs

The investigation undertaken within the mHealth Hub project and in particular WP4 has shown that there are national mHealth Hubs or equivalent set up in several but not all MS. These Hubs vary as to their organisation, public/private composition, scope of services and funding mechanisms. There are at the same time several commonalities and a sufficient overlap area with the areas of operation of the mHealth Hub, sufficient to allow for the consideration of an option to leverage national initiatives in order to create the European mHealth Hub as an umbrella organisation.

The role of such an umbrella organisation would be to mutualise effort and resources, support national Hubs through harmonised resources (e.g., common criteria, classifications, search criteria etc) and work towards greater consistency across borders. By making national Hub resources accessible through federated searches or through pooling of evidence, experiences and exchange of good practices the EU Hub would have direct access to needed resources for creating

added value reports and enhancing in intelligence for its customised MS support and it will also have an extended pool of national experts for implementing activities such as common training programmes in local languages. Last but not least it will be in a position to support and encourage the establishment of new national Hubs and promote their role and integration into the national digital networks.

The EU Hub could take a suitable legal form that would allow it the needed flexibility; it could be hosted by one of the partner organisations but run as an independent entity governed by its key stakeholders.

In its sustainable phase, its income should mainly come from added value services and from sponsorships, while Option 1 will remain a choice for funding the design of new services and innovations in its area of operation.

Option 4: A single non-for-profit Organisation

A Non-Profit Organization (NPO) is an organization that uses surplus revenues to achieve its goals rather than distributing them as profit or dividends. NPOs have controlling members or a board of directors. Many have paid staff including management, whereas others employ unpaid volunteers and even executives who work with (occasionally nominal) compensation or without compensation.

In this option, the Hub would invite expressions of interest from organisations that operate in the digital health domain, can demonstrate a strong relevance of their work focus to that of the Hub, and they can also demonstrate good match to the criteria including those for neutrality and transparency. The latter can be reinforced through features included in the governance of the Hub, such as the composition and powers allocated to its managing board.

At the operational level, the MHealth Hub would orchestrate co-creation and production of assets with the competent players/stakeholders whether at national or EU level and facilitate the active participation of the private sector.

It should be, however considered that as the organisation will have the final responsibility for its sustainable operation, it will be expected that this solution will be viable only in cases where the Hub will be streamlined and fully integrated in the mission and operations of the organisation. Balancing control by stakeholders outside the organisation on one hand and trust by national public organisations on the other, would remain a key challenge to properly address.

The acronym “QUANGO” is often used to refer to an organisation to which a government has devolved power, but which is still partly controlled and/or financed by government bodies. The term was originally a shortening of "Quasi-NGO", where NGO is the standard acronym for a non-government organization.

5.2 Criteria for assessing the options

All four models described above have advantages and disadvantages. Some options are more suitable for the transitional phase characterised by the need for agility to develop the most viable products and services, while some are fit for purpose to

ensure long-term sustainability. To evaluate these different options, it is necessary to consider multiple governance and management aspects along the transitional and long-term phase.

Nine assessment criteria have been selected to compare organizational options: (1) agility, (2) scalability, (3) stability, (4) costs, (5) stakeholder engagement, (6) official buy-in, (7) adaptability, (8) administrative burden, and (9) governance and management integration.

Agility: ability to move quickly and easily. It refers to the capacity of the organisation to adapt continuously and swiftly its priorities and the related actions to an evolving context in order to achieve its key objectives. This requires a clear and shared understanding usually facilitated by a very simple management structure and light decision-making process.

Scalability: capacity to change in size or scale. It refers to the ability to adapt, particularly in regard to growth and increased demand. Scalability is essential as it contributes to competitiveness, efficiency, reputation and quality. Scalability is closely connected to agility but is also very much connected to the services to be offered as for some of them their scalability requires an initial investment which considers this criterion for its own sake.

Stability: capacity to secure operations with the adequate level of quality over a long period of time. This criterion is closely associated with the funding structure (guarantee of funding), the capacity of the structure to control staff turnover, the maturity of the infrastructure and the elements of protection which have been put in place (legal, statutory or regulatory).

Costs: this criterion is not only related to the total amount of expected costs but most importantly to the capacity to allocate dynamically resources according to needs and priorities. The ratio of fixed versus variable costs is here of particular importance. Creating an independent entity generates initial investment costs and a higher level of fixed costs. Light-weight, outcomes focused organisations, are however usually more capable to achieve results within the remits of a defined budget and in a limited time spam. Here again the choice of services to be offered directly impacts on this criterion. While policy support, education and advocacy do not require a sophisticated infrastructure, the development of libraries do require investments to ensure service level agreements (SLA). Finally, the capacity to reuse and reengineer the resources already produced by other trusted organisations rather to develop a fully independent service has also a high impact on costs.

Stakeholder engagement: capacity to engage the stakeholders of the mHealth value chain into the process. This criterion is also dependent of the services to be developed and the capacity of key stakeholders to act both as client and provider for each service.

Official buy-in: is the official credit achieved by operating under an official legal national or European mandate. This condition has a direct influence on the level of buy-in and trust by National Authorities. However, it can be mitigated by an internal governance body that would guarantee an official backing.

Adaptability: capacity to adapt swiftly not only activities (agility) but also objectives. mHealth is nowadays a moving target as the concept is often considered as too narrow to cover the initial overarching health and societal objectives. The

criterion tries to highlight the need to perform continuous analysis and question regularly the pertinence of the objectives assigned. One might for example analyse how the mHealth Hub fits with the emerging Digital Innovation Hubs.

Administrative burden: level of legal and regulatory constraints which may apply. The rules that usually apply to Public Bodies in term of resources engagement (long-term budget planning, political approval, tendering processes, ex-ante controls, engagement procedures etc..) usually require that processes are already well established and in routine operation mode. Organisations which are publicly funded also need to abide to a number of those rules, but their concrete implementation can be made much lighter.

Governance and management integration: it refers to the way governance and management are or not connected. When the responsibility of operations lies with a single entity, governance is a separate objective which is managed for its own sake and thus follows a pre-defined path. Where several organisations are collectively responsible for service delivery, governance is usually integrated in the management process. It can also happen that in this kind of setting different levels of governance coexist dealing on one side with the operations governance and on the other side with the overall objectives. Although critical and clearly connected to the buy-in, governance can be a cumbersome and heavy resource demanding process.

Aside from these assessment criteria, **neutrality, reputation and trust** are also important elements to consider but they might not discriminate in this specific context. However, offering services with new added value and relying on initiatives and partners which already benefit from a large recognition and positive public image will positively impact on these criteria.

The following table compare the four options based on the nine assessment criteria taking into account the transition and long-term phases as well as the service area focus.

Table 2. Governance and management options comparison

Options	1A Consortium Agreement	1B European Economic Interest Grouping	3 Network of National Hubs	4 Single non-for-profit organisation	2 European Agency
Transition phase	●	(●)	(●)	●	
Long-term		●	●	●	●
Services areas (focus)	Personalised support	Personalised support (with ad hoc services)	Education, networking and mHealth advocacy	Personalised support and Education, networking and mHealth advocacy	Personalised support and independent assessment framework
Agility	+	+	+	+++	++
Scalability	+	++	+	++++	++
Stability	++	+	++	++	++++
Costs (fixed and variable)	+	+	++	+++	++++
Stakeholder Engagement	+	++	++	+++	++++
Official Buy-in	+++	++	+++	++	++++
Adaptability	+	++	++	+++	+
Administrative burden	++	++	+	++	++++
Governance/Management	Integrated	Separated	Integrated	Separated	Integrated

According to this benchmark analysis, two options are more suitable for the transitional phase: (1A) Consortium agreement and (4) Single non-for-profit organisation. Consortium agreement would bear less costs while ensuring official buy-in, while a Single non-for-profit organisation would provide higher agility, scalability and adaptability at the expense of higher costs and reduced official buy-in.

For the long-term phase, four options are possible. However, the choice seems more leaned to options (2) European Agency, (3) Network of National Hubs or (4) Single non-for-profit organisation. The European Agency stands out in stability, stakeholder engagement and official buy-in, while is a less attractive option from a cost and administrative burden perspective and, at some extent, less agile. The Network of National Hubs provides a balance between agility and official buy-in. Both options offer an integrated governance and management structure. At this phase, the Single non-for-profit organisation remains an attractive option as in the transitional phase.

Following the elaboration of those options, the project beneficiaries have reviewed them and have come to the conclusion, that option 4 is most appropriate for the Hub in connection with applying a Transitional Period (see section 6).

6 Preparing for the mHH Transitional Period

6.1 Background

It was recognised part way through the Hub project's duration that the project deliverables, the web hosted resources, the programme support services to countries being piloted and the online community being engaged through Hub Talks were valuable to sustain, but would not have sufficient committed and investing organisations to finance the Hub immediately after the project. It is not yet self-sustaining. A Transitional Period was envisaged as a period of time when an assured budget would be available to cover the operating infrastructure, service development and business development costs whilst income streams from memberships, services and consultancy could grow.

In order to formalise that Transitional Period, it was necessary to confirm:

- which parties could offer what transitional funding, over what duration
- if one or more existing consortium members would be willing to lead the sustained Hub, either to take it over fully, or to run it on behalf of the main beneficiaries
- which of the existing consortium members wished to be associated with the sustained Hub (in various possible ways)
- what core resources and services the budget would permit it to maintain and grow
- how it should best utilise the transitional funding to attract future revenue streams
- whether a legal entity (such as an EISG, AISBL) should be formed early post-project or downstream
- what role the EC could play in supporting the sustainability of the Hub.

The last nine months of the project focused on addressing these questions and preparing for the launch of the Transitional Period.

6.2 Consortium activities to plan and prepare the transitional phase

In July 2021 the ITU launched an open and transparent call for all Hub consortium members to express their interest and commitment in being part of a Sustainability Leadership Team (SLT) to lead and plan actions until the end of the project in February 2022 and to consider taking over the Hub ownership and management starting March 2022.

SLT mission was to:

- Create the business plan for a 2 to 3 years Transitional Period of the Hub towards a revenue generating model that will pave the way towards a fully sustainable Hub in the future.
- Determine the Minimum Viable Product(s) and catalytic funding required to maintain minimum operations.

In more concrete terms the SLT was expected to:

- Review the drafts or deliverables of the Sustainability group in the context of Work Package 4 – (Operationalization and Capacity Building) of the project to make concrete choices particularly around the services portfolio and governance models.
- Lead the discussion and initiate needed actions to start the Transitional Period in March 2022. This could include activities for resource mobilization, proposals development, engagement with EU, etc.
- Develop a concrete workplan for the Transitional Period with an estimated budget and business plan
- Explore fund raising opportunities, hold meetings with EC/Head of Unit eHealth, Well-Being and Ageing (CNECT.H.3) - DG Connect) and DG Santé to discuss provisional co-financing for the Transitional Period of 2-3 years towards a fully sustainable Hub.
- Provide in-kind contributions in terms of time and commitment towards Hub sustainability.

One important mission of the SLT was to establish a Core Strategic group and designate two chairs from organizations willing to manage the Hub after Feb 2022, as well as to hold regular meetings with this Core Strategic group to reach agreements on topics above.

By the end of August 2021, the following partners from the Hub Consortium confirmed their commitment to the Sustainability Leadership Team:

- i~HD (Belgium)
- EHTEL (Belgium)
- Empirica (Germany)
- Unina, University of Naples Federico II (Italy)
- Ericsson NT, Zagreb (Croatia)
- Promis (Italy)
- University of Vienna (Austria)
- HL7 (USA NGO)
- PCHA/HIMSS (USA NGO)
- RJH/Region Jämtland Härjedalen (Sweden)

i~HD and EHTEL came forward and expressed their interest in forming the Core Strategic group of the SLT. The group, having welcomed the offer of these two organisations and proposed that Dipak Kalra and Marc Lange would then chair this group. Between September 2021 and end of October 2021, the appointment of i~HD and EHTEL to run the Transitional Period of the Hub was formalised, and the terms for this handover were explored.

Progress has been made to formalise a prioritised list of activities and services that the Hub should offer in the future, by promoting or extending the existing deliverables, the cost of those activities and how they might incrementally be put them into practice as the budget permits.

A governance model has been defined to enable an agile operational team to run the Hub whilst involving the beneficiaries strategically and a pathway for engaging the expertise of all members of the existing project. A candidate approach to membership fees has also been proposed, including an initial free membership period and subsequent discounts for existing consortium members, although that needs more work before definitive fee levels can be set. All of these items have been included in a Terms of Reference document that defines the Transitional Period.

Partnerships have also been explored with 3rd parties, in particular Oulu University and OuluHealth Finland DigiHealthHub who have expressed interest in forming part of the next generation European mHealth Hub. Because of their strength and position in the digital health ecosystem, their interest was welcomed in joining at the start of the Transitional Period. Oulu University/Health Finland therefore joined the SLT Strategic group with a quantifiable in-kind contribution of 50k, in particular for innovation related activities such as:

- Innovation match-making events
- Communication campaigns
- Sponsored events
- Hub talks and beyond
- Promoting membership to governmental and regional agencies

In October 2021 a contribution of 100.000€ was confirmed jointly from ITU and WHO as seed funding of the Transitional Period towards a fully sustainable Hub, for the year March 2022 to February 2023. The proposed activities are summarised in the next section. Because this level of funding is only available for one year, whilst the plans made for reaching sustainability were anticipated to require three years, some downscaling of the Transition Period activities has been necessary, with the priority given to business development. The 100.00€ in cash budget will be used jointly by i~HD and EHTEL for the implementation of core resource maintenance and community building activities (with a provisional allocation of a third of the budget) and the business development activities (two thirds of the budget) of the first year of the Transition Period. The in kind OuluHealth contribution will be in complementary areas supporting both the business development and community building (as indicated above). Efforts are also continuously being made to find additional revenue streams for the 12-month Transition Period, and beyond it.

By mid-February 2022, the Core Strategic group of the SLT formed by i~HD and EHEL, ITU and WHO defined the Terms of Reference for the New Hub.

Different entity models have also been evaluated, in particular EEIG and AiSBL, to create a new legal entity structure for the new Hub. A recent evaluation was undertaken in addition to a prior in-depth analysis of multiple entity options reported earlier in deliverable 4.5. The recent evaluation findings are summarised in the table below.

	EEIG	AISBL
Purpose	• To minimise the legal, fiscal, and psychological difficulties that companies and other bodies face in cooperating across borders • To facilitate or develop the economic activities of its members by a pooling of resources, activities, or skills	• The international non-profit association is a grouping of natural or legal persons pursuing a disinterested goal of international benefit
Formation	• At least 2 members from different EU countries, up to 20 organisations • The contract for the formation must include duration of the grouping, except where this is indefinite. • The contract must be filed at any EU country • Does not necessarily have to be formed with capital. Members are free to use alternative means of financing	• The registered office must be located in Belgium • Once a common project has been determined, the statutes representing the founding principles of the organization must be drafted by notarial deed • -As an association, the members of a non-profit association may not receive any material benefit from the non-profit association
Governance	• A decision to admit new members shall be taken unanimously by the members of the grouping. • EEIG may have organs and voting rights are foreseen. • Each entity has 1 vote. Certain entities may have more than 1 vote provided that no 1 member holds a majority of the votes. • Must have at least 2 organs: 1) the members acting collectively and 2) the manager or managers. • Each member may obtain information from the manager concerning the grouping's business and to inspect the grouping's books and business records. • Only the manager shall represent a grouping in respect of dealings with third parties. • Grouping should not make profits for itself – profits of an EEIG will be deemed to be the profits of its members	• The non-profit association consists of two bodies: the general assembly and the operational board. The Statutes determine the form, composition, working method and powers of the administrative bodies

Both i~HD and EHTEL were in faour of the AISBL option, and would foresee challenges with the EEIG option. It was concluded that due to the complexities of the process and the time constraints it would be better to postpone the creation of this new legal entity and to make a reassessment of the situation near the end of the first year of the Transition Period when there will be more clarity on the long-term plans for Hub sustainability. As part of these Transitional Period arrangements, it was agreed that the ownership of the Hub assets would remain with WHO and ITU until there is a legal entity to take them over.

The outcomes of the work of this Sustainability Leadership Team are informing the Hub's future and will be the basis for how the Hub will be operated and how it will be governed during the Transition Period. In accordance with the governance model, outlined later in this section, SLT members will all be invited to become part of a General Assembly during the Transition Period (and perhaps beyond it), and to collectively nominate some of their members to sit on the planned. Both ITU and WHO have committed to be part of the SLT and will each have a dedicated position on the Strategy Board.

6.3 Proposed Hub activities and services during the Transition Period

This section summarises the main areas of activity that are currently being proposed during the first year of operation. This is not a prescriptive proposal and will be adapted on advice of the Strategy Board as new opportunities arise including funding opportunities, collaborative opportunities, strong stakeholder interest and other changes in the mobile health and digital health ecosystem.

Overall mission for the Transition Period

Developing and performing, on a best effort basis, a set of activities aiming at leading to a self-sustainable European mHealth Hub.

Business development

- Promote the value of Hub membership to the clinical research and the health ICT sector, to healthcare providers and to digital health stakeholders.
- Participate in digital health related conferences and start to grow
    - a network of public authorities for the scale up of mHealth and DTx as a necessary component of the digital transformation of health and care systems
    - a network of industry champions for the scale up of mobile health in healthcare and in research.
- Facilitate five WG calls for three types of stakeholders: the assessment frameworks, the MedTech and ICT industry and the public/private mHealth implementers.
- Support the work of innovation hubs and other developer networks, through presentations, workshop participation, panel discussions and match-making events.
- Identify and market mHealth Hub membership to relevant i~HD and EHTEL members, OuluHealth networks pf governmental and regional agencies, and wider contacts.

- Monitor for and participate in mobile health data and digital innovation EC calls for proposals where the mHealth Hub can deliver value.
- Determine, through the Strategy Board, if and when it is most appropriate to establish a new legal entity, and in what form, or if the sustained legal entity should be formed in collaboration with one or more other initiatives.

Resources and communications

- Undertake targeted communication campaigns.
- Promote the mHealth Hub resources and services to stakeholders who create and use personal health data, across Europe and beyond to mHealth and DTx implementers and associated stakeholders.
- Maintain the state of the art innovation trends areas relating to data quality, assessment frameworks, interoperability and data protection.
- Take responsibility for delivering future Hub Talks e.g. on the protection and management of health data, data quality, citizens' engagement and assessment frameworks.

On-line presence

- Maintain the static information and education resources on the mHealth Hub website, update the content related to the activities of the mHealth Hub.
- Offer online training courses in various data and quality oriented aspects of mHealth.
- Host Hub Talks by EHTEL, i~HD, OuluHealth and other invited experts and initiatives.
- Offer online briefing notes and documentation on deployment aspects of mHealth.
- Grow and manage an online community of stakeholders engaged in the deployment of mHealth and DTx services, and those interested in personal health data, including interoperability, good practices in data management and data protection, data sharing models and quality assessment.

Operations

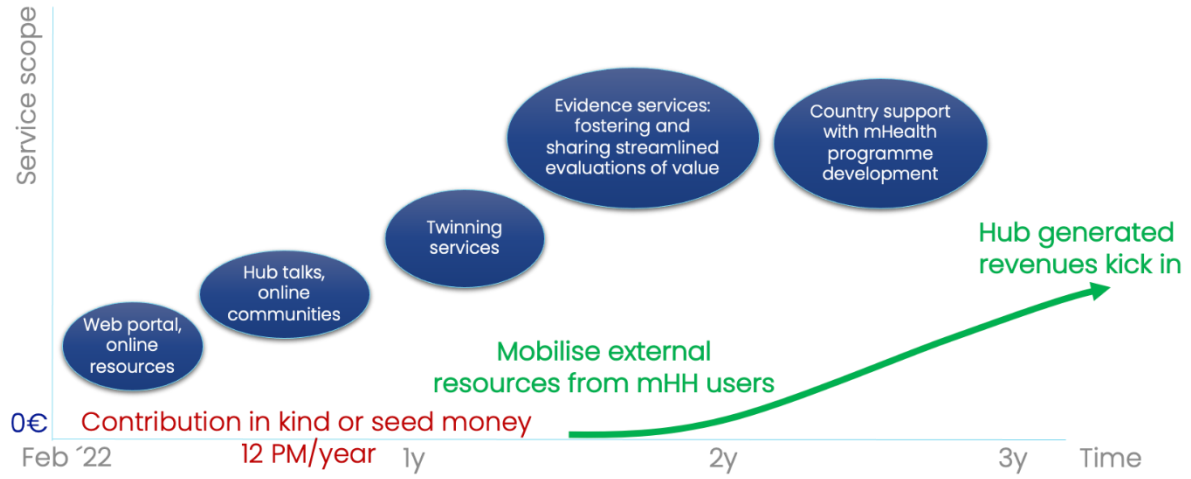
- Convene and support the meetings, reports and decisions of the Strategy Board and General Assembly.
- Represent the operations team on the Strategy Board and General Assembly.
- Provide regular reports to the WHO and ITU as required by contracting arrangements on the mHealth Hub activities, meetings, events and sustainability perspectives.

6.4 Service development trajectory

The chart below is a high-level illustration of the timeline over which the mainstream resources and services would be developed during the first year and progressively provided as services over a three-year period. As indicated in the section above, maintaining and enriching the static content currently hosted on the website, and growing the online activities are expected to be within scope of the currently assured budget, and can be delivered relatively quickly.

Twinning services are also considered a potential early service to be provided, building on the twinning expertise of empirica and the matchmaking experience of

OuluHealth. They can be positioned in the second half of the Transition Period because they have limited start-up costs, and their operating costs are primarily financed by one or both of the twinning parties seeking that service. External grants for twinning support are also sometimes available, for example through European projects and national innovation funds. By incorporating an overheads approach to this kind of service, twinning can be modestly income generating for the Hub whilst promoting the value of the Hub and offering some business opportunity to Hub collaborators.



More sophisticated services will need to be developed to some extent during the transition period but will probably not be ready for active promotion and procurement until the second year, provided that some further continuity funding is found.

Not shown on this chart are additional service areas that are currently under discussion with existing mHealth Hub consortium members, for example interoperability consultancy and testing services. Whilst some content on this topic will be provided as part of Hub standard operations, for example educational content and a Hub Talk, more specific and in-depth organisation-specific interoperability guidance and assessments would be provided by Hub collaborators for a fee, on which the Hub could take an agreed overhead.

A further important topic not shown on the above chart, because it is in early discussion, is the potential for collaboration with a forthcoming (approved) European project Label2Enable, which will be developing and promoting a European quality label and certification scheme for mobile health and wellness apps, underpinned by the recently published ISO 82304-2 Technical Specification. The European mHealth Hub project has verified through stakeholder engagement and response to its deliverable on the topic, a strong interest in scaling up the available guidance to developers about assessment frameworks and a comparison of the certification processes in different European countries. This is an attractive area to enrich the Hub offering. However, i~HD and EHTEL have informally agreed

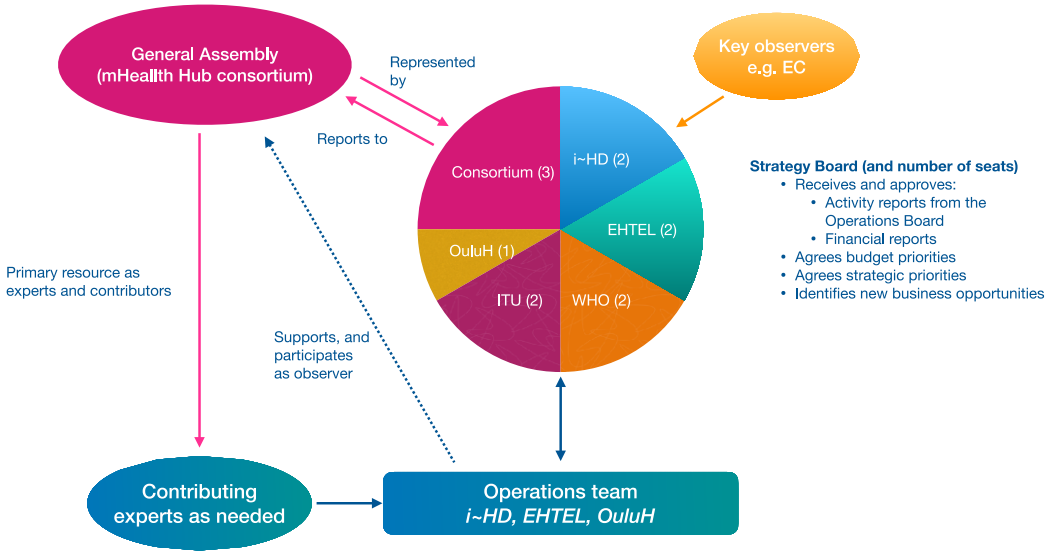
not to duplicate or clash with Label2Enable, but rather to develop a mutually reinforcing collaborative relationship. This is expected give rise to future joint business opportunities.

The above chart should therefore be seen only has the initial proposal for incremental service development and income generation, to be further elaborated and evolved in the coming months.

6.5 Governance model

As indicated above, most members of the original project consortium expressed a willingness to join the SLT and have also expressed an intention to remain involved next year. They understandably would like to be involved in decision-making, given their historic investment of time, energy and expertise in deliverables and in their ideation of how the Hub might deliver value in the future. They would also like to be involved contributing their expertise through online discussion fora, providing (sometimes on a goodwill basis) content in the form of materials or contributing to Hub Talks. At times their contribution might be a win-win: enriching the Hub and thereby making it more attractive to future members and purchasers of services, but also increasing their own visibility and perhaps attracting future opportunities for themselves (but not any direct marketing through the Hub).

A governance model has been developed that is inclusive of the valued commitment of the SLT members whilst endeavouring to be practical in the organisation of meetings and decision-making. This is illustrated through the governance diagram below.



The existing SLT members (but not including WHO, ITU, EHTEL or i~HD who are separately provided for) would constitute a General Assembly and elect three representatives onto a Strategy Board. This Board would also have representation, two seats each, from WHO, ITU, EHTEL and i~HD, and one from OuluHealth. The Strategy Board would be responsible for determining the priorities, activities and business development strategies that the hub should pursue, through its operations team comprising EHTEL, i~HD and OuluHealth. The operations team would report financially and managerially to the Strategy Board. The GA would be updated by and influence the Strategy Board through its three representatives.

The European Commission, and potentially other policy-making bodies, would be invited as observers. Organisations such as the EC would not be expected to play any influential or decision-making roles.

6.6 Next Steps

The business development roadmap, the intended activity portfolio, the governance model and the specific contractual arrangements between WHO, ITU, i~HD, EHTEL and Ouluhealth are still being finalised, so the above description should be seen as provisional and therefore subject to change.

The next steps in preparation for the Transitional Period are:

- ITU & WHO finalizing Contract Agreements with i~HD and EHTEL for the implementation of the 1st year of the TOR, and a parallel contract for the in-kind contributions from OuluHealth
- Work on estimated realistic Profit & Loss projection until year three
- Refining budget for 1st year up to a period of 3 years
- Official request to Regional MOH Andalusia for continuation of engagement with the Hub

Annex 1: Stakeholder analysis

A desk research was performed in the period February-April 2020, aiming to:

- Identify the stakeholders involved in implementing mHealth programmes in countries from the WHO Europe Region
- Map the stakeholders in the ecosystem to better understand their motivations and roles, and
- Identify different needs that can be addressed through the European mHealth Hub services

SUMMARY OF RESULTS

1. The majority of countries in the European Region don't have a dedicated mHealth strategy or policy in place. Strategic aspects of mHealth are observed in the countries' eHealth policies and strategies, national telehealth strategies.
2. mHealth programmes and initiatives implemented often lack an evaluation aspect. Consequently, there is an overall lack of evidence on related aspects, such as cost-effectiveness, proven scientific and clinical effectiveness, validity and reliability.
3. Legislation and regulation are often seen as hampering wider adoption of mHealth solutions. Policy should clarify a number of aspects related to use of health information, patient data, medical and wellness domains, liability of health professionals and third-party providers, etc.
4. Knowledge, education and (digital) skills both for patients and healthcare professionals need to be approached in a more systematic manner
5. Lack of collaboration between relevant stakeholders, e.g. agreement among key parties in the health care sector about common use of terminologies and codes to ensure standardized data for research and development

RESULTS IN DETAIL

Sponsorship and link to national/regional strategies and policies

mHealth overview in the Member States (2016 WHO report[4])

The report is based on data provided by 47 Members States in the 2015 global survey, aiming to capture the eHealth status and provide information about major areas of development, perceived barriers to adoption and potential areas of growth.

- 49% of respondents (22 Member States) have **government-sponsored** mHealth programs
- 73% (33 Member States) **no entity** responsible for the **regulatory oversight** of the quality, safety and reliability of mHealth applications.
- The use of mHealth for access to patient records has increased by 25% since the 2009 survey.

[4] From Innovation to Implementation: eHealth in the WHO European Region, 2016

- The use mHealth for appointment reminders has risen by 21% since the 2009 survey.
- Three Member States (7%) have carried out **evaluations** of government-sponsored mHealth programs.
- All Member States reported having **no dedicated national mHealth strategy or policy.** This is particularly revealing, as Member States within the WHO European Region are the most active in mHealth globally.
- mHealth programs in 59% (13 countries) are **guided by eHealth policy or strategies,** whereas 18% (four countries) report that mHealth is **guided by the national telehealth strategy** and 27% (six countries) report that no specific policy or strategy guides mHealth.

Barriers to mHealth implementation

mHealth overview in the Member States (2016 WHO report[5])

The top barriers listed by Member States were:

- Funding
- Knowledge
- Lack of evidence on Cost-effectiveness
- Legal issues – lack of legislation or regulations
- Competing health system priorities
- Lack of evidence on effectiveness of mHealth programs

Barriers identified in Netherlands[6]

- Stewardship
  - Lack of adequate set of core standards
    - **Lack of specific regulation on mHealth** to ensure health information obtained by mHealth applications complies to privacy and data security standards.
    - End-users suggested to define **a set of clear principles** applied to all use of patient data and to all data controllers to guarantee the protection of mHealth data.
    - **Allowing patients access to their own health information** is a first step in enabling mHealth implementation
    - Despite a new regulation, barriers exist in the **interoperable exchange** of health data. Healthcare providers cannot directly transfer patient data received from sensors or applications to an EHR. This prevents (self-measured) mHealth data to be saved in health records. There is a need to produce a set of **core standards and specifications** that enable EHRs to communicate seamlessly
  - Difficulties to inform on mHealth
    - Established research methods aiming to measure effectiveness of mHealth applications lag behind

[5] From Innovation to Implementation: eHealth in the WHO European Region, 2016

[6] Bally, E. L., & Cesuroglu, T. (2019). Toward Integration of mHealth in Primary Care in the Netherlands: A Qualitative Analysis of Stakeholder Perspectives. Frontiers in public health, 7.

- appropriate assessment methodologies are needed to measure validity and reliability of mHealth apps in order to provide recommendations to consumers
- Encourage flexible learning
  - There is a **lack of collaboration** between stakeholders.
  - More specifically, the **Ministry of Health** was appointed to have an important role in this process of bringing stakeholders together.
- Collecting evidence
  - need for **scientific evidence** on the effectiveness of mHealth solutions
  - possible explanation for the lack of evidence is the large, non-regulated (international)market for digital health technologies, making it hard to assess what technologies can be successfully adopted. Due to a lack of time and resources, **GPs are hesitant to adopt mHealth services** without **proven effectiveness**.
- Financing of mHealth apps
  - A lack of time and resources to establish **financial flows for mHealth**
    - GPs mentioned that existing budgets were not satisfying to realize mHealth service provision
  - Thinking about a revenue model
    - Health insurers noted a better chance of receiving funding, if a GP presented a long-term revenue model.
    - GPs indicated a lack of knowledge to develop a smart financing model. Better cooperation between GPs and health insurers is needed to make existing budgets fit for implementing new innovations.
- Resources
  - **Lack of digital skills**
    - Particularly, older generations may experience difficulties in using mHealth technologies as they need to switch to a new way of working. A lack of digital skills results in extra time needed to enter or process data.

Regulatory aspects

- mHealth devices[7]
  - **governed by two regulatory frameworks**, the Radio Equipment and Telecommunications Terminal Equipment (RTTE) and the EU Medical Devices Directive (MDD) (not explicitly)
    - queries regarding the application and coordination between these two regulations
    - need to **develop appropriate classification skills due to broad range of mobile medical devices** which can vary in both technical aspects as well as type of service
  - there is a need to **refine the boundaries between mobile** medical applications and mobile **wellness applications**
  - **issue of liability**: in mHealth solutions as in addition to product liability or potential liability of healthcare professionals and third-party service

[7] Emmanouilidou, M. (2016). The status of mHealth in Europe and a review of regulative challenges. In *Multi conference on computer science and information systems: eHealth* (pp. 203-206).

providers, there are also the actual patients who are heavily encouraged to self-manage their medical conditions
- possible **issue of data privacy and security** when the transmission of sensitive health data is performed via wireless networks in mHealth services

- Medical devices[7]
  - In the EU, each member state can file an approval application for a high-risk medical device. The device is then evaluated by a notified body (NB) established within that state and authorized by the state's public health agency. **NBs have the authority to issue the device a Conformité Européenne (CE) mark.** This mark denotes conformity with relevant EU requirements for medical devices. A device bearing a CE mark can be sold in any EU member state. Europe has about 76 NBs, which are private for-profit companies that contract with manufacturers to supply the certifications for a fee.
    - **NBs may be reluctant to deny approval of a medical device for fear of losing its client to a competitor**
    - although the CE mark indicates that the device is in full compliance with European legislation, **medical devices approved in Europe need only show safety and performance, but not clinical efficacy**

- key regulatory domains relevant to developers[8]
  - consumer privacy
  - data security
  - content
  - promotion and advertising
  - consumer finances
  - medical device efficacy and safety
  - professional ethics

- List of EU policies
  - Consumer privacy, Data security Opinion 02/2013 on Apps on Smart Devices EU Privacy[9]
  - Consumer privacy, Data security, Promotion and Advertising**:** Commission Staff Working Document on the Existing EU Legal Framework Applicable to Lifestyle and Wellbeing Apps[10]
  - Consumer privacy, Data security, Consumer finances, Medical device efficacy & safety myhealthapps.net[11] and related references[12] UK

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8 Parker, L., Karliychuk, T., Gillies, D., Mintzes, B., Raven, M., & Grundy, Q. (2017). A health app developer's guide to law and policy: a multi sector policy analysis. *BMC medical informatics and decision making*, *17*(1), 141**.**

9 Article 29 Data Protection Working Party: Opinion 02/2013 on apps on smart devices. Brussels: European Commission. 2013. [http://ec.europa.eu/justice/dataprotection/article-29/documentation/opinion-recommendation/files/2013/wp202_en.pdf].

10 European Commission. Commission Staff Working Document on the existing EU legal framework applicable to lifestyle and wellbeing apps. Brussels, Belgium. 2014. [https://ec.europa.eu/digital-single-market/en/news/commission-staff-working-document-existing-eu-legal-framework applicablelifestyle-and].

11 myhealthapps.net. my health apps: tried and tested by people like you, London. [http://myhealthapps.net/].

12 myhealthapps.net. The myhealthapps directory 2015-2016. London. 2015. [http://www.patient-view.com/uploads/6/5/7/9/6579846/the_myhealthapps_directory_2015-2016.pdf].

mHealth Assessment

- Relevant Criteria for app assessment[13]:
  - Privacy
  - Transparency
  - Reliability
  - Validity
  - Interoperability
  - Safety
  - Technical stability
  - Effectiveness

- Stakeholders comments on the challenges to agree on common terminology about specific criteria[13]:
  - **Transparency or privacy**: Issues relating to Transparency raised by many respondents are addressed by data protection law, specifically addressed by art 12-14 of the General Data Protection Regulation (GDPR). They may therefore be best considered under the Privacy criterion.
  - **Transparency or Validity:** Payers and Social Health Insurance raised the following issues under a discussion of the transparency criterion: "Where do the content and the scientific concept of the app come from?" "Where can the scientific documentation of the app and its algorithms be found?" These issues are directly relevant also to the assessment of data under the validity criterion.
  - **Scalability or Interoperability:** The following comment was made by Public Health Authorities "the most crucial aspect of scalability is being able to easily capture the results in the patient's EHR". This seems more relevant under the criterion interoperability.
  - **Safety and Accuracy or Validity:** Many of the concerns raised in stakeholder responses about safety, may in fact be better considered as the consequences of insufficient validity of data. Academia/Research and patient stakeholders raised the possibility of including accuracy as an additional criterion, as a subcriterion of validity or a separate criterion. In any case, it appeared that, accuracy certainly is an important aspect of validity and more specifically the accuracy of (data produced by) algorithms, is directly relevant to assessment of validity.

- Published guidelines:
  - Andalusia: Complete list of recommendations on design, use and assessment of health Apps
  - Germany: Health apps & co: safe digital care products with clearer regulations
  - United Kingdom: Guidance: Medical device stand-alone software including apps

Conceptualization of a Global Framework[14]

[13] Report of the Working Group on mHealth Assessment Guidelines, February 2016, March 2017, EC

[14] Bradway, M., Carrion, C., Vallespin, B., Saadatfard, O., Puigdomènech, E., Espallargues, M., & Kotzeva, A. (2017). mHealth assessment: conceptualization of a global framework. *JMIR mHealth and uHealth*, *5*(5), e60.

The insights and suggestions provided by the authors of the paper are intended for the groups that are completing evaluations, developing apps, and creating health policy and infrastructural support for mHealth implementation.

- **Assigning the Evaluation Team**
  - A single organization cannot be expected to accomplish the diversity of tasks and successfully address the challenges of mHealth evaluation (e.g., results of safety, usability, and health change assessments)
  - **Representative organizations should be involved in tasks associated with their competencies**, thus providing even distribution of responsibilities as well as relevant input.
  - **the evaluation team** should possess a **broad scope of perspectives** that are **representative** of the following **stakeholder groups**: patients or patient organizations; commercial and research-based mHealth developers; health care providers, medical professionals, and system administrators; insurance or other reimbursement bodies; and authorities within governmental health and medical system organizations.
- **Pre-Assessment of mHealth Solutions**
  - The pre-assessment phase is meant to classify any mHealth app (they further describe a risk matrix assessment in the article)
  - In order to address mHealth solutions within any stage of development, **pre-assessment guides should be distributed to developers who are still in the process of designing health solutions** as well as for **members of evaluation teams** within any medical system or country.
- **Checklists**
  - preparative resources for the evaluation team
  - The checklist will vary from country to country and be **provided to the evaluation team**
  - should **ensure that documentation** related to the following categories is **provided** for **each mHealth solution:** designation of mHealth solutions by intended use, for example, reference guides (e.g., for nutrition or weight control), monitoring devices (e.g., for blood sugars or blood pressure), or other types of solutions within a matrix
    - level of development
    - security and privacy
    - interoperability standards
    - usability
    - functionalities and content

Currently**,** few functional and representative checklists (e.g., Catalonia, Andalucía, and WHO's mHealth Technical Evidence Review Group). Most others are not fully available, are under development (e.g., European Commission mHealth assessment working group), or are focused only on mobile medical devices (e.g., Future Internet-STAR checklist model).

- **mHealth Evaluation Aspects and Methods**
  - **Assessment initiatives** should be **focused on summative** (i.e., during or post implementation) as well as formative (throughout the development life cycle) **evaluation**.
  - Assessment initiatives should be focused on summative (i.e., during or post implementation) as well as formative (throughout the development life cycle) evaluation.

- Ideally, the chosen set of domains and subdomains should address the following needs:
  - **Determine the appropriate use of each mHealth solution** (i.e., as a medical device or a health and wellness tool, based on the target and breadth of functionalities as well as status of interoperability and safety standards)
  - **Develop expedited and conclusive methods to evaluate the effect(s)** that an mHealth solution has on respective clinical outcomes and/or patient lifestyle habits, based on its appropriate and intended use
  - **Assess risk related to (1) patients and their caregivers** in relation to personal data security, self-management decision making, and disease understanding; (2) clinicians, including liability to their practice and a greater trust of and reliance on patient-gathered data; and (3) overall health care organizations and systems, including financial impact and liabilities.
  - **Inform stakeholders** of relevant results through respective and accessible platforms.

Success factors

Sweden[15]

- **Adoption of necessary legal changes to make digital documents equally valid with paper documents** and to ensure security and privacy rules etc. (In Sweden the patient has the right to see their own medical records, decide on information sharing and block access to information). Transparency of health data for the patients is also essential from a democratic aspect.
- **Agreement among key parties in the health care sector about common use of terminologies** and codes to ensure standardized data for research and development.
- Focus on **changing processes in health care when implementing new technology**. When medical records were first computerized in Sweden, the administrative burden for doctors increased. The main reason for this was that routines for writing medical journals did not change. Demands increased on doctors and nurses to report more data. Today there is **too much documentation in health care which jeopardizes patient security**. Swedish doctors spend 60% of their working hours with patients.
- **Infrastructure for mHealth/eHealth**. Use what is already working and available. One example of this is mobile ID in Sweden which was introduced by banks and is now applicable in health care.
- **Develop reimbursement systems/financing systems that enhance mHealth/eHealth development**. For example, in some areas in Sweden, doctors only get paid if they see the patient in person, not online.
- **Set up clear governance to ensure possibilities for private entrepreneurs**. Governance should focus on infrastructure and standardization, and free up private business to develop IT applications through an authorization process.

[15] [15] Catharina Barkman & Lars Weinehall (2017) Policymakers and mHealth: roles and expectations, with observations from Ethiopia, Ghana and Sweden, Global Health Action,10:sup3, 1337356, DOI: 10.1080/16549716.2017.1337356

- **Prioritize financial investments in mHealth/eHealth**. In Sweden the IT share of the healthcare budget has been constant at a level of 2.83% since 2003, while eHealth/mHealth development and IT users have increased by 90%.
- **Focus on evaluation when installing or testing new mHealth applications**.

Finland[16]

- **Align the new solution with a country's existing infrastructure and health strategies as well as economics of health care within the government**. Development and scaling of information and communication technologies (ICT) are largely driven by communication and commerce needs in general. To facilitate the improvement of mobile infrastructure in resource-limited settings mobile health solutions should be considered in a broader context and coupled with similar solutions for education, agriculture and small businesses.
- **Identify the real needs, understand the local settings**, e.g. existing health care, mobile infrastructure language requirements, cultural practices, understand what motivates the end-user and what contributes to user satisfaction. Engage the community from the beginning and monitor the perceived usefulness closely.
- **Use agile product development**, i.e. start the implementation and field tests as early as possible in the process. Get feedback from the end-users through rigorous usability studies and the perceived ease of use. Correct mistakes in design and usability early, perform rapid iterations of the solution and then redeploy the new version. This approach has proven highly effective as com-pared to traditional approaches where implementation happens late in the project.
- **Involve all stakeholders, including health ministry and telecommunications agencies, network operators, donors and end-users right from the start of the project**. Describe benefits to both end-users and business partnerships, under-stand all partners' success metrics. All stakeholders must be presented with a compelling value proposition to ensure sustainability.
- **Take scalability factors into consideration from the start.** A business model is needed to ensure scaling, it cannot rely on short-term funding. A financially viable business is the only way to ensure perennity.
- Financing of projects is typically a problem and seed money often comes from private philanthropists and donors. It should rather be main-streamed and include industry, telecom companies, pharmaceutical companies and NGOs.
- **Promote the use of standards and integration with the local health information-management systems**. Join global data and application repositories, promote joint collections of data and images. Within image-based diagnostics, access to large annotated image databases is instrumental both in the development of new algorithms and in validation of existing ones.
- **Evaluate feasibility and monitor the impact and cost efficiency of a new method,** considering the local financial (e.g. different level of subsidy) and technical resources (e.g. mobile network coverage). Currently only a very small proportion of mobile health solutions are evaluated. There needs to be investment in the evaluation, both financial and human resources. Scale-up should be preceded by efficacy and effectiveness trials so that it is founded on an appropriate evidence base.

[16] Johan Lundin & Guy Dumont (2017) Medical mobile technologies – what I sneeded for a sustainable and scalable implementation on a global scale? Global Health Action,10:sup3, 1344046, DOI: 10.1080/16549716.2017.1344046

Partnerships/Stakeholders in mHealth

Netherlands[17]

Three main groups:

- individual patients/consumers and their representative organizations.
- healthcare professionals interacting with patients (e.g., GPs, practice nurses, medical specialists), and their professional organizations/associations
- institutions and organizations not directly in contact with patients/consumers, but able to affect their health (e.g., governmental institutions, health insurers, mHealth providers).

Stakeholder influence analysis

- **Supportive Stakeholders with High and Medium-High Influence:**
  - primary care groups (legal entities owned by GPs in a particular region) and health insurers
  - Core function of care groups are to coordinate chronic illness care and to negotiate a fixed fee per patient with a health insurer
  - Care groups – potential promotors of mHealth integration. They are interested in implementing health technologies, such as mHealth, for three reasons:
    - To reduce the workload of health professionals
    - To increase the quality of care
    - To meet the expectations of the patient population they serve
  - Possible issue: funding
- **Supportive Stakeholders with Medium / Medium-Low Influence:**
  - mainly working in government agencies under the Ministry of Health, including the Program of Innovation and Healthcare, the Directorate Medicine and Medical Technology and the Centre of Expertise in eHealth (NICTIZ).
  - important stakeholder in the integration of mHealth in primary care as they set the standards for health information data exchange and are responsible for the eHealth application already used in primary care, such as online tools for making a GP appointment.
- **Supportive Stakeholders with Low Influence:**
  - Supportive stakeholders who agree that mHealth should have a profound role in chronic care delivery but have less influence on the integration of mHealth in primary care, include chronically ill patients and practice nurses.
  - They are the main potential users of mHealth technologies. Among all end-users, chronically ill patients expressed the highest interest in mHealth adoption. This group noted some perceived benefits of mHealth, such as quick and easy communication with healthcare providers, and increased patient autonomy.

Recommendations

For Member States[18] (WHO 2016 Report)

[17] [17] Bally, E. L., & Cesuroglu, T. (2019). Toward Integration of mHealth in Primary Care in the Netherlands: A Qualitative Analysis of Stakeholder Perspectives. *Frontiers in public health*, *7*.

[18] From innovation to implementation, eHealth in the WHO European Region, 2016

- **National health authorities** are recommended to **provide guidance on data ownership, security and data privacy in relation to the development and use of mHealth** and should **address quality, safety and reliability of mobile devices and software used in health care provision** through appropriate national regulation.
- **Member States** should **address liability, licensing and informed consen**t through policies and legislation regarding mHealth
- A **national entity in each Member State** should be identified to **promote use of mHealth** and **raise awareness of best practices** for the development and adoption of mHealth.
- **National health authorities and the health research community** should **develop and use a common methodology to evaluate mHealth programmes**, particularly government-sponsored initiatives. These evaluations should address usability, functionality and meaningfulness of mHealth solutions for end users. The evidence from evaluations should be actively used to support investment and implementation decisions:
- **National health authorities** should **develop reimbursement models for mHealth tools** and services. These should be based on demonstrated benefits of mHealth and support the achievement of national health objectives.
- **All major stakeholders** should continue **international cooperation in developing regulations**, **policies and best practices on the use of mHealth**. This will facilitate continuity in the uptake of mHealth and aid in the development of cross-border programs.

For mHealth developers[19]

- Data privacy
  - **App developers** should ensure that any **practices to share/sell consumer data are transparent and appropriate** about protection of privacy and the interests of the general public.
  - **encourage public discussion and advocacy** in this field with the aim of increasing public awareness of current practices and possible implications, and **generating public input into regulatory standards or a government endorsed code** about what is and what is not acceptable in terms of health app data-sharing.
  - **App distributors** should **enforce the inclusion of user friendly privacy policies for all health apps**
  - **device manufacturers** should **ensure that privacy-friendly settings are the default setting on phones**,
  - **data-brokers and other third parties** should **develop strong self-regulatory systems** around practices for obtaining, sharing, using and retaining consumer data.
- Data security
  - **Developers should pay strict attention to the security advice contained within legislative guidelines** and **implement strong security protections** on all health apps.

[19] Parker, L., Karliychuk, T., Gillies, D., Mintzes, B., Raven, M., & Grundy, Q. (2017). A health app developer's guide to law and policy: a multi-sector policy analysis. *BMC medical informatics and decision making*, *17*(1), 141.

- **encourage greater public debate** and discussion to increase public awareness about **the inherent insecurities of digital technology**
- **encourage industry to prioritize innovation in health app security**.

- Digital content
  - App **developers** should be **aware of and adhere to legislation around digital content**. Due to the near market-monopoly positions of Apple App Store and Google Play Store, legislation will likely play less of a role than the content guidelines from these major app distributors.

- Promotion and advertising
  - **app developers** should become aware of and **adhere to legislative and industry standards on advertising**. For health apps, this includes NOT making claims that are unsupported by clinical evidence.
  - In order to increase the levels of consumer protection, we encourage **increased consumer awareness of consumer complaints mechanisms,** together with **increased funding of government consumer protection agencies.**
  - Consumer-focused legislation pertaining to trade promotion and advertising has proven to be a powerful regulator of health apps in other jurisdictions and may be the most suitable tool to provide strong oversight in this field

- Consumer finances
  - app **developers** should **conform to acceptable refund practices and avoid making repeated offers for in-app purchases,** particularly within the context of a mental health app
  - **app developers should adhere to consumer advertising legislation**, and this includes being **transparent in advertising materials about the financial costs associated with app download and use.**
  - **consumers and governments** should **exert pressure on app distributors to exclude apps that promote in-app purchases within apps targeted at vulnerable consumers**.
  - urge **distributors** to **mandate time-limits on subscription payments when apps remain unused for long periods.**

- Medical device efficacy and safety
  - all health app **developers familiarize** themselves with the **legal requirements of their local medical device regulator,** particularly in relation to any requirements for supporting evidence of efficacy
  - encourage all developers of health apps to **provide information to users about factors that may influence the apps' likely efficacy and risk of harms** (for example, whether or not the app was developed in conjunction with health experts, whether or not it incorporates recognized healthcare guidelines or is informed by other scientific evidence, and who is funding the app).
  - **transparency about the scientific evidence (or lack of evidence)** underpinning the **app's effectiveness** on health outcomes is key.

- Professional ethics

- app **developers** should **provide details on key stakeholders, scientific sources, and the app's monetization strategy.**
- **Developers** should **ensure** that their **privacy policies, privacy practices and consent processes are not just box-ticking exercises that aim to limit their own legal liability**, but actually **enable consumers to protect their privacy while using apps**.

Grouping of stakeholders following the desk research results

This document distinguishes 13 main stakeholder categories. Some adaptation to these categories may be agreed later.

Patients and the public		
EXAMPLES	Patients, caregivers, Patient organisations, Healthy citizens, Wellbeing and prevention organisations	
USER ROLE	e.g. to find case studies they can use to promote the benefits of mHealth to their members	
PARTNER ROLE	*Content provider on user perspectives*	health needs, mHealth requirements, usability criteria, digital literacy requirements, health outcomes impacts
	Content provider on evidence	clinical guidelines suitable for mHealth solutions, validity of the clinical content, quality and patient safety considerations, evaluation and outcome indicators
CUSTOMER ROLE	*Sponsor*	charitable sponsorship of knowledge content relevant to the patient organisation, because of the impact on health outcomes and patient empowerment

Health and care professionals		
EXAMPLES	Individual health and care professionals, Professional scientific associations, Professional negotiating bodies and unions	
USER ROLE	e.g. to learn about successful use cases and benefits, best adoption practices, to promote mHealth to their members	
PARTNER ROLE	*Content provider on user perspectives*	health needs, mHealth requirements, usability criteria, digital literacy requirements, health outcomes impacts
	Content provider on evidence	clinical guidelines suitable for mHealth solutions, validity of the clinical content, quality and patient safety considerations, evaluation and outcome indicators
	Content provider on acceptance	training needs, handling of professional accountability, impact on fees and reimbursements
	Content provider on adoption	fit of mHealth within care pathways, integration with EHRs, workload impact of adoption, skills requirements
	Evaluation	evidence of value to their members when providing input on the design of mHealth programmes or when using mHealth solutions
	Promotion	of the mHealth Hub to their members, and to decision makers about future mHealth programmes

CUSTOMER ROLE	*Sponsor*	charitable sponsorship of knowledge content relevant to the professional organisation

Health and care provider organisations		
EXAMPLES	Hospitals, Primary care and GP practices, Social care providers, Nursing homes, residential care, Health and care provider charities, Regional healthcare networks	
USER ROLE	e.g. to learn about use cases and strategies that optimise health outcomes, to find information to develop a business plan, to identify the most useful evaluation metrics	
PARTNER ROLE	*Content provider on user perspectives*	health needs, mHealth requirements, usability criteria, digital literacy requirements, health outcomes impacts
	Content provider on acceptance	training needs, handling of professional accountability, impact on fees and reimbursements
	Content provider on adoption	fit of mHealth within care pathways, integration with EHRs, cost of deployment and adoption, skills requirements, organisational accountability, organisational governance
	Evaluation	demonstrating the value of the hub when designing an mHealth intervention, or when procuring the mHealth solutions, or when conducting an evaluation of their programme
	Promotion	of the mHealth Hub within their provider organisation (for other disease or prevention areas), and to decision makers about future mHealth programmes
CUSTOMER ROLE	*Sponsor*	charitable sponsorship of knowledge content relevant to the organisation

Non-profit and charitable health organisations		
EXAMPLES	Charities developing support resources (e.g. education) for specific disease groups or prevention areas, not for profit bodies active in investigating health needs, developing and running health promotion strategies and campaigns	
USER ROLE	e.g. to discover how to incorporate the use of mHealth solutions within their strategies and campaigns	
PARTNER ROLE	*Content provider on user perspectives*	health needs, mHealth requirements, usability criteria, digital literacy requirements, health outcomes impacts

	Evaluation	demonstrating the value of the hub when designing an mHealth intervention, or when procuring the mHealth solutions, or when conducting an evaluation of their programme
	Promotion	of the mHealth Hub to their community, and to lobby decision makers to develop and finance mHealth programmes
CUSTOMER ROLE	*Sponsor*	charitable sponsorship of knowledge content relevant to the organisation

Health and care payers		
EXAMPLES	Regional health ministries, National health ministries, National/regional Health Insurance Funds, mutual societies, Public health insurers, Private health insurers	
USER ROLE	e.g. to discover good practices and example case studies when considering the business case for a new mHealth programme, design success factors, to identify the most useful evaluation metrics, to formulate their reimbursement policies	
PARTNER ROLE	*Content prioritisation*	suggest the knowledge areas of greatest importance to decision making, levels of detail for impact on decision makers, suitable language, currency, breadth, range of case studies needed
	Content provider on adoption	fit of mHealth within care pathways, integration with EHRs, cost of deployment and adoption, skills requirements, organisational accountability, organisational governance
	Content provider on business models	business case for adoption, KPIs for sustainability, economic indicators, reimbursement models
	Evaluation	demonstrating the value of the hub when designing an mHealth intervention, or when procuring the mHealth solutions, or when conducting an evaluation of their programme
	Promotion	of the mHealth Hub across the provider network they work with, and to decision makers about mHealth programmes
CUSTOMER ROLE	*Core funder*	could provide the substantial funding base for mHealth Hub sustainability, because of the potential impact on healthcare costs and outcomes through the use of mHealth solutions

Public health agencies		
EXAMPLES	Public Agencies specialized in Public Health, Health Services Research (HSR), Evidence-based Practice (EBP), Institutes of Public Health including those located in Universities	
USER ROLE	e.g. to identify the health care and outcomes impacts mHealth could make, and how best to incorporate mHealth into public health strategies, to find the elements of a business case for a new mHealth programme, to discover the programme success factors, to gain procurement guidance, to identify the most useful evaluation metrics, to formulate their reimbursement policies	
PARTNER ROLE	*Content prioritisation*	suggest the knowledge areas of greatest importance to decision making, levels of detail for impact on decision makers, suitable language, currency, breadth, range of case studies needed
	Content provider on evidence	clinical guidelines suitable for mHealth solutions, validity of the clinical content, quality and patient safety considerations, evaluation and outcome indicators
	Content provider on adoption	fit of mHealth within care pathways, integration with EHRs, cost of deployment and adoption, skills requirements, organisational accountability, organisational governance
	Content provider on business models	business case for adoption, KPIs for sustainability, economic indicators, reimbursement models
	Evaluation	demonstrating the value of the hub when designing an mHealth intervention, or when procuring the mHealth solutions, or when conducting an evaluation of their programme
	Promotion	of the hub to mHealth programme decision makers and operational leads
CUSTOMER ROLE	*Core funder*	could provide the substantial funding base for mHealth Hub sustainability because of the potential impact on population health including prevention, offering scalable (affordable) interventions

Assessment and licensing bodies	
EXAMPLES	Medicines regulators, Medical device regulators, HTA bodies, eHealth competence centres, Other assessment bodies, Agencies setting reimbursements and fees

USER ROLE	e.g. to determine the mHealth products and solutions that have been certified, to learn about the effectiveness of different use cases and designs, to formulate their reimbursement policies	
PARTNER ROLE	*Content provider on evidence*	clinical guidelines suitable for mHealth solutions, validity of the clinical content, quality and patient safety considerations, evaluation and outcome indicators
	Content provider on business models	business case for adoption, KPIs for sustainability, economic indicators, reimbursement models
	Content provider on safety	patient safety assurances, medical device compliance, regulatory conformance, safety and reliability
	Content provider on data	interoperability standards, data quality, provenance, communications, information security
	Content provider on ethics	compliance with data privacy and protection regulations, public confidence in using the solutions, acceptable reuse of mHealth data for research and strategy, ethical use of mHealth, equity of access to mHealth
	Evaluation	of the accuracy and regulatory conformance of the mHealth Hub guidance
	Promotion	of the hub to mHealth programme decision makers and operational leads

eHealth Competence Centres		
EXAMPLES	National eHealth Competence Centres in each EU Member State, EU level bodies such as the eHealth Network	
USER ROLE	e.g. to find the elements of a business case for a new mHealth programme, to discover the programme success factors, to gain procurement guidance, to identify the most useful evaluation metrics	
PARTNER ROLE	*Strategic role*	what roles the mHealth Hub has to fulfil in order to meet country-level needs, how it should be presented and promoted, what endorsements of content are needed for acceptability
	Content prioritisation	knowledge areas of greatest importance to decision making, levels of detail for impact on decision makers, suitable language, currency, breadth, range of case studies needed

	Content provider on business models	business case for adoption, KPIs for sustainability, economic indicators, reimbursement models
	Content provider on procurement	examples of tender calls, vendor selection criteria, risk and quality management, programme monitoring
	Evaluation	of the hub to mHealth programme decision makers and operational leads
CUSTOMER ROLE	*?*	

Policymakers		
EXAMPLES	National policymakers: Ministries of health, Ministries of welfare, social care, Ministries of science and technology, Ministries of Finance Multi-national policymakers: WHO, European Commission	
PARTNER ROLE	*Strategic role*	what roles the mHealth Hub has to fulfil in order to meet country-level needs, how it should be presented and promoted, what endorsements of content are needed for acceptability
	Content prioritisation	knowledge areas of greatest importance to decision making, levels of detail for impact on decision makers, suitable language, currency, breadth, range of case studies needed
	Content provider on business models	business case for adoption, KPIs for sustainability, economic indicators, reimbursement models
	Evaluation	of the hub to their mHealth programme decision making
	Promotion	of the hub to fellow decision makers (e.g. in other ministries, to other countries) and to their operational leads to use it
CUSTOMER ROLE	*Core funder*	could provide the substantial funding base for mHealth Hub sustainability, because of the potential impact on healthcare costs and outcomes through the use of mHealth solutions
	Core funder	could provide the substantial funding base for mHealth Hub sustainability because of the potential impact on population health including prevention, offering scalable (affordable) interventions. However, the division (sharing) of responsibilities between

		several authorities and agencies might also be a problem for active engagement (and thus support)

Innovation sponsors		
EXAMPLES	Innovation hubs, Business catalysts, Entrepreneur and start-up networks, Agencies promoting adoption of digital innovations	
PARTNER ROLE	*Content provider on markets*	how best to present ICT innovations, how best to present healthcare delivery innovations, how to promote sustainability and scalability, how to stimulate the mHealth products and services sector
	Content provider on business models	business case for adoption, KPIs for sustainability, economic indicators, reimbursement models
	Content provider on safety	patient safety assurances, medical device compliance, regulatory conformance, safety and reliability
	Evaluation	of the mHealth Hub on the market and to innovators
	Promotion	of the mHealth Hub to companies (e.g. to SMEs) and to programme operational leads they interact with
CUSTOMER ROLE	*Sponsor*	charitable sponsorship of knowledge content relevant to the organisation because of the impact on health outcomes and patient empowerment

Industry associations		
EXAMPLES	COCIR, MedTech Europe, EFPIA, National associations	
PARTNER ROLE	*Content provider on markets*	how best to present ICT innovations, how best to present healthcare delivery innovations, how to promote sustainability and scalability, how to stimulate the mHealth products and services sector
	Content provider on business models	business case for adoption, KPIs for sustainability, economic indicators, reimbursement models
	Content provider on safety	patient safety assurances, medical device compliance, regulatory conformance, safety and reliability
	Content provider on evidence	clinical guidelines suitable for mHealth solutions, validity of the clinical content,

		quality and patient safety considerations, evaluation and outcome indicators
	Evaluation	of the mHealth Hub on the market of each industry sub-sector
	Promotion	of the mHealth Hub to their industry members, to decision makers and to programme operational leads they interact with
CUSTOMER ROLE	*Sponsor*	could provide a supplementary funding stream for the mHealth Hub, because of the potential impact on the mHealth market and on the outcomes value of solutions

Industry		
EXAMPLES	Bio-pharma, MedTech, medical devices, diagnostics, Health software, apps, AI, Health record systems (EHR, PHR), Mobile devices and sensors, eHealth infrastructures, Big data (research) networks, ITU	
PARTNER ROLE	*Content prioritisation*	suggest the knowledge areas of greatest importance to decision making, levels of detail for impact on decision makers, suitable language, currency, breadth, range of case studies needed
	Content provider on markets	how best to present ICT innovations, how best to present healthcare delivery innovations, how to promote sustainability and scalability, how to stimulate the mHealth products and services sector
	Content provider on business models	business case for adoption, KPIs for sustainability, economic indicators, reimbursement models
	Content provider on safety	patient safety assurances, medical device compliance, regulatory conformance, safety and reliability
	Content provider on evidence	clinical guidelines suitable for mHealth solutions, validity of the clinical content, quality and patient safety considerations, evaluation and outcome indicators
	Evaluation	of the mHealth Hub on the market of their company and their industry sub-sector
	Promotion	of the mHealth Hub to decision makers and to programme operational leads they interact with
CUSTOMER ROLE	*Core funder*	could provide the substantial funding base for mHealth Hub sustainability, because of

		the potential impact on healthcare costs and outcomes through the use of mHealth solutions
	Core funder	could provide the substantial funding base for mHealth Hub sustainability because of the potential impact on population health including prevention, offering scalable (affordable) interventions

eHealth ecosystem		
EXAMPLES	SDOs, eHealth related stakeholders and multi-stakeholder not for profits promoting eHealth solutions, adoption, good practices, governance	
PARTNER ROLE	*Content prioritisation*	suggest the knowledge areas of greatest importance to decision making, levels of detail for impact on decision makers, suitable language, currency, breadth, range of case studies needed
	Content provider on safety	patient safety assurances, medical device compliance, regulatory conformance, safety and reliability
	Content provider on education	training needs of different kinds of user, syllabus recommendations, skills and assessments
	Content provider on ethics	compliance with data privacy and protection regulations, public confidence in using the solutions, acceptable reuse of mHealth data for research and strategy, ethical use of mHealth, equity of access to mHealth
	Evaluation	evaluating the use and impact of all aspects of the mHealth Hub
	Promotion	of the mHealth Hub across their multi-stakeholder communities, through events, exhibitions, and through its inclusion within mHealth educational courses
CUSTOMER ROLE	*Sponsor*	could provide a supplementary funding stream for the mHealth Hub, because of the potential impact on the mHealth market and on the outcomes value of solutions

Annex 2: Analysis of needs assessment

INSIGHTS FROM THE WEBINAR "EUROPEAN MHEALTH HUB SUPPORT FOR COUNTRY-LEVEL IMPLEMENTATION" HELD ON 30 JUNE 2020

- Germany would be willing to offer supporting and guidance role regarding aspects in the EU toolbox for the use of mobile applications for contact tracing and warning, such as quality guidelines for EU mHealth Apps
- (Germany) consideration for mHealth Hub are code of conduct in data protection issues for mHealth, bring together medical societies in Europe and discuss standards on mHealth guidance.
- (Finland) evaluating the app effectiveness in terms of patient empowerment; digital divide; privacy issues conversation; standardization with regards to a more technical orientation, connected to regulatory issues;

RESULTS FROM A HUB SURVEY ADDRESSED TO THE MEMBERS OF THE EHEALTH NETWORK

- Topics
  - Spain: KPIs, effectiveness monitoring
  - Finland: Evaluation and accreditation of national apps, monitoring the effectiveness of the apps
  - Denmark: Particularly monitoring the effectiveness of the app but also evaluation and accreditation of national apps, integration of mHealth solutions into health systems.
  - Croatia: Possibly on all the topics.
  - Estonia: Any input is welcome so if the mHealth hub has good ideas on how to monitor the effectiveness of the app, we will read them. For evaluation, we got a lot of help from the ENISA Cybersecurity guidelines
  - Poland: Monitoring the effectiveness of the apps.
  - Portugal: In monitoring the effectiveness of the apps, Integration of mHealth solutions into health systems
- Preferred delivery methods
  - Lithuania: checklists, technical notes
  - Finland: technical guidance
  - Denmark: As relevant depending on the topic
  - Croatia: Technical notes and policy briefs
  - Estonia: Probably checklists and technical notes
  - Poland: Policy briefs, technical notes

FEEDBACK FROM THE HUB'S 2020 CALL FOR EXPRESSIONS OF INTEREST, ANSWERED BY SEVERAL COUNTRIES

- Needs
  - exchange of best practices and getting policy and technical advice and guidance (Croatia)

- strengthening already existing activities such as ensuring the public integration necessary for the effective use of mHealth and fulfilling the social awareness phase of this process, especially in the area of chronic diseases monitoring (Turkey)
- exploring possibilities of launching mobile solutions within rollout of eHealth service platform (Poland)
- develop legal framework, methodology and organization for assessment of validity and reliability of mHealth apps, including their efficacy and safety (The Czech Republic)
- relevant national laws regarding the legislation of telemedicine services (Hungary)
- technical development; citizen's empowerment policies; coordinated actions in developing different kinds of apps (Finland)

- Expectations
  - Advancing processes for integration of mHealth services in the national health system, as well as providing knowledge base from which we can efficiently learn and adopt. (Croatia)
  - Personnel exchange programs between the Hub and the countries in certain periods and quotas (Turkey)
  - A platform for know-how transfer and project partnerships with events that bring leading countries together. (Turkey)
  - Mutual transfer of knowledge and good practices with relevant experts on issues such as the processes of roll-out, development (Poland)
  - Provide successful models for integration of mHealth apps into health services and methodology for assessment to the apps in various EU countries, as samples for inspiration for particular country
  - Any opportunity for EU wide coordination, standardization, joint database of good practices and implementations of mHealth. (Czech Republic)
  - Viable examples from other countries can help to influence decision-makers at national level, to initiate similar regulations, technical developments as well as financing changes (Hungary)
  - Raise awareness and increase skills of the topic nationally (Finland)
  - Standardized approach to scaling up of proven validated mHealth apps to other countries in general. It means possibly not only concrete apps (products) but essential attributes, features of such apps that can be replicated in other counties, without necessity to repeat the same processes for assessment of their efficacy and safety.

DERIVING POSSIBLE SERVICE GROUPS BASED ON NEEDS ASSESSMENT

Annex 3: Service portfolio v1

- **ACCESS TO EXPERT INFORMATION ON A VARIETY OF MHEALTH TOPICS**, e.g.:
  - **mHealth app assessment and certification**: existing frameworks in Europe, relevant aspects when setting up a framework, example approaches to assessment processes (KT1)
  - **mHealth service integration into healthcare systems**: good practices with details about approaches and lessons learnt when integrating mHealth services into healthcare systems
  - **mHealth policy implementation**: good practice examples (WP5) covering the following topics:
    - mHealth strategies, governance models and change management.
    - Integration mechanisms with EHR and interoperability.
    - Business models, innovation funds and reimbursement.
    - Ethical and regulatory issues. Secondary use of data and data security: privacy, confidentiality, integrity and availability.
    - Human centered design and patient safety. Patient empowerment, health literacy and digital skills.
    - Assessing the impact of the innovations.
    - ICT infrastructure and backend technical infrastructure.
    - Policy for addressing countries health priorities in times of emergency
- **IMPLEMENTATION SUPPORT TO SCALING UP MHEALTH PROGRAMMES**
  - Support in implementing mHealth-supported behavioral programmes on different topics, such as diabetes, hypertension, tobacco cessation, ageing, etc.
- **NETWORKING, MATCHMAKING, and KNOWLEDGE EXCHANGE**
  - Facilitating networking among mHealth stakeholders through events
  - Facilitating matchmaking of demand and supply towards knowledge exchange and scaling up of mHealth solutions
  - Supporting knowledge exchange in the form of twinnings (owner of a good practice transfers knowledge to one or more adopters, leading to a replication of the practice)

Annex 4: Report from mHealth Hub webinar on 23 October 2020

OBJECTIVES

The Hub invited **potential target groups of the future Hub services to co-develop the Hub service portfolio**. The webinar on the 23rd October 2020 aimed to engage potential target groups in elaborating needs related to the adoption and scaling up of mHealth practices and solutions that will form the basis for the definition of the service portfolio.

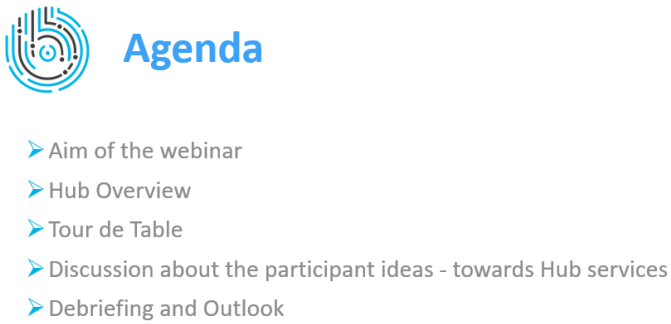
ATTENDEES

A total of 18 representatives of various mHealth target stakeholder groups accepted the invitation and attended the webinar, belonging to the following categories:

- **Governments** (Hungary, Czech Republic)
- **Industry Associations** (MedTech Europe)
- **Healthcare professionals / providers** (Absym Belgium, Region Jämtland Härjedalen, European Forum for Primary Care)
- **Insurers** (Estonia Health Insurance Fund, Kazakhstan Ministry of Health, North Macedonia Health Insurance Fund, Catalan Health Service, AOK Rheinland)
- **Innovation Hubs** (DHI Scotland, Starthubs Holland)
- **Developers** (Kinetikos)

AGENDA

The webinar took place on the 23rd October 2020, 10:00-11:30 CET, online, on the GoToMeeting platform. The aim of the webinar was explained and a Hub overview was provided. To allow participants to familiarise with each other and with the organisers, a tour de table took place.



PRE-WEBINAR BRIEFING KIT

A briefing document summarising the objectives of the Hub, the aims of the webinar, and the Hub services defined so far was provided two weeks in advance to the webinar. In addition, to capture the stakeholders' perspectives about needs and services, a pre-webinar questionnaire was added to the briefing kit, asking them to reflect on the following questions:

- What value do you see from the envisaged Hub?
- Based on the services listed so far, what kind of topics are you most interested in the service to include? What are the burning issues of the mHealth community you represent?
- How do you image you or your organization can contribute to the Hub?
- Can you think of further services or cases of use, which the Hub should aim to provide?

The collected answers were used to guide the webinar discussions around real needs and services, complementing the first set of defined services.

PRE-WEBINAR RESPONSES OVERVIEW

Hub's perceived value

When asked about their opinion about the value the mHealth Hub might bring, the participants' questionnaire answers conveyed that the Hub could bring value by sharing and disseminating knowledge on a variety of topics: implementing mHealth in health systems, good practices, evidence on the efficacy of mHealth tools to support the various stakeholders, availability of information about assessment framework for mHealth applications, successful evidence based mHealth solutions (for NCDs) and programmes that can be considered for scaling up. The Hub should provide evidence on ethics related topics and interconnection and collaboration with mHealth insiders, doers, and experts in mHealth. Furthermore, the Hub should provide assistance and support on the most efficient and effective ways for implementing mHealth in health systems and introducing mHealth interventions into the clinical routine. Furthermore, participants mentioned the idea that the Hub could collect and analyse the problems and challenges within the mHealth sector which could prove a significant boost for development. The Hub could also highlight the essential role mHealth should play in digital transformation of healthcare sector, especially during current COVID-19 pandemic. Participants endorsed in their answers that, over long term, it will be beneficial for the Hub to become an independent and self-sufficient entity, that will keep providing support to countries to scale up their national mHealth initiatives.

Participants suggested further services that the mHealth Hub might be able to offer:

- Access to expert information
- Implementation support
- Networking, matchmaking and knowledge exchange

Access to expert information

- Evidence based recommendations and use-cases oriented on Universal Health Coverage and adapted to the country context.
- Drafting of standards and policy for integration of mHealth into national health and healthcare information model, including interoperability with HIS, EHR and EMR.
- Personalised care plan development.
- New organisational models for improved delivery of integrated care.
- Guidelines for management of changes in the models of care delivery, considering diversity of European national and regional systems.
- Self-management training materials for increasing patient adherence to care plans.
- Educational material for stakeholders.
- Essentials of medical device software regulation (in EU), AI in mHealth apps – specific aspects and issues induced by using AI in apps.
- Cost-effectiveness data, possibility to start using already existing and testing tools instead of reinventing the wheel, support for healthcare providers.
- Support/knowledge share on how to promote mHealth solutions uptake and trust among patients and healthcare providers.
- New organizational models, assessing impact innovations; deliver integrated care with focus on NCDs; Funding schemes, leadership / policy makers engagement - on all levels.
- Support in defining digital health strategy.

Implementation support

- Clinical guidelines, create evidence-base, clinical trials, piloting of solutions.
- Assessment of strategies and/or projects implementation, based on clinical and cost-effectiveness.
- Scaling up across more than one region.

Networking, matchmaking and knowledge exchange

- Networking with other areas of good practice and learning about models for change.
- Comparing opportunities and environments in different countries.
- Being able to access a network of experts that allows knowledge exchange among peers. If possible, not influenced by companies but by public servants with no commercial interest. A catalogue of mHealth services including the provider details, implementation areas, costs etc.
- A distributed network model coordinated by the mHealth Hub. The partners already represent several European countries and regions which are committed to serve as national/regional nodes of the Hub. The strategy for expanding the Hub and ensuring its sustainability will be informed by key national level stakeholders including the eHealth Network and the national eHealth competence centres.

WEBINAR DISCUSSION

The discussion with the participants focused on four main topics, each guided by an expert. The blocks concerned subtopics of the draft services ideas collected so far: Access to expert information, Implementation support and Networking, Matchmaking, and Knowledge Exchange, as well as the major topic of stakeholders' possibilities of engaging with the Hub.

Access to expert information

When asked about which types of mHealth expert information they would need to access, specific areas of interest such as reimbursement and evidence were mentioned. Regarding evidence of mHealth effectiveness, a larger discussion took place emphasising the multiple dimensions which need to be addressed, such as time, costs, and clinical outcomes. mHealth was emphasised as an outstanding issue in which typical effectiveness requirements must be reconsidered and more pragmatic approaches need to be developed, as the usual assessment models do not always fit (e.g. randomised clinical trials). Attendees expressed the interest in learning how other countries are drafting laws and requirements for mHealth tools to be part of the regional or national catalogues. The same was expressed in the case of reimbursement, where the focus was on how different organisations address the reimbursement issue, as this is a complex topic which needs to be tailored according to the specific context. Further need of financing was expressed in areas such as:

- scaling-up support for available solutions,
- patient self-assessment based solutions and the wider concept of integrated care.

In the discussion, it was also considered that mHealth should support existing roles, rather than replacing traditional ones, and that communication and trust are factors with influence in a successful adoption of these tools.

Implementation support

Throughout the discussion there were a few areas that presented a potential need for implementation support services. It was also felt that some budget could be allocated e.g. by organisations or projects to paying for such services.

The following areas were briefly discussed:

- Supporting countries or regions scale up mHealth/integrated care programs and/or inform their legislative initiatives, in a way that is contextualized to local culture and health systems
- Offering training and education opportunities

In expressing their needs, participants reverted often to their request for evidence, including successful examples with demonstrable impact. They considered it quite likely that an organization would for example pay a subscription fee to the Hub for having access to such evidence, **t**o be invited to annual events and to be able to consult online resources.

Networking, matchmaking and knowledge exchange

Networking

- Identify the network of experts
- Develop content-specific communities of practice: legal aspects, reimbursement, outcomes-based financing, change management, maturity assessment, scaling-up, impact assessment, clinical evidence, etc.
- Make use of network organisations (MedTech, EFPC, EHTEL) to promote the mHealth Hub
- Explore networking and collaboration between industry and end-users

Matchmaking

- Use of the Twinnings scheme with one or more originators and multiple adopters
- Learn from matchmaking modalities used by network organisations (MedTech, EFPC, EHTEL, etc.): use of national associations, organisation of matchmaking events

Knowledge exchange

- Provide access to exchange of experiences (DiGA and mHealth Belgium on reimbursement)
- Provide access to experts qualified by the mHealth Hub (frontrunners)
- Seek experiences from end-users (especially health professionals)
- Make evidence readily available
- Emphasise how trust in mHealth has been developed in good practice examples
- Promote and feature good practices for different topics

DISCUSSION ON STAKEHOLDER CONTRIBUTIONS TO THE SUSTAINABILITY OF THE HUB

There was a discussion about the different roles the webinar attendees could foresee for their communities to engage with the Hub. In the role of users, it seemed that a need would be to have access to evidence of health outcomes impact, user acceptance and cost benefit ratio derived from mobile health innovations in different countries. They would also like to use the Hub as a resource to find a) people with adequate expertise and experiences, with whom they could engage and b) existing initiatives from which they could learn. They also perceived value in interacting through the Hub with other peers tackling similar issues, who might give some confidence in, or advice on, an approach they wish to pilot or a solution they wish to adopt.

It was recognised that budget would be required to be able to sustain the services of the Hub after the project. It was suggested that health insurers might be willing to subscribe if this provided access to evidence resources, to good practice guidance and provided networking channels. MedTech companies might be willing to pay for membership if this gave access to evidence that they could leverage on their outreach to potential customers. MedTech Europe could foresee promoting the Hub to its members if it could deliver that. Healthcare provider organisations and their

networks would probably be less well placed to pay, but would value peer engagement on mHealth approaches, experience and evidence.

It was pointed out that the eHealth Network, which has in the past had a mobile health working group, should be approached to consider promoting sustainable support to its Member State representatives. It was also noted that regions, who are more likely than countries to implement mobile health programs, could be separately approached through other representative organisations. European level organisations could also have a strong role to play in promoting the Hub and also in providing useful resources that the Hub could host, either themselves or through the projects and initiatives they fund. It was suggested that it should be a requirement that European Commission funded projects that have a mobile health component should be asked to provide some of their results as resources to the Hub, perhaps as they are currently asked to provide open access data sets if they can.

SUMMARY AND OUTLOOK

The first webinar focusing on its service portfolio aimed at eliciting the needs of various stakeholders, such as payers, industry associations, physicians, etc. and the potential services the mHealth Hub could offer. The first set of draft services was validated and complemented by the webinar additions and is given below. This will be followed by a next webinar whose aim is to define the services in more depth.

Attendees' additional ideas for the draft hub services

ACCESS TO EXPERT INFORMATION ON A VARIETY OF MHEALTH TOPICS, e.g.:

- **mHealth app assessment and certification**: existing frameworks in Europe, relevant aspects when setting up a framework, example approaches to assessment processes (KT1)
- **mHealth service integration into healthcare systems**: good practices with details about approaches and lessons learnt when integrating mHealth services into healthcare systems
- **mHealth policy implementation**: good practice examples (WP5) covering the following topics:
    - mHealth strategies, governance models and change management.
    - Integration mechanisms with EHR and interoperability.
    - Business models, innovation funds and reimbursement.
    - Ethical and regulatory issues. Secondary use of data and data security: privacy, confidentiality, integrity and availability.
    - Human centered design and patient safety. Patient empowerment, health literacy and digital skills.
    - Assessing the impact of the innovations.
    - ICT infrastructure and backend technical infrastructure.
    - Policy for addressing countries health priorities in times of emergency
- Evidence based recommendations and use-cases oriented on Universal Health Coverage and adapted to the country context.
- Personalised care plan development.

- New organisational models for improved delivery of integrated care.
- Guidelines for Management of Changes in the Models of Care Delivery, considering diversity of European national and regional systems.
- Self-Management Training Materials for Increasing Patient Adherence to Care Plans.
- Educational material for stakeholders.
- Essentials of Medical Device software regulation (in EU), AI in mHealth apps – specific aspects and issues induced by using AI in apps.
- Cost-effectiveness data, possibility to start using already existing and testing tools instead of reinventing the wheel, support for healthcare providers
- Support/knowledge share on how to promote mHealth solutions uptake and trust among patients and healthcare providers.
- New organizational models, assessing impact innovations; deliver integrated care with focus on NCDs; Funding schemes, leadership / policy makers engagement - on all levels.
- Support in defining digital health strategy
- Reimbursement: how others are addressing it; not a great one fits all models.
- Scaling-up support for available solutions
- Integrated care

IMPLEMENTATION SUPPORT TO SCALING UP MHEALTH PROGRAMMES

- Support in implementing mHealth-supported behavioural programmes on different topics, such as diabetes, hypertension, tobacco cessation, ageing, etc.
- Clinical guidelines, create evidence-base, clinical trials, piloting of solutions
- Assessment of strategies and/or projects implementation, based on clinical and cost-effectiveness
- Scaling up across more than one region
- Supporting countries or regions in scaling up mHealth/integrated care programs and/or inform their legislative initiatives, in a way that is contextualized to local culture and health systems
- Offering training and education opportunities

NETWORKING, MATCHMAKING, and KNOWLEDGE EXCHANGE

Networking

- Facilitating networking among mHealth stakeholders through events
- Identify the network of experts
- Develop content-specific communities of practice: legal aspects, reimbursement, outcomes-based financing, change management, maturity assessment, scaling-up, impact assessment, clinical evidence, etc.
- Make use of network organisations (MedTech, EFPC, EHTEL) to promote the mHealth Hub
- Explore networking and collaboration between industry and end-users
- Networking with other areas of good practice and learning of models for change
- Comparing opportunities and environments in different countries.

- Being able to access a network of experts that allows knowledge exchange among peers. If possible, not influenced by companies but by public servants with no commercial interest. A catalogue of mHealth services including the provider details, implementation areas, costs, etc.
- A distributed network model coordinated by the mHealth Hub. The partners already represent several European countries and regions which are committed to serve as national/regional nodes of the Hub. The strategy for expanding the Hub and ensuring its sustainability will be informed by key national level stakeholders including the eHealth Network and the national eHealth competence centres.

Matchmaking

- Facilitating matchmaking of demand and supply towards knowledge exchange and scaling up of mHealth solutions
- Use of the Twinnings scheme with one or more originators and multiple adopters
- Learn from matchmaking modalities used by network organisations (MedTech, EFPC, EHTEL, etc.): use of national associations, organisation of matchmaking events

Knowledge exchange

- Supporting knowledge exchange in the form of twinning activities (owner of a good practice transfers knowledge to one or more adopters, leading to a replication of the practice)
- Provide access to exchange of experiences (DiGA and mHealth Belgium on reimbursement)
- Provide access to experts qualified by the mHealth Hub (frontrunners)
- Seek experiences from end-users (especially health professionals)
- Make evidence readily available
- Emphasise how trust in mHealth has been developed in good practice examples
- Promote and feature good practices for different topics

Annex 5: Analysis of the Hub service portfolio validation survey

BACKGROUND

A broad validation survey was launched in January and was open for responses until April. A dissemination package with infographics and promotional materials for all social media channels was prepared and distributed to all Hub partners, ensuring a wide diversity of received responses. The survey consisted of thirteen questions and aimed to understand what are the demand-driven services that the Hub could offer to its potential customers, what features of the proposed Hub are most attractive and likely to be most useful to each stakeholder group, and to discover what in-kind or financial contributions might be acceptable.

SURVEY QUESTIONNAIRE

Q1. Which of the following stakeholder groups best reflect the community or communities whose viewpoint you can reflect in your answers? (in case you represent multiple groups, please select the one you primarily associate with)

Please tick		Please tick	
	Patients or citizens or representative organisations		eHealth Competence Centres
	Health and care professionals or representative organisations		Policymakers
	Health and care provider organisations		Innovation sponsors
	Non-profit and charitable health organisations		Industry associations
	Health and care public payers or health insurers, mutualities		ICT or MedTech industry
	Public health agencies		Life sciences or Biotech industry
	Assessment, regulatory and licensing bodies		Other (please describe):

Q2. For each of the following features of the proposed mHealth Hub, please could you indicate:

- If you find the feature **useful** for your stakeholder group
- If having access to this feature would increase your willingness to pay for Hub **membership**, through an annual fee (the amount of this fee is still to

be determined, but will be stakeholder-specific based on expected ability to pay)

- If you would be more likely to only **pay for access** just to this area of the Hub, if your need arises
- If you might directly fund (**sponsor**) the development of new content in this area
- If you could envisage being able to **contribute** new content in this area
- If you would be likely to **promote** the Hub to your community on the basis of this feature

You may tick as many columns as you feel might apply.

Feature	Useful for your stakeholder group	Membership	Pay for access to specific area	Sponsor	Contribute	Promote	
Summaries of success factors, initiatives, solutions and evaluation evidence							
Policy initiative areas							
Evidence of health outcomes, costs-benefit and user acceptance assessments							
Reimbursement and incentive models							
App certification criteria, models and frameworks							
Digital health literacy initiatives							
mHealth programme implementation support							
Innovations and horizon scanning relevant to mHealth solutions							
Q1.2 Networking resources							

Access to the Hub's network of mHealth experts							
Webinars, conferences, workshops							
Membership of mHealth communities of practice							
Matchmaking and twinning between mHealth initiatives							
Q1.3 Expertise resources							
Personalised advice and consultancy							
Recommendations and assessments by the Hub on key mHealth aspects							
Training courses offered by Hub experts							
Searchable dataset of mHealth solution suppliers, testimonies, B2B and B2C connections							
Q1.5 News							
Blogs and news							
Social media							

Additional questions

Q3 Are there any other features that your stakeholder group would strongly value if included in the Hub?

Q4 Apart from the actual fees, which are still being considered, are there other influences on your willingness to contribute financially to the Hub?

Q5 Apart from editorial independence and transparency about how all Hub content is determined, are there other influences on your willingness to endorse, promote and contribute content to the Hub?

Q6 Is your organisation or stakeholder group amongst those we should contact to explore sponsoring the Hub itself?

Q7 Is your organisation or stakeholder group amongst those we should contact to explore partnering us with enriching and promoting the Hub?

Q8*: About you and your stakeholder group

- Your name:
- Your organisation:
- Your email address:

MHEALTH HUB SURVEY RESPONSES

In total, 89 respondents completed the survey. Of these, 53 respondents were mHealth users, 14 were mHealth payers and decision makers, and 22 were providers and enablers of mHealth solutions.

Table 3. Number of respondents per stakeholder group

Stakeholder group	N
Total	89
mHealth users	53
• Patients or citizens or representative organisations • Health and care professionals or representative organisations • Health and care provider organisations • Non-profit and charitable health organisations	

- eHealth Competence centres
- Researchers

mHealth payers and decision makers	14

- Health and care public payers or health insurers, mutualities
- Public health agencies
- Policymakers
- Life sciences or Biotech industry

mHealth providers	22

- ICT and MedTech sector
- Industry associations
- Innovation sponsors
- Assessment, regulatory and licensing bodies
- SMEs

SERVICE OVERVIEW

All respondents

► Usefulness

The vast majority of survey respondents regarded the proposed services or features of the mHealth Hub useful. Agreement with the respective feature's usefulness ranged from 64% for personalised advice and consultancy to 84% for evidence of health outcomes, costs-benefit and user acceptance assessment. The groups of networking resources features (between 78-83% agreement for items) and catalogues (80%) were especially considered useful. Regarding expertise resources, respondents considered recommendations and assessments on key mHealth aspects most relevant (74%). Blog posts and news items were found considerably more useful than social media content (78% vs. 71%). Additionally, more than 80% agreed that policy initiative areas, access to mHealth expert network, and webinars/conferences/workshops were useful services.

► Membership

Taking the average agreement across all items, more than 30% of all survey respondents would be willing to pay for a mHealth Hub membership through an annual fee in order to access any one of the proposed features. Respondents were most willing to pay a membership fee for accessing the Hub's network of mHealth experts (43%) as well as mHealth communities of practice (40%), and least willing to pay a membership for social media content (17%). Respondents would comparatively more likely pay a membership fee for catalogues, expertise and networking resources than for other services.

► Pay for access

Few survey respondents would be willing to pay for accessing one specific service when needed. Less than one in ten would pay for accessing policy initiative areas, mHealth communities of practice, matchmaking and twinning, as well as news. In contrast, about one fourth would pay for participating in training courses offered by Hub experts (25%) and for receiving personalised expert advice and consultancy

(24%). Approximately 19% would pay for accessing app certification criteria, models and frameworks.

► Sponsor

Taking the average agreement across all features, around 3 to 4 % might sponsor the development of new content in any of the proposed services. Respondents would be most willing to fund digital health literacy initiatives (10%), followed by webinars/conferences/workshops as well as matchmaking and twinning (6%). Respondents were most hesitant to sponsor the development of evidence of health outcomes, costs-benefit and user acceptance assessments, reimbursement and incentive models, training courses, and blogs (2 to 3%).

► Contributing

Being asked which areas they could envisage contributing to, reimbursement and incentive models were the least selected feature (22%). In contrast, 62% of respondents could envisage contributing to webinars, conferences and workshops, and almost half would contribute to matchmaking and twinning (49%). The remaining features were chosen by 35-45%.

► Promoting

Many respondents were positive about promoting the services of the Hub within their community, especially regarding digital health literacy initiatives (58%) and webinars/conferences/workshops (61%). Further, more than half would be likely to promote policy initiative areas (53%), innovations and horizon scanning (55%), matchmaking and twinning (55%), as well as news. Respondents are least likely to promote reimbursement and incentive models (40%).

Feature	Useful	Member-ship	Pay for access	Sponsor	Contribute	Promote
Summaries of success factors, initiatives, solutions and evaluation evidence						
Policy initiative areas	0,82	0,24	0,06	0,03	0,46	0,53
Evidence of health outcomes, costs-benefit and user acceptance assessr	0,84	0,29	0,16	0,02	0,45	0,48
Reimbursement and incentive models	0,73	0,24	0,11	0,02	0,22	0,40
App certification criteria, models and frameworks	0,73	0,33	0,19	0,02	0,36	0,45
Digital health literacy initiatives	0,74	0,25	0,12	0,10	0,46	0,58
mHealth programme implementation support	0,79	0,28	0,15	0,03	0,43	0,48
Innovations and horizon scanning relevant to mHealth solutions	0,75	0,30	0,11	0,04	0,46	0,55
Networking resources						
Access to the Hub's network of mHealth experts	0,81	0,43	0,10	0,02	0,48	0,49
Webinars, conferences, workshops	0,83	0,34	0,15	0,07	0,62	0,61
Membership of mHealth communities of practice	0,78	0,40	0,08	0,03	0,44	0,47
Matchmaking and twinning between mHealth initiatives	0,79	0,31	0,07	0,06	0,49	0,57
Expertise resources						
Personalised advice and consultancy	0,64	0,31	0,24	0,03	0,42	0,48
Recommendations and assessments by the Hub on key mHealth aspect:	0,74	0,36	0,13	0,03	0,46	0,47
Training courses offered by Hub experts	0,73	0,35	0,25	0,01	0,39	0,51
Catalogues						
Searchable dataset of mHealth solution suppliers, testimonies, B2B and	0,80	0,34	0,16	0,02	0,39	0,48
News						
Blogs and news	0,78	0,24	0,01	0,01	0,38	0,55
Social media	0,71	0,17	0,02	0,03	0,36	0,54

Figure 4 Service overview, all respondents (n = 89)

mHealth users

Among the 53 survey participants grouped as mHealth users, the survey elicited the following key points:

1. Catalogues, as well as webinars, conferences and workshops are considered most **useful** (87%). Personalised advice and consultancy are considered least useful (63%).
2. Especially willing to pay **membership fee** for accessing Hub's network of mHealth experts (42%), mHealth communities of practice (43%) and recommendations and assessments (40%). Least willing to pay a membership for policy initiative areas, reimbursement and incentive models and social media.
3. One third would **pay for accessing** training courses offered by Hub experts (32%), followed by personalised advice and consultancy (26%).
4. Considerably more are willing to **sponsor**, **contribute** to and **promote** digital health initiatives compared to all respondents (11% vs. 10%; 51% vs. 45%; 70% vs. 60%, respectively).
5. Approximately 70% would **contribute** to webinars, conferences and workshops.
6. **Overall**: more willing to pay membership fee or pay for access to needed service, sponsor, contribute to and promote new content in the Hub compared to all respondents (contribution – promotion: 20-71%).

Feature	Useful	Member-ship	Pay for access	Sponsor	Contribute	Promote
Summaries of success factors, initiatives, solutions and evaluation evidence						
Policy initiative areas	0,81	0,28	0,08	0,02	0,47	0,64
Evidence of health outcomes, costs-benefit and user acceptance assessr	0,81	0,32	0,15	0,02	0,53	0,55
Reimbursement and incentive models	0,70	0,25	0,11	0,02	0,21	0,47
App certification criteria, models and frameworks	0,74	0,32	0,17	0,04	0,36	0,51
Digital health literacy initiatives	0,79	0,28	0,15	0,11	0,51	0,70
mHealth programme implementation support	0,77	0,28	0,17	0,04	0,51	0,51
Innovations and horizon scanning relevant to mHealth solutions	0,74	0,30	0,11	0,06	0,53	0,62
Networking resources						
Access to the Hub's network of mHealth experts	0,83	0,42	0,11	0,02	0,57	0,49
Webinars, conferences, workshops	0,87	0,36	0,19	0,08	0,70	0,64
Membership of mHealth communities of practice	0,74	0,43	0,09	0,02	0,51	0,51
Matchmaking and twinning between mHealth initiatives	0,75	0,32	0,08	0,08	0,53	0,62
Expertise resources						
Personalised advice and consultancy	0,64	0,30	0,26	0,04	0,47	0,51
Recommendations and assessments by the Hub on key mHealth aspect:	0,74	0,40	0,11	0,04	0,53	0,55
Training courses offered by Hub experts	0,77	0,38	0,32	0,02	0,47	0,58
Catalogues						
Searchable dataset of mHealth solution suppliers, testimonies, B2B and	0,87	0,36	0,21	0,02	0,45	0,57
News						
Blogs and news	0,77	0,30	0,02	0,02	0,49	0,64
Social media	0,68	0,21	0,04	0,04	0,43	0,62

Figure 5 Service overview, mHealth users (n = 53)

mHealth user respondents:

- Patients or citizens or representative organisations (5 responses)
- Health and care professionals or representative organisations (13 responses)

- Health and care provider organisations (16 responses)
- Non-profit and charitable health organisations (5 responses)
- eHealth Competence centres (7 responses)
- Researchers (Other) (7 responses)

mHealth payers and decision-makers

Among the 14 survey participants grouped as mHealth payers and decision-makers, the following key results were obtained:

- All respondents agreed that policy initiative areas are **useful**, and all except one regarded digital health literacy initiatives and mHealth programme implementation support useful (93%).
- 36% each willing to pay **membership fee** for catalogues and networking resources (except for matchmaking and twinning; 29%).
- Most willing to **pay for access** to app certification criteria, models and frameworks (21%).
- Less willing to **sponsor** (7% each willing to sponsor 12 out of 17 proposed features).
- Mostly willing to **contribute** to webinars/conferences/workshop and **promote** innovations and horizon scanning (57% each).
- **Overall**: very positive towards usefulness of all proposed features (more than 70% agreement), less willing to pay, contribute to and promote new content in the Hub compared to all respondents (contribution – promotion: 21-57%).

Feature	Useful	Member-ship	Pay for access	Sponsor	Contribute	Promote
Summaries of success factors, initiatives, solutions and evaluation evidence						
Policy initiative areas	1,00	0,21	0,00	0,07	0,43	0,36
Evidence of health outcomes, costs-benefit and user acceptance assessments	0,79	0,29	0,14	0,00	0,29	0,36
Reimbursement and incentive models	0,79	0,14	0,14	0,00	0,21	0,29
App certification criteria, models and frameworks	0,79	0,29	0,21	0,00	0,29	0,43
Digital health literacy initiatives	0,93	0,21	0,07	0,07	0,43	0,50
mHealth programme implementation support	0,93	0,29	0,07	0,07	0,29	0,50
Innovations and horizon scanning relevant to mHealth solutions	0,71	0,29	0,14	0,07	0,21	0,57
Networking resources						
Access to the Hub's network of mHealth experts	0,86	0,36	0,14	0,07	0,29	0,50
Webinars, conferences, workshops	0,79	0,36	0,07	0,07	0,57	0,50
Membership of mHealth communities of practice	0,86	0,36	0,07	0,07	0,29	0,43
Matchmaking and twinning between mHealth initiatives	0,86	0,29	0,14	0,07	0,36	0,50
Expertise resources						
Personalised advice and consultancy	0,71	0,29	0,14	0,07	0,21	0,50
Recommendations and assessments by the Hub on key mHealth aspects	0,79	0,21	0,14	0,07	0,29	0,36
Training courses offered by Hub experts	0,71	0,29	0,07	0,00	0,36	0,36
Catalogues						
Searchable dataset of mHealth solution suppliers, testimonies, B2B and B2C connections	0,71	0,36	0,14	0,07	0,43	0,36
News						
Blogs and news	0,79	0,29	0,00	0,00	0,21	0,43
Social media	0,86	0,29	0,00	0,07	0,21	0,36

Figure 6 Service overview, mHealth payers (n = 14)

mHealth payers and decision-makers respondents:

- Health and care public payers or health insurers, mutualities (3 responses)
- Public health agencies (6 responses)
- Policymakers (2 responses)
- Life sciences or Biotech industry (2 responses)
- ICT or MedTech industry (1 response)

mHealth solution providers and enablers

Among the 22 survey participants grouped as mHealth solution providers and enablers, the following key points were identified:

- Evidence of health outcomes, costs-benefit and user acceptance assessment were considered the most **useful** feature (95%), digital health literacy initiatives the least useful (50%). Expertise resources features and catalogues were considered less useful compared to all respondents. The perceived usefulness appears to not correlate with willingness to pay for and sponsor the features.
- Most willing to pay **membership fee** for accessing app certification criteria, models and frameworks (36%), the Hub's network of mHealth experts (50%), and expertise resources (36%).
- Most willing to **pay for access** for app certification criteria and personalised advice (23% each).
- Willingness to **sponsor**: around 9% willing to sponsor digital health literacy initiatives, and 5% would sponsor evidence of health outcomes, policy initiative areas, reimbursement and incentive models, and membership of mHealth communities.
- Most willing to **contribute** to matchmaking and twinning (50%), innovations and horizon scanning as well as recommendations and assessments on key mHealth aspects (45%, respectively 41%).
- Most willing to **promote** webinars/conferences/workshops (59%)
- **Overall**: considerably less willing to sponsor, contribute to and promote new content compared to all respondents (contribution – promotion: 16-53%).

Feature	Useful	Member-ship	Pay for access	Sponsor	Contribute	Promote
Summaries of success factors, initiatives, solutions and evaluation evidence						
Policy initiative areas	0,73	0,14	0,05	0,05	0,45	0,36
Evidence of health outcomes, costs-benefit and user acceptance assessr	0,95	0,23	0,18	0,05	0,36	0,41
Reimbursement and incentive models	0,77	0,27	0,09	0,05	0,27	0,32
App certification criteria, models and frameworks	0,68	0,36	0,23	0,00	0,41	0,32
Digital health literacy initiatives	0,50	0,18	0,09	0,09	0,36	0,36
mHealth programme implementation support	0,73	0,27	0,14	0,00	0,32	0,41
Innovations and horizon scanning relevant to mHealth solutions	0,82	0,32	0,09	0,00	0,45	0,36
Networking resources						
Access to the Hub's network of mHealth experts	0,73	0,50	0,05	0,00	0,41	0,50
Webinars, conferences, workshops	0,77	0,27	0,09	0,05	0,45	0,59
Membership of mHealth communities of practice	0,82	0,36	0,05	0,05	0,36	0,41
Matchmaking and twinning between mHealth initiatives	0,82	0,32	0,00	0,00	0,50	0,50
Expertise resources						
Personalised advice and consultancy	0,59	0,36	0,23	0,00	0,41	0,41
Recommendations and assessments by the Hub on key mHealth aspect:	0,73	0,36	0,18	0,00	0,41	0,36
Training courses offered by Hub experts	0,64	0,32	0,18	0,00	0,23	0,41
Catalogues						
Searchable dataset of mHealth solution suppliers, testimonies, B2B and	0,68	0,27	0,05	0,00	0,23	0,36
News						
Blogs and news	0,77	0,05	0,00	0,00	0,23	0,41
Social media	0,68	0,00	0,00	0,00	0,27	0,45

Figure 7 Service overview, mHealth providers and enablers (n = 22)

mHealth solution providers and enablers respondents:

1. ICT and MedTech sector (11 responses)
2. Industry associations (4 responses)
3. Innovation sponsors (1 response)
4. Assessment, regulatory and licensing bodies (1 response)
5. Others, including SMEs (5 responses)

SERVICE RANKING

Being asked to rank the top five features or services that are of highest priority to have access to, assessments of evidence of health outcomes, costs-benefit and user acceptance were considered highly important. Social media and news or blogs were of the least priority to have access to, after services related to expertise resources.

Taking all respondents, the following top five features were selected:

1. Evidence of health outcomes, costs-benefit and user acceptance assessments
2. Policy initiative areas
3. Reimbursement and incentive models
4. App certification criteria, models, and frameworks
5. mHealth programme implementation support

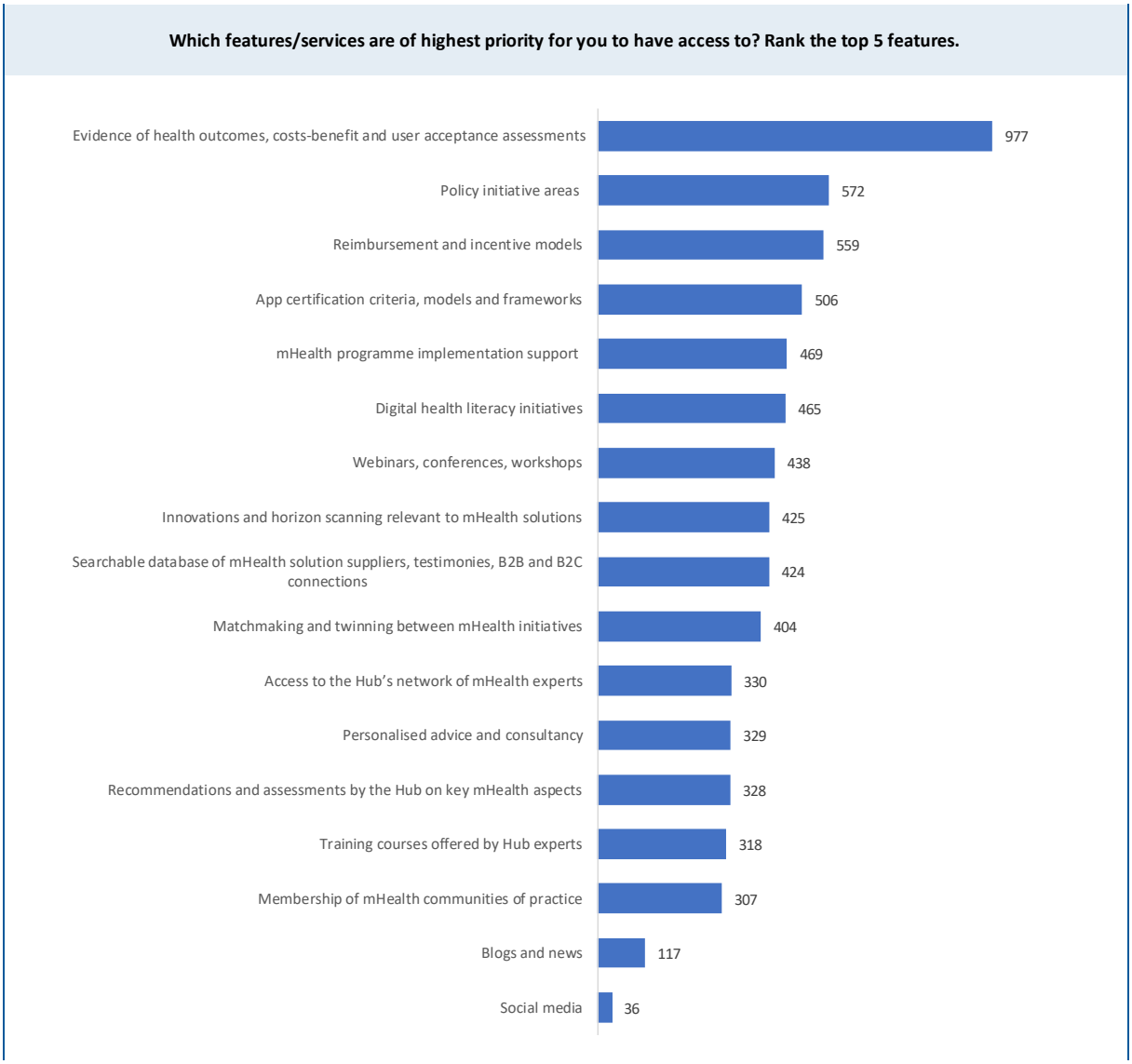


Figure 8 Service ranking, all respondents (n = 89)[20]

mHealth users

The 53 responses revealed a larger emphasis on accessing support and training features regarding digital health and mHealth implementation compared to the overall ranking, although evidence of health outcomes, costs-benefit and user acceptance assessments remain the highest priority. The top five features or services of highest priority to have access to for mHealth users are:

1. Evidence of health outcomes, costs-benefit and user acceptance assessments
2. Digital health literacy initiatives

[20] **Ranking calculation:** Each ranking position is awarded points based on the number of explored statements, in this case 17 items (17 points items ranked by survey participants as Nr. 1, 16 points for rank 2, ..., 1 point for rank 17). These points are multiplied by the number of participants who have rated an item with a specific rank. The sum of all points for a given item can be compared with the other statements and ordered to represent the aggregated rank positions for each item.

3. Policy initiative areas
4. mHealth programme implementation support
5. Webinars, conferences, workshops

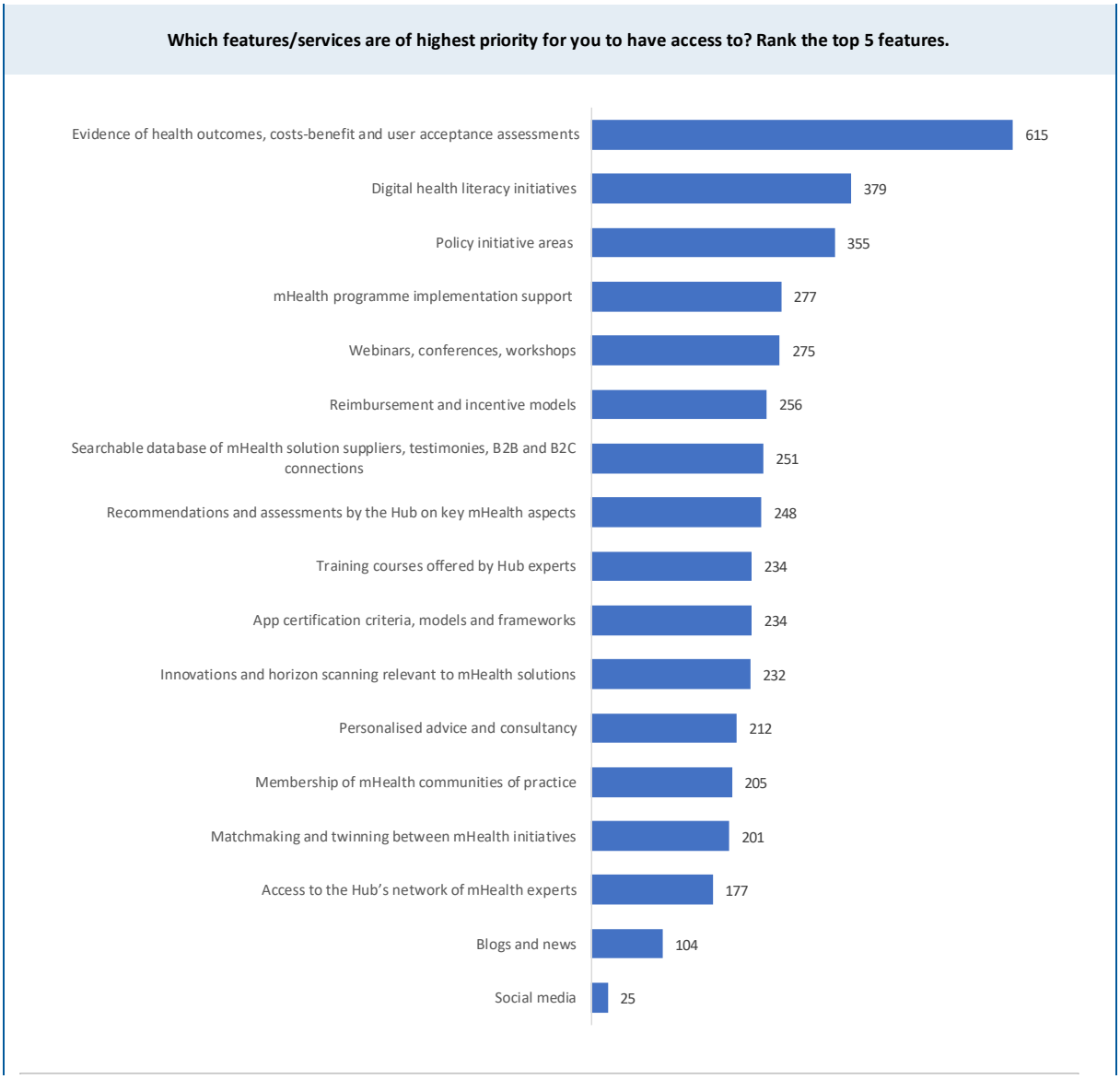


Figure 9 Service ranking, mHealth users (n = 53)

MHEALTH PAYERS AND DECISION-MAKERS

Among the 14 mHealth payers and decision-makers participating in the survey, the highest priority was again access to evidence of health outcomes, costs-benefit and user acceptance assessments, followed by policy initiative areas. Payers considered access to training courses or digital health literacy initiatives less important, but ranked implementation support high. Only among this stakeholder group, catalogues were ranked in the top five features:

1. Evidence of health outcomes, costs-benefit and user acceptance assessments

2. Policy initiative areas
3. Reimbursement and incentive models
4. mHealth programme implementation support
5. Catalogues

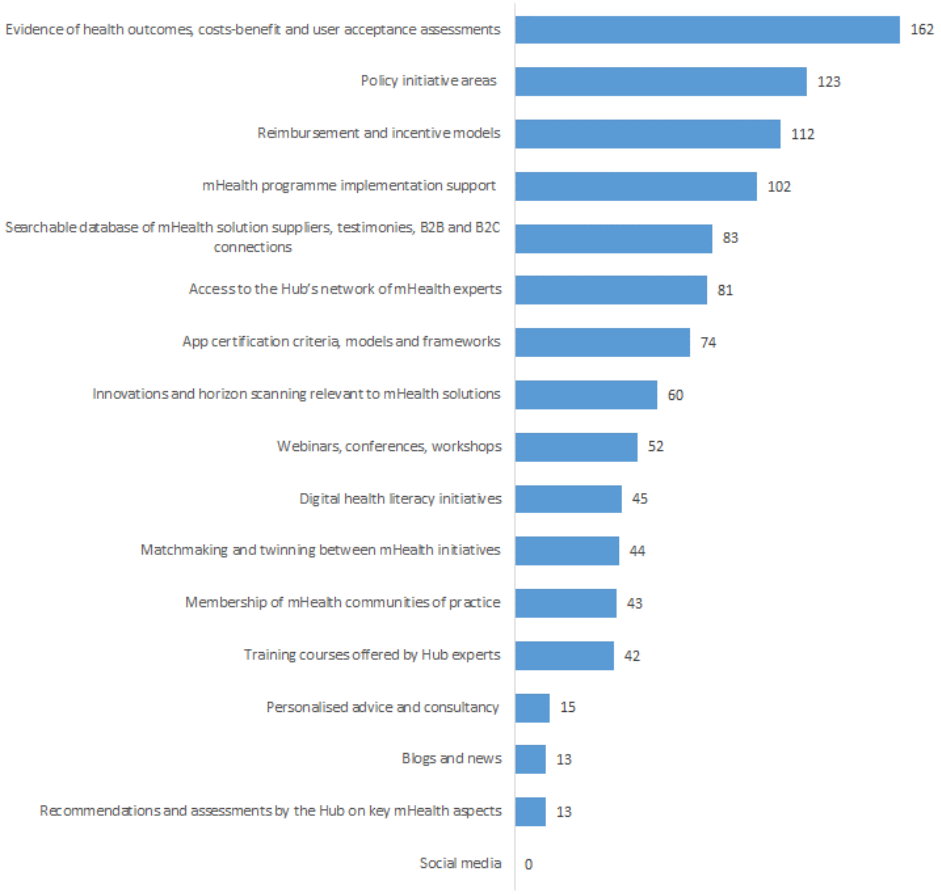


Figure 10 Service ranking, mHealth payers and decision-makers (n = 14)

mHealth solution providers and enablers

The 19 mHealth solution providers and enablers ranked the priority features quite differently compared to the ranking of all respondents, with an emphasis on app certification and reimbursement and incentive models. Only mHealth providers and enablers ranked matchmaking and twinning as well as innovations and horizon scanning in the top five:

- Evidence of health outcomes, costs-benefit and user acceptance assessments
- App certification criteria, models and frameworks
- Reimbursement and incentive models
- Matchmaking and twinning between mHealth initiatives
- Innovations and horizon scanning

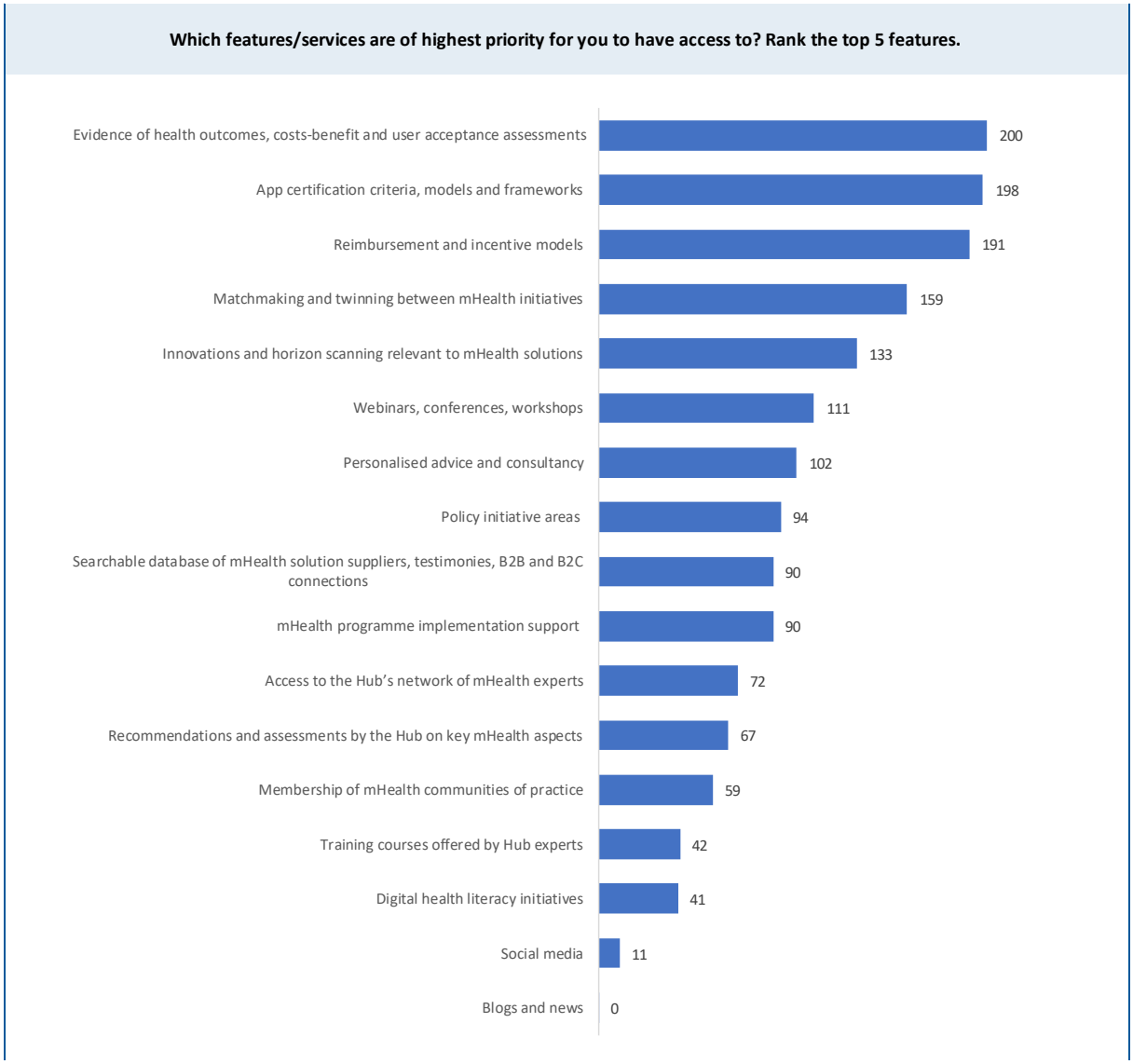


Figure 11 Service ranking, mHealth providers and enablers (n = 22)

FURTHER FEATURES

Survey respondents had the possibility to provide additional comments about whether there were any other features that their respective stakeholder group would strongly value if included in the Hub. In this regard, particularly training opportunities, information on financial aspects, FAIR datasets, as well as matchmaking between stakeholders and knowledge sharing regarding clinical implementation, validation and market authorization (HTA) of mHealth technologies, were suggested.

The stakeholder group of **mHealth users** highlighted access to HTA assessments, clinical best practices, ethical, social and legal aspects, training opportunities and experience-sharing, as well as matchmaking between stakeholder groups such as patients.

Regarding **mHealth payers and decision-makers**, features on the clinical implementation and validation of mHealth apps would be valuable, such as a ranking based on clinical experience.

For **mHealth providers and enablers**, market access as well as funding support were valuable.

Table 4. Respondents' comments on further features

Are there any other features that your stakeholder group would strongly value if included in the Hub?
• *Access to clinical best practice. A comprehensive clinical ontology.* • *Promote trainings and Workshops* • *FAIR Datasets* • *Implementation experiences, and outcome reports, including problems and adverse outcomes.* • *None* • *Health Technologies Assessment, social value* • *None* • *No* • *I'm consider that are included all features.* • *Regular training and feedback on new technology and strategies in health management through mHealth.* • *Having a "fund watch" for grants and financial support to develop mHealth solutions* • *Implementation of mHealth in integrated care pathways* • *Providing framework and recommendations to aid the process from mHealth's evidence to action in the Regional Health Service Models' context.* • *Funding Support for innovation* • *mHealth apps validated against criteria* • *Peer to peer experience sharing* • *Funding opportunities – e.g., in the format of awards/competitions* • *Some health observing features that keep track of my own Health. Example heart or pulse, temperature, how I sleep, moving, etc…and send data to the hub for analyse and recommendations* • *Market Access. Standardization.* • *The ethical and legal aspects* • *Knowledge and information to politicians and leaders on national, regional and local level* • *Clinical validation of mHealth apps – ranking (may however be covered by "Evidence of health outcomes", but in case of plethora apps, ranking of them according to clinical experience in particular area of the apps can be useful or both the potential procurers of the apps and manufacturers of truly successful apps).* • *N/A* • *Innovation & horizon scanning for mHealth solutions* • *The members of EHTEL will much more look for a collaborative environment with people active in the field rather than an educational one* • *Facilitating cross border activities in mobility* • *Matchmaking between specific stakeholder groups (e.g., patient to patient)* • *Matchmaking between specific stakeholder groups (like patient to patient)* • *List is quite extensive* • *Online library.* • *"The discussion about mHealth solutions (and on many other topics as well) is currently too complex for the public to follow? Clear, crisp presentations of the basic facts and knowledge might help. Communication with large groups might then follow up on these facts? Politics might like help on that end? E.g., "digital" aspects are not part of the public dispute at the moment, it is virologists only.*

- *We do not see very much clear, crisp presentations of the basic facts and knowledge about mHealth in "the press" and media these days. The information is there, but maybe the barrier to grasp it is just too high?"*
- *A multistakeholder working group that can provide mHealth programme implementation support- this should ideally be through an accelerator program.*

INFLUENCES ON WILLINGNESS TO CONTRIBUTE FINANCIALLY

Being asked whether there are any other factors that influence their willingness to contribute financially to the Hub, some survey respondents highlighted the challenge of receiving funds in academia, which limits their ability to pay. Consequently, one participant proposed to facilitate students' participation through sponsorships. Further, some respondents (mHealth payers and decision-makers, mHealth users) remarked that the national (e.g., Ministry of Health, health insurance funds) or EU level (EC) could get involved to promote the development of mHealth technologies. mHealth users particularly emphasised that patient organisations should not be asked to contribute financially. Others underlined that they would be willing to contribute financially if the provided information was comprehensive and up-to-date, and if they benefitted from it. However, one respondent commented that access to knowledge should not be charged any fees.

Table 5. Respondents' comments on influences on willingness to contribute financially

Apart from the actual fees, which are still being considered, are there other influences on your willingness to contribute financially to the Hub?

- *Promoting European based EPR system development.*
- *Trainings*
- *Funds availability is an issue in academia. Sponsoring students for internships, workshops and conference participation is an alternative in-kind contributions one might consider useful.*
- *Totally opposed to charging fees for knowledge. In line with EU policy, and programmes such as Horizon Europe, knowledge should be free to all, and agencies should contribute pro bono. This is for altruistic reason on accord with the European vision, and also to avoid bias and also exclusion of the citizen or new innovator.*
- *Information provided by Hub should be evidence based, up to date and comprehensive. Always.*
- *Yes, if it contains a searchable database that is updated regularly*
- *No*
- *Nothing other*
- *None*
- *Topics*
- *No*
- *I'm consider that should are included European funding, contributes by Organisation for Economic Co-operation and Development (OECD) and other organisation for develop.*
- *Trainings, webinars, recognition and certification, match-making, participation in policy, support in implementing, and getting fund*
- *As a researcher, it is difficult to obtain funds, so unfortunately I don't think I would be in a position to be able to make big financial contributions any time soon*
- *As a membership organisation we have limited resources to contribute to the hub. Our members' pockets are deeper than ours. The Hub should develop a membership model that would allow access for individual companies. For them networking opps would be good.*

- *1) Fund resource constraints, 2) Would partners/service providers be required to pay for membership of the hub?*
- *Financial contribution to the hub should be on a EU member state or national level*
- *Quality/novelty of provided Hub support, information, expertise*
- *Our willingness to contribute to the Hub is related the balance between what we pay and we get in return.*
- *Yes I am open to discuss further, what kind of financial contribution? Please share your ideas and your offer.*
- *If this is designed to support mHealth developments this should be a resource funded by the EC with potential of industry sponsorship/collaborations*
- *If the Hub actually can prevent me to travel to hospital, this might be a saving for me that can be payed to the hub instead.*
- *Health insurance Fund is public institution, so as such I think there are legal limits in direct financing membership and partnership with other international institutions. I think Ministry of health can be included in membership or partnership with international institutions, and indirectly the Health insurance Fund can participate.*
- *Cost/benefit, time, economic support or project*
- *Contribution should be linked to: commercial success and more customers because of the activities in the Hub – and/or a successful proposal with finance.*
- *As a non-for-profit association, we cannot contribute financially to the Hub.*
- *No – university sponsorship or funding is unfortunately quite complicated for these types of partnerships.*
- *N/A*
- *NO*
- *Getting tangible benefits in return from membership fee or sponsoring fee will be the main decision criteria*
- *We believe that patient organisation should not be paying for any of the services. Institutional partners such as universities, governmental bodies, companies etcetera should be; we also believe that for a proper and independent functioning public (EU, national) funding should be a substantial part of the Hub's resources. This to avoid that topics drift too much towards the interest of the payers.*
- *We believe the Hub's service should be free for patient and citizen organisations*
- *Ability to reach policy makers and a large community – facilitate feedback to the HL7 standards and specification development*
- *No, unfortunately not.*
- *Organisations do have own resources and skills. Typically they will contribute as well, in different ways. Organisations might not like to pay, if the services they then receive again require large efforts from themselves.*
- *Think that the model should be reviewed, with focus on tangible value created. For example, corporates could be sponsors of programmes that help identify leading mHealth solutions. Should this Hub be at the forefront of mHealth services, it would certainly be able to be self sustainable on advice and consultancy services. It would most certainly need to establish itself first as a thought leader and needs to, at least initially, be as inclusive as possible.*
- *Play a regional championship role*
- *- The ability of the Hub to customize and provide personalized support pulling expertise across different areas*

INFLUENCES ON WILLINGNESS TO ENDORSE

Being asked whether there are other factors besides editorial independence and transparency that influence respondents' willingness to endorse, promote and contribute content to the Hub, comments suggested the possibility to engage with EU decision-making on mHealth and national or regional key stakeholders, receiving support for developing and implementing mHealth solutions, as well as accessing relevant, vendor neutral and high-quality information, including adverse outcomes. The latter aspect was especially mentioned by mHealth users and

providers/enablers. One respondent remarked that time commitments would negatively influence the willingness to promote and contribute content to the Hub. Further, endorsement by other stakeholders such as the WHO influenced own willingness. Another aspect to consider is availability of content in different EU languages as suggested by some mHealth users.

Table 6. Respondents' comments on influences on willingness to endorse

Apart from editorial independence and transparency about how all Hub content is determined, are there other influences on your willingness to endorse, promote and contribute content to the Hub?
• *Engage at national and regional level MoH, ICT and other health communities institutions* • *Commercial impartiality, and search for all learning and outcomes including adverse ones as key learning points. Application and inclusion of all social groups and illness types, not just those with most commercial value – e.g., homeless health, mental illness* • *See above* • *None* • *No at the moment* • *Evidence* • *None* • *Austrian Content* • *No* • *I'm consider that information for standards to build a mHealth and programmes implementation support are very important.* • *Maximum opportunity for people to participate in the decision-making and policy development process for mHealth in EU* • *The information provided so far is a little confusing, to be honest… is it not clear for me, as a researcher (looking for partners and funding) how the Hub can be helpful for me.* • *Quality. Relevance.* • *No* • *Yes, already a member of the hubs project team* • *Availability of compensation for contributed content (or contributed resources in more general, e.g., expertise, consultancy, training, etc.)* • *Yes* • *That I can stay at home even when I am sick and old* • *I am willing to promote and contribute to content to the Hub if I experience that it gives something back.* • *Vendor neutrality.* • *Time commitment to university job requirements, such as teaching.* • *N/A* • *NO* • *The perception of other's engagement* • *Quality of the contents: The stark participation of patient / citizen organizations in the governance of the Hub. Language: English is not always good for patients/citizens across Europe* • *We believe the Hub should be at least in part be funded by public bodies. This to ensure that the focus remains wide, beyond the interests of the private funders. Language: please consider multiple languages. English is not always the best choice for patients and citizens* • *Who else has endorsed. What is the quality of the brand of the Hub. The degree to which WHO continues to endorse the hub. Success stories that the hub made happen.* • *No.* • *An independent source of knowledge, and a discussion platform for all who are interested in mHealth, on all layers from political down to doctors and patients will be very welcome. It may support discussions and opinion building in groups relevant to mHealth and to the larger public. Peer to peer support across regions and member states also may help and speed things up. Many organisations will be happy to promote and support this type of*

activity. This support might not come in the form of financial resources, but in other forms.

- *Believe that the Hub needs to help accelerate mHealth solution into the market. The biggest challenge is access to the market, specifically in public health. To achieve this, there's a need for a multi-stakeholder approach. Is the hub able to reduce the red tape and bring together diverse stakeholders that help accelerate existing mHealth solutions into the market?*
- *No*

SPONSORING

In total, 15 survey participants confirmed that their organisation or stakeholder group is amongst those that should be contacted to explore sponsoring of the Hub. These organisations include international and regional bodies, as well as industry stakeholders and healthcare organisations.

Organisations mentioned: WHO, Velametis, ASP DI CATANIA, Unidade Local de Saude de Matosinhos, Care Innovation Corporation, Region Jämtland Härjedalen, Kinetikos, Federico II University, HL7, ITU

PROMOTING

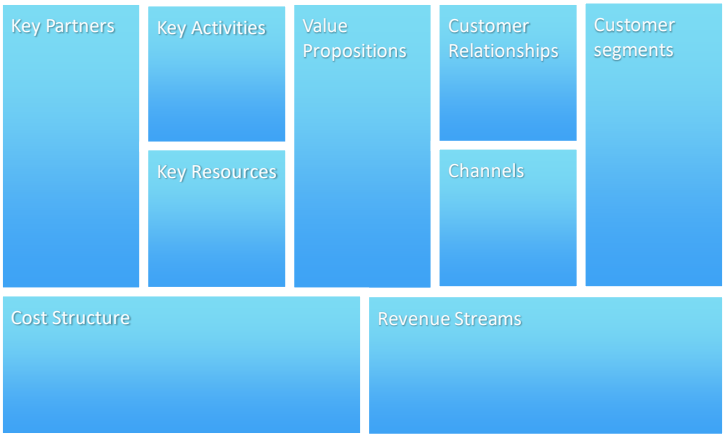
67 survey participants confirmed that their organisation or stakeholder group can be contacted to explore a potential partnership to enrich and promote the Hub. These include the WHO, universities, research institutes, healthcare organisations, healthcare providers and regional bodies.

Annex 6: The Business Model Canvas technique

BUSINESS MODEL CANVAS

Business Model Canvas (BMC) is a strategic management and lean startup template for developing new or documenting existing business models. It is a visual chart with elements describing a firm's or product's value proposition, infrastructure, customers, and finances. The model is descrbied via nine “building blocks”:

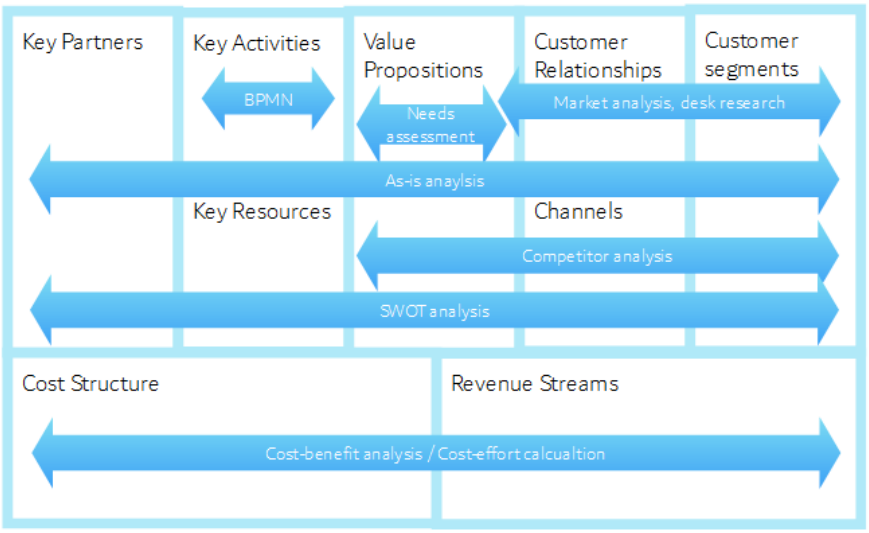
- **Customer segments**: this block defines the different groups of people or organisations an enterprise aims to reach and serve. Customers comprise the heart of any business model. They may be grouped in different segments in order to better satisfy their needs. A business model can be designed only with a strong understanding of specific customer needs.
- **Value propositions**: this block describes the bundle of products and services that create value for a specific customer segment.
- **Channels** describe how a company communicates with and reaches its customer segments to deliver a value proposition. They serve several functions, including raising awareness, delivering a value proposition, and providing of customer support.
- **Customer relationships** specify the types of relationships a company establishes with specific customer segments – they range from personal to automated.
- **Revenue streams** represent the cash a company generates from each customer segment. Each revenue stream may have different pricing mechanisms, such as fixed list prices, prices resulting from bargaining or auctioning, market dependent or volume dependent prices, or yield management.
- **Key resources** are the most important assets required to make a business model work. They can be physical, financial, intellectual, or human and can be either leased by the company or acquired from key partners.
- **Key activities** are the most important actions a company must take to operate successfully. They also differ according to the business model. For example, for PC manufacturer Dell, key activities include supply chain management. For consultancy McKinsey, key activities include problem solving.
- **Key partnerships** comprise a network of suppliers and partners that make the business model work. Four different types of partnerships can be seen in practice: strategic alliances between non-competitors, between competitors, joint ventures to develop new businesses, and buyer-supplier relationships to assure reliable supplies.
- **Cost structure** describes all costs incurred to operate a business model. They can be calculated after defining the key activities, resources and partnerships.



METHODS AND FRAMEWORKS COMPLEMENTARY TO THE CANVAS

- **As-is analysis (current state analysis):** process management strategy that identifies and evaluates the current processes of a business. It can focus on an entire business organisation or on one or more specific processes within a department or team. Implementing as-is analysis has been shown to lead to improvements in customer satisfaction, business coordination and organizational responsiveness, higher compliance to new regulatory standards and improvements in existing processes or creation of new processes. As-is analysis is particularly useful in cases where:
    - The team members are in a new domain and do not have a complete picture of how things work
    - Too many mistakes have been made in the past and you would like to correct those mistakes or avoid them in the future
    - In understanding the current state, there are some specific areas the analyst should focus on business processes, business rules, user requirements or problems.
- **Value proposition development**: Statement which identifies clear, measurable and demonstrable benefits consumers get when buying a particular product or service and should be based on needs assessment.
- **Market analysis:** Provides information about industries, customers, competitors, the relationship between supply and demand for specific products and is a start for development of marketing strategies.
- **Desk research (secondary research):** Finding relevant data which already exists; quick and inexpensive; can provide useful information about the current landscape.
- **Competitor analysis:** Analysis of the strengths and weaknesses of current and potential competitors.
- **SWOT (Strengths, Weaknesses, Opportunities and Threats) analysis:** strategic planning technique which can be used to identify strengths, weaknesses, opportunities, and threats related to business planning. Usually performed in the preliminary stages of decision-making processes.
- **Business process modelling:** Graphical representation of a company's business processes, for them to be analysed, improved, and automated. Usually performed through different graphing methods (flowcharts, data-flow diagram etc).

- **Cost-benefit analysis / cost-effort calculation:** Process used to analyse decisions. It sums the benefits of an action and then subtracts the costs associated with it.



REVENUE STREAMS

Contributions to sustaining the hub may be in kind or in cash.

- **In kind contributions** are mostly manifest as strategic partnerships. These partner roles may include:
  - providing guidance on the most valuable services and content the hub should contain in order to be useful and attractive for sustainability;
  - providing specific areas of content, to supplement and update what is already held or to populate proposed new areas of content;
  - providing evaluation feedback from using the hub;
  - endorsing and promoting the hub amongst its own stakeholder networks.

- **In cash contributions** as a sponsor of some content or services, or as a core funder of the hub as a whole. For the purposes of the business model canvas, these are kinds of customer, but recognising that their business value might be
  - direct (because they gain value directly from using the hub themselves).
  - indirect (because the impact of the hub is favourable to their corporate objectives through its use by other stakeholders)

Annex 7: Landscape and competitor analysis

To create clear value propositions, a mapping of the **current ecosystem related to mHealth** has helped to position the Hub within the mHealth domain as a unique initiative with a clear vision, mission, and service offer. There were two main categories of organisations that were identified: A first category of "adjacent" organisations, that are either mutual reinforcing with the Hub or competitors, and a second category of "role-models", organisations that are not situated directly in the mHealth sphere but can serve as a role-model for the mHealthHub.

The mHealthHub was characterised as being at the intersection of:

- Digital health Hubs
- Multi-stakeholder digital health organisations networks
- Organisations that involve mHealth assessment services and health technology assessment
- Implementation/consultancies for mHealth programmes
- European initiatives such as the eHealth Network, JASEHN

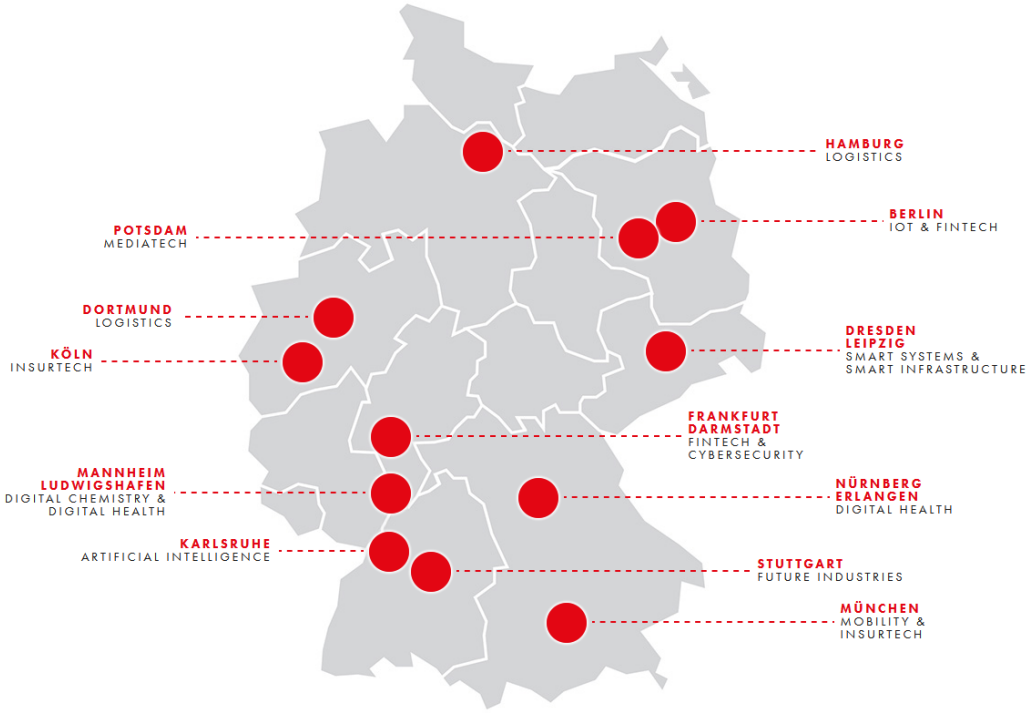
DIGITAL HEALTH HUBS

Several digital health hubs were identified. In a European landscape, digital health hubs exist at a national, regional or local level. They have different funding streams or business models and address different target audiences. There are both for-profit and non-for-profit entities. Some are subscription based, charging for offering spaces, events, and networking services. The majority are targeted at health and care start-ups and industry players.

List of digital health hubs identified:

- Barcelona Health Hub (Spain)
- mHealth Israel
- Digital Health Malta
- FreshBlood (Romania)
- The DigiHUB (Belgium)
- OuluHealth (Finland)
- Finnish DigiHealth Hub
- Galen Growth (Singapore & Switzerland)
- eHealth Hub
- Hih – health innovation Hub
- https://www.de-hub.de/ (DE, network of twelve Hubs)
- Digital Innovation Hub Healthcare Robotics

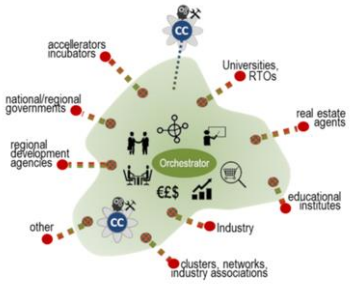
An interesting example of a digital health hub network is the example of the German Network. The Digital Hub Initiative aims at creating partnerships by connecting SMEs and corporations with the newest innovators from the science and start-up scene. Twelve digital Hubs provide a strong network that stimulates innovation by promoting the exchange of expertise in technology and business[21].



Another interesting example to learn from is the Digital Innovation Hub Healthcare Robotics, an independent and sustainable platform for all those who are active in the healthcare ecosystem. The project started in January 2019 funded by the European Community and is financially supported until December 2022 with the mission is to create a sustaining network that connects players in the healthcare sector and to support small and medium sized enterprises. The aim is to speed up innovation and reduce time-to-market with a pan-European network. Then from January 2023 and further DIH-HERO will stand on its own as healthcare network.

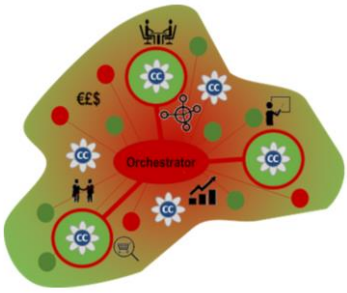
[21] https://www.de-hub.de

Digital Innovation Hub



- One tech/market domain focus
- Supporting regional SMEs
- Multi-actor partnership
- Creating business with non-tech expertise

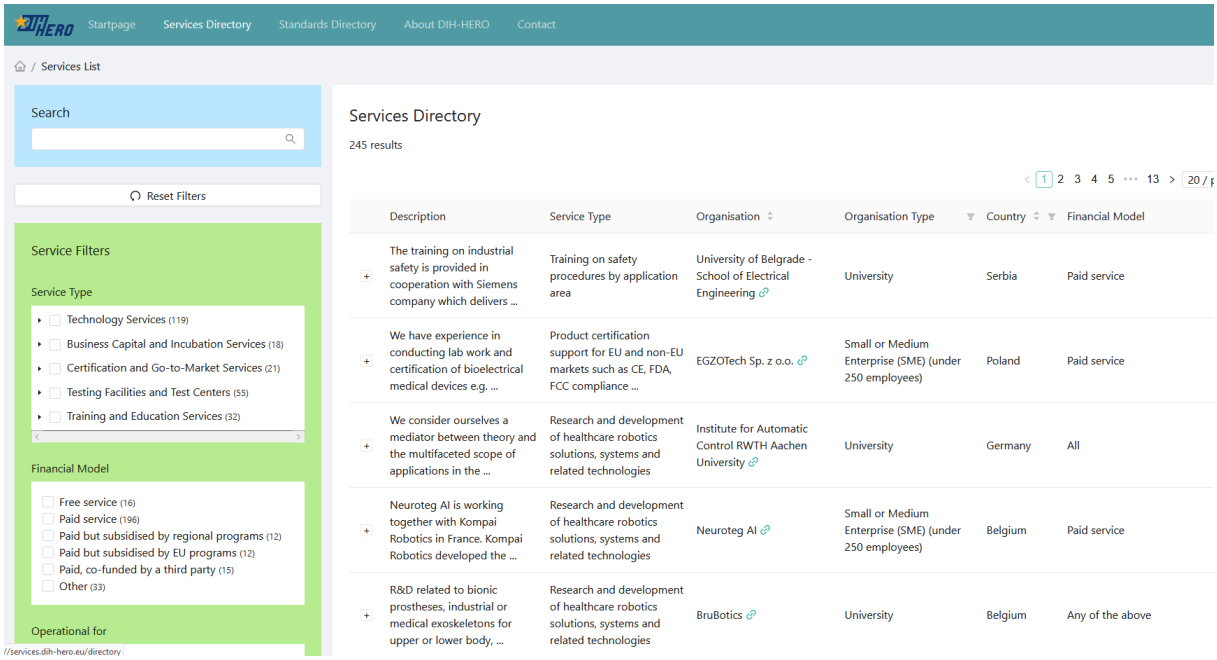
Regional DIH network



- Multi tech/market domain focus
- Regional ecosystem develop.
- Coordination multiple DIH nodes
- Benefit of Economy-of-Scale
- Implementing Smart Specialisation and pan-EU collaboration

Pan-EU DIH network

- One tech/market domain focus
- Initiating pan-EU colaboration and Smart Specialisation
- Facilitate regional learning
- Creating EU awareness on new topics



MULTI-STAKEHOLDER DIGITAL HEALTH ORGANISATIONS NETWORKS

- European Connected Health Alliance (ECHAlliance)
- Healthcare Information and Management Systems Society (HIMSS)
- Digital Therapeutics Alliance (DTA)
- European Institute of Innovation and Technology (EIT Health)
- International Society for Telemedicine and eHealth (ISFTeH)
- European Health Telematics Association (EHTEL)
- Frontiers Health
- RSCN

EUROPEAN INITIATIVES

- eHealth Network
- JASEHN

ORGANISATIONS THAT INVOLVE MHEALTH ASSESSMENT SERVICES AND HEALTH TECHNOLOGY ASSESSMENT

- Express Script
- ORCHA
- XHealth
- IQVIA
- Our Mobile Health
- Ranked Health
- M-Habitat
- Xcertia
- PsyberGuide
- MindTools.io
- MindTech
- GGD-Netherlands
- Appsalut- Spain
- KNMG – Netherlands
- DHXGroup
- In Health Care
- Therappx

IMPLEMENTATION/CONSULTANCIES FOR MHEALTH PROGRAMMES

- WHO – BHBM initiative

Annex 8: Hub partners' capacities mapped to the service portfolio

Another step towards sustainability was to understand Hub partners' (3 beneficiaries and 18 subcontractors) strengths and capacities to support the future Hub services. The partners were firstly asked to fill in the survey, and based on their responses, they to further elaborate on the services they could generally contribute to. They were asked to focus on clear strengths and realistic capacities of their organisation and give concrete examples. The overall mapping is being used to elaborate on the business models of each of the service areas, by inviting Hub partners to co-creation workshops in the following months and understand the different types of partnerships under which the organisations would be more likely to partner with the Hub and what types of contributions they would be able to make.

Organisation	Policy initiative areas
HIMSS/PCHA	We could bring our Policy expertise and network into MHH policy initiatives / 3 to 4h per year
HL7	HL7 affiliates in 24 individual European Countries and in collaboration with HL7 Europe, HL7 International Working Groups & the HL7 Policy Advisory Committee can provide specific input in this area. 1 day (6 hours) per HL7 Working Group Meeting so total of 18 hours/year. / Three times a year (this will be linked to the 3 Working Group Meetings that HL7 holds every year)
ITU	Share any lessons learned or country experiences related to Digital Health Policy/Strategy development or assessment including non-European countries
PROMIS	The Mattone Internazionale Salute Programme -ProMIS is an institutionalised network led by the Veneto Region and involving the Ministry of Health, the National Agency of regional healthcare services (Agenas) and all Italian Regions including the Autonomous Provinces of Trento and Bolzano, aiming at promoting the internationalisation of health systems. The daily objective is to strengthen regional cooperation and links between Italian regions with respect to innovative health practices and policies and EU health initiatives. In particular: - Providing information and training opportunities; - Fostering capacity building of public administrations at any level of governance of the national health and social system; - Responding to the needs expressed jointly by Italian regions and local health and social authorities; - Stimulating the participation of Italian clusters in national and European clusters and in transnational/EU initiatives; - Supporting regions and other public administrations in transferring innovations, knowledge and competences across the network and not

	only within the EU level; - Promoting and supporting the "Health in All Policies" approach.
RJH	We are working with national authorities re the coordination and implementation of eHealth

Organisation	Evidence of health outcomes, costs-benefit and user acceptance assessments
University of Agder	UiA could offer their competence and facilities for scientific user acceptance assessment. A "user acceptance assessment" could be supported with consultancy and facilities, on a "per time/needed efforts basis" 40-80 hours per user acceptance externally funded assessment project
iHD	Not a major contribution, but we could be part of a network of organisations who are on the lookout for publications and other evidence, and contribute occasionally if we come across something to add to the repository.
ITU	Share any collected evidence of health outcomes with the Hub and vice-versa to disseminate knowledge from the Hub to all ITU member states.
Osakidetza Kronigune	Codesign, and user acceptability and usability assessment of: • New version of Personal Health Record of Osakidetza • App “Osasun On” for management of diabetes type I • App prevention of obesity in children • App for Patient Reported Outcome Measurements (PROMs) collection for breast and lung cancer
RJH	We can be reference/sounding-board
Organisation	mHealth programme implementation support
University of Agder	UiA has competence and experience in the scientific implementation and evaluation of mHealth regional and national pilots / Needed efforts/ resources can be estimated per implementation project
Ericsson Tesla	We can assist as advisor in mHealth programmes implementation.
HIMMS/PCHA	We could bring our legal and ethics expertise/ 3 to 4 h per year
HL7	HL7 can facilitate with IEEE-Standards Association (SA) an initiative that IEEE-SA has recently started on “Mobile Health Apps – Standards and Laboratory Services”.
ITU	Sharing any ITU contributions on handbooks, toolkits, reports on country implementation support on advancing digital health agenda (BHBM program in particular).
Osakidetza Kronigune	Experience in the implementation of: • App My Treatment for pharmacological treatment adherence • App for Patient Reported Outcome Measurements (PROMs) collection

	for breast and lung cancer. • App “Osasun On” for management of diabetes type I • App prevention of obesity in children • App Radar COVID for COVID-19 transmission control • App “Living without tobacco”
PROMIS	ProMIS has activated working groups on key issues with other national ministries (research, social, tourism, territorial cooperation), Agenas (National Agency for Health Policies), the Istituto Superiore di Sanità. Recently, it has launched a working group called “Digital Innovation Hubs” specifically aiming at setting up an ecosystem able to facilitate the matching of supply and demand of digital innovation in the healthcare field. ProMIS supports all Italian regions in the management of European projects deriving from direct and indirect funds (including reporting) and is involved in particular in all communication and dissemination activities. It then participates directly in projects representing all Italian regions. Since 2014, ProMIS has activated a tool called Open Lab (codesign laboratories). That is, it activates working groups with Italian regions, and other key actors/stakeholders, with the aim of creating projects on European calls (direct and indirect funds) and in particular supports the establishment of the transnational partnership, the methodological drafting of the project, the budgeting phase and the formal presentation of the projects to the financial institutions
WHO	Sharing new BHBM handbooks, BHBM country support reports, monitoring and evaluation results.

Organisation	App certification criteria, models and frameworks
University of Agder	UiA and UiA's partner network could offer competence in relevant app certification criteria, standards and frameworks/ Needed efforts/ resources can be estimated per app certification
Ericsson Tesla	As an ICT company with experience in developing and maintaining health applications and central information health systems, Ericsson Nikola Tesla (ENT) can contribute in defining app certification criteria and assist in developing certification frameworks. We hope to be part of the Croatian assessment framework development.
HL7	HL7 has specific standards (like cMHAFF: consumer Mobile Health Application Framework, UMHAI: Unique Mobile Health Application Identifier, MH-ADE: Mobile Health App Data Exchange) that may be leveraged by mHealthHUB. HL7 Mobile Health Working Group and HL7 (Medical) Devices Working Group, HL7 Patient Care Working Group, HL7 SOA (Services Oriented Architecture), HL7 CDSL Clinical Decision Support & HL7 FHIR Implementation Working Group will directly contribute to this activity. The HL7 Europe Technical Coordination Team can promote the development of European HL7 standard based guides and facilitate the technical collaboration among HL7 Affiliates. There are also US specific ‘Accelerator” Programs that can easily transformed to apply to European model. HL7 affiliates in 24 individual European Countries and in collaboration with

	HL7 Europe, HL7 International can further contribute HL7 partners like IEEE-SA, IHE International and ISO/TC215 are also actively involved in this space and HL7 will coordinate with these organizations to bring in their contribution to his effort. HL7 is also part of JIC: Joint Initiative Council on Global Health Informatics Standards. / This is a large effort and will need to be estimated separately (based upon mHealthHUB requirements). Suggest a 2-4 hour session to identify points of collaboration.
iHD	We have an interest in this topic, and we need to do some more thinking about whether we could play a significant role in this knowledge repository.
PROMIS	ProMIS collects information and best practices on App developed by Italian regions. An example is the mapping and collection of COVID app available on the mHUB website
RJH	We can be reference/sounding-board
SPMS	SPMS has developed and is updating its assessment framework mySNS Selecção. https://www.mysns.min-saude.pt/mysns-selecao/ Being in a modernization process for this, SPMS has the experience to provide guidance and serve as example on the process of creating and implementing an assessment framework for mobile health applications.
SSPA	Based on our experience: Providing assessment services, Analysis of assessment frameworks, Development of methodological bases for the creation of frameworks, Collaboration in consultancy reports on certification models, Sharing our publications; participation in workshops (in kind)
WHO	Sharing WHO app development and clearance process, as well as WHO clearing house, when is ready, currently working on it at Be He@lthy, Be Mobile (BHBM) and Digital Public Health Technology Unit at WHO Digital Health and Innovation Department (DHI), respectively.
Organisation	**Digital health literacy initiatives**
University of Agder	UiA is collaborating with the Southern Norwegian Hospital (SSHF) in the initiative for patients' digital literacy: "The patient knows the best digital patient course for HIV positive". UiA could offer a workshop for digital health literacy / 1 workshop per year
HIMMS/PCHA	we can support any MHH initiative that other partners may set up (but not as a lead) 1h/session
HL7	HL7 International has an expansive focus on Education and Training on HL7 Standards, including professional certifications. European HL7 Affiliates have also educational and training programs calibrated to the country needs. Other partner SDOs are also in this space and HL7 can facilitate a cross-

	SDO cooperation under mHealthHUB umbrella, coordination and leadership.
iHD	Contribute
ITU	Sharing any ITU contributions on guidelines, material on Digital Health literacy
Osakidetza Kronigune	• Digital Kronik ON programme for multimorbid patients (and caregivers) empowerment • Virtual programme for tobacco cessation (group sessions) • Virtual "Active Patient Program" for chronic patients, diabetes, congestive heart failure, cancer patients and gypsy community (group sessions) • Virtual maternal care sessions
PROMIS	ProMIS organizes webinars that enhance the technical contents of the IT solutions adopted by healthcare organizations. Furthermore, ProMIS collects information and best practices on the topic carried out by Italian regions and transferred between Italian and European regions and health organizations
SSPA	Based on our experience: - Barometers/surveys in health systems to understand digital literacy levels and attitudes of health professionals / citizens towards mHealth - Collaboration in training actions on digital literacy
UAS Vienna	IHE-ICP (https://academy.technikum-wien.at/zertifizierungen/ihe-certified-professional-ihe-foundations/) ELGA-IHE-HL7 (https://academy.technikum-wien.at/zertifizierungen/elga-ihe-hl7/) CDA-Crashcourse (https://academy.technikum-wien.at/zertifizierungen/elga-cda-zertifizierung/) HL7 Fundamentals (https://academy.technikum-wien.at/zertifizierungen/hl7-zertifizierung/)
WHO	Sharing WHO Digital Health and Innovation Department (DHI) published guidelines, material.
Organisation	**Innovations and horizon scanning relevant to mHealth solutions**
University of Agder	UiA has experience in the scientific screening/scanning of innovations relevant to mHealth solutions / 40 hours per scanning report / 1 scanning report per year
Ericsson Tesla	As our daily work we try to follow innovations relevant to mHealth solutions, we would like to participate on workshops and meetings.
HIMMS/PCHA	We could ask our internal communities and members for support (but not as lead expert) / 1h/session
iHD	We could contribute to this, because we often come across innovation areas that could be summarised. However, we would be open to taking an

	editorial responsibility for this area, although not being the exclusive content provider.
ITU	Sharing any ITU contributions on guidelines, material, reports on Digital Health Innovation
PROMIS	ProMIS collects information and best practices through surveys and questionnaires, in order to develop a repository of solutions that can be transferred between Italian and European regions and health organizations
RJH	Continuous desk research on innovations/best practises
WHO	Sharing WHO Digital Health and Innovation Department (DHI) published guidelines, material.
Organisation	**Recommendations and assessments on key mHealth aspects**
University of Agder	UiA could provide recommendations and assessments on project / solution / service specific key mHealth aspects through its innovation hub "I4H AS" and its professional, commercial partner network
Ericsson Tesla	We can contribute by writing and reviewing recommendations and assessments on key mHealth aspects.
HIMMS/PCHA	We could participate in the Legal and Ethics aspects on the recommendation / 2 to 5 hrs per year
HL7	Yes, HL7 can surely contribute in this aspect.
iHD	We are considering if we can play a role in mHealth assessments, or the development of criteria. We need to do some more thinking about this.
ITU	As appropriate and as related to requests coming from ITU member states
RJH	Probably but only against payment
SPMS	On mHealth integration with health systems
UAS Vienna	Development of recommendations for the design of IT systems as part of implementation strategies, considering the local environment (e.g. workflows, IT infrastructures, stakeholder views), considering IT standards and interoperability architectures. Hospital@Home - User workshops in a realistic, connected environment (e.g. medical intramural field: ICU vs. @Home environment with telemedical applications) including optional professional user experience assessment Assessment of interoperability in workshops, on-site and online, using available IHE specifications and test tools, in a Connectathon type of setting

WHO	BHBM Country support on implementing mhealth programs. Sharing WHO Digital Health and Innovation Department (DHI) published guidelines, material.
Organisation	Training courses
HL7	HL7 Education can create (adapt from its catalogue) mHealthHub specific training courses on a revenue-sharing model basis.
iHD	We are developing courses in GDPR/data protection, data quality, EHRs during 2021, which we could promote via the Hub. We do not currently have firm plans to develop Hub specific course modules but would be open to this if a viable business model can be defined.
ITU	Support, help in organising training courses in digital health
Promis	ProMIS organizes an online National Training Plan, dedicated to the Italian regions that adhere to the network, on specific aspects of EU planning and on the topics of the EU funding programs 2021 - 2027. For example, One-hour specific webinars to discuss about the alignment between local / regional programs and EU programs, effective strategies for communicating project results, how to define the expected impacts and build a coherent sustainability plan with the full involvement of different stakeholders.
RJH	Probably but only against payment
UAS Vienna	Topics: IT Basics, Interoperability, IT Standards, IT Security Online and on-site training, in all training settings (from lectures to completely self-guided learning using training material provided, incl. videos, quizzes), hands-on training on-site On all skill levels: beginner to expert
WHO	Sharing information on WHO Academy (https://www.who.int/about/who-academy) related courses.
Organisation	**Access to the partner's network of mHealth experts**
University of Agder	UiA could provide access to its industry and public partner network through its innovation hub "I4H AS"
HIMMS/PCHA	We could help but not as a lead / 1 h per year
HL7	HL7 affiliates in 24 individual European Countries and in collaboration with HL7 Europe, HL7 International Working Groups can provide specific input in this area.
iHD	We are connected to a lot of European (and some international) experts in mHealth and eHealth, in care and research. This is mostly not one large community but multiple connection points. We would be open to helping

	to discover a suitable expert for a given client need, and to help to broker consultancy relationships.
ITU	Sharing ITU's network of mHealth /digital health network and reaching out to ITU focal points
Osakidetza Kronigune	• ADLIFE European project Consortium (https://adlifeproject.com/) • Gatekeeper European project Consortium (https://www.gatekeeper-project.eu/) • C3Cloud European Project Consortium (https://c3-cloud.eu/) • OpenDei Large Scale Pilots sector Healthcare (https://www.opendei.eu/healthcare-sector/) • Spanish Digital Health Association (https://salud-digital.es/) • Sociedad Española de Informática de la salud (https://seis.es/)
Promis	ProMIS is a network of Regions that includes experts from different fields (Health and Care Organization, IT, Policy makers, Managers), nationally and internationally. They are invited and involved in knowledge exchange and training activities
RJH	Our collaboration networks through projects, EIPonAHA, EHTEL
SPMS	Case by case. available upon prior analysis and approval
WHO	The Be He@lthy, Be Mobile (BHBM) initiative set up by the World Health Organization (WHO) and the International Telecommunication union (ITU) in 2012 (https://www.who.int/activities/Addressing-mobile-health ; https://www.who.int/initiatives/behealthy) is moving forward towards a Global Network of Digital Health Hubs, where WHO/ITU creates program content for these Hubs and advise on how to help countries/regions to leverage it Through the Global Network of Digital Health Hubs both Hub's infrastructure and WHO/ITU content together can facilitate program implementation, as well as facilitate the knowledge sharing from the Hubs to other countries searching for guidance from the Hub's lessons learnt We are having conversations with PAHO regarding a PAHO Digital Health Hub and Digital Health Network of Experts. We may foresee, when both European mHealth Hub and PAHO's Digital Health Hub are mature enough, collaborative connections between Hubs when appropriate.
Organisation	**Webinars, conferences, workshops**
University of Agder	UiA could offer 2-hour workshop per year focusing on Usability/UX and Accessibility UiA could offer 2-hour workshop per year focusing on Human-centred design and participatory approaches
Ericsson Tesla	Participation as a listener and as presenter.
HIMMS/PCHA	We can help in organising these MH webinars/conferences/workshops (and if needed use our tools) / 1 -2 hrs per event

HL7	Covered by HL7 Working Groups weekly activities, HL7 Education year-round activities and HL7 Working Group Meetings that are held three times a year.
iHD	We have a lot of expertise in running online and in person events at different scales. We would be open to including Hub content within our events, contributing to Hub events, or organising dedicated webinars on topics in which we have expertise.
ITU	Support, help in organising webinars, conferences, workshops and disseminate outcomes to ITU network
Osakidetza Kronigune	We can prepare webinars to present concrete success stories such as those mentioned before (digital health literacy initiatives and apps implemented) and the technical aspects related to their deployment in real practice
Promis	Throughout the course of 2020, 39 webinars were held, of which: 20 training sessions and 19 thematic workshops. Around 50 webinars have been scheduled in 2021 and some of these have been and will be focus on the topic
RJH	Yes, mainly through our current projects where workshops will take place in collaboration with business, academic sector and research organisations in eHealth
SPMS	Subject: mHealth integration mechanisms with health systems Subject: Development environments for mHealth Subject: Policy on mHealth
SSPA	Collaboration is feasible on several aspects: organization, platform, dissemination and materials creation after the event.
UAS Vienna	Topics: Interoperability, IT Standards, IT Security, Usability
WHO	The Capacity Building and Collaboration (CBC) Team at WHO DHI, asked BHBM about European mhealth Hub and representatives from this Team have been attending to European mHealth Hub Talks 2021. This team could have in mind to contract the services of the European mhealth Hub experts for future WHO online courses / training in a specific section / lesson regarding mhealth (nothing concrete / sure yet). The person in charge of designing the global course contacted BHBM asking for information in this regard, when they design the mhealth section of the course, they may contact us. It will be good to share the concrete service portfolio with this Team.
Organisation	**mHealth communities of practice**
University of Agder	UiA could offer access to established UiT (Telehealth, Norway), DIT (Digital Health, Germany) and DIH (Digital Innovation Hub- Health network, Europe) of mHealth communities, Norwegian Smart Care Cluster (NSCC)

Ericsson Tesla	We would like to be part of this kind of networking, to find about different mHealth initiatives, and to be able to fully assist Croatia in mHealth initiatives creation and upgrade. And maybe one day to present/matchmake/twin Croatian mHealth initiatives in collaboration with Croatian Ministry of Health.
HIMMS/PCHA	We could help by using our members and communities' network / 1-2 hrs per year
HL7	HL7 FHIR Chat is unique and can be adopted for mHealthHUB.
iHD	We have patchy coverage of this specific community but would be happy to contribute to a pooled effort to establish one.
ITU	Support in building an mHealth community of practice
Osakidetza Kronigune	• Open Dei Health Cluster
Promis	ProMIS coordinates the thematic network INCASO (Improving INtegrated people-centred healthCAre Solutions) aimed at: putting the comprehensive needs of people and communities at the centre of health systems - empowering people to have a more active role in their own health; defining a common vocabulary, specific priorities and interests; creating synergies with existing European networks/partnerships; mapping European good practices related to integrated services. ProMIS is partner of the Joint Action "Jadecare" which aims to reinforce the capacity of health authorities to successfully address important aspects of health system transformation, in particular the transition to digitally-enabled care In the framework of the European Partnership on Active and Healthy Ageing (EIP-AHA), ProMIS takes part in the activities of the working group dedicated to the initiative "Blueprint on Digital Transformation of Health and Care for the Ageing Society", which reflects the common policy vision of European policy makers, civil society, professional organisations and industry on how innovation can transform health and care provision in our ageing society.
UAS Vienna	Austrian Society of Telemedicine and eHealth (OeGTeleMed) Link to several international, European and national medical societies e.g. cardiology, diabetes
WHO	As WHO, we are approached by many countries, we could redirect them to the European mHealth Hub solutions when appropriate. BHBM has been already contacted by WHO Ageing unit, Mental health unit and Physical activity unit asking for information about European mHealth Hub, its offer and the costs of its services, in order to offer these solutions to the countries they may be in contact with. The Ageing Unit also approach asking the possibility of European mHealth Hub as the business partner in the "Advancing inclusive Health & Care solutions for ageing well in the new decade" AAL 2021 Call. It will be good to share the concrete service portfolio with these Teams.

Organisation	Personalised advice and consultancy
University of Agder	UiA could provide access to personalised advice and consultancy services through its innovation hub "I4H AS" and its professional, commercial partner network
HL7	HL7 has a very large collection of consultants and experts in its membership. HL7 Europe can facilitate their involvement with mHealthHUB.
iHD	Taking our own core organisation and its contact network, we do have access to expert who could have to take consultancy activities, not limited to Europe. We would have to consider each request on a case-by-case basis, including the workload and travel implications and concurrent workload and deadlines.
ITU	As appropriate and as related to requests coming from ITU member states
RJH	Probably but only against payment
SPMS	Case by case. available upon prior analysis and approval
UAS Vienna	Requirements analysis and harmonisation, with local stakeholders, considering medical workflows (e.g. for disease management), with a focus on IT system requirements Harmonisation and development of IT interoperability specifications (e.g. implementation guidelines for electronic medical reports based on IT standards, standards based , reference architecture for telemonitoring) and IT interoperability architectures, considering IT standards, harmonised between medical experts and IT experts For early stages of system design: Workshops for system development planning and user and system requirement analysis in realistic connected environment (e.g. medical intramural field: ICU vs. @Home environment with telemedical applications) including optional professional user experience assessment For testing during later stages of system design: Health & Care Data Center - Test environment with professional medical IT infrastructure (e.g. virtual machines, FHIR server, application server, database, cloud systems for home monitoring), functional tests and interoperability tests
WHO	BHBM (https://www.who.int/initiatives/behealthy) technical expertise: scaling evidence based health services/solutions/programs where mobile technology is an enabler - Technology agnostic across the board of GPW and SDG priorities - Evidence- based - Not restricted to NCDs - Look at priority areas of research - BHBM's role is not to generate evidence
Organisation	**Matchmaking and twinning between mHealth initiatives**

University of Agder	North Sea Living Lab
Promis	ProMIS is a beneficiary partner of the VIGOUR project (EU Third Health Program), to support European regions in the identification and mutual exchange of good practices in integrated care. The project foresees the development of twinnings for the study and the transfer of good practices.
RJH	Yes, especially through the webinars and workshops.
SPMS	Assessment frameworks
SSPA	Andalusia might participate as region, with experience in participation on several past twinnings, both from originator and adopter perspectives.
WHO	It may be interesting keeping in mind the Finnish DigiHealth Hub (https://www.oulu.fi/cht-fi/digihealthhub), Global Health Hub Germany (https://www.globalhealthhub.de/) and Health Innovation Hub Germany (https://hih-2025.de/en/magazin/) that contacted us regarding willingness for cross collaboration, co-organizing workshops together, cross sharing experts/speakers, matchmaking and twinning activities, including application of joint grant proposals.

Annex 9: Report of first sustainability workshop

A first sustainability workshop with all Hub partners took place on 27.05.21. After the partners were introduced to the latest developments made in the service portfolio and business modelling activities, two discussion streams took place. The first part focused on the service areas, the mission and vision of the Hub and high-level business model, while the second one focused on the possible governance structures of the future Hub. All partners were invited to provide their feedback, and the continuation of the discussion is foreseen in a second sustainability workshop in the current timeline of the project.

PART I: FEEDBACK ON SERVICE AREAS, SERVICES, MISSION AND VISION, AND HIGH-LEVEL BUSINESS MODEL

- **EC as a Hub customer**

It was discussed that the EC could be a potential customer of the Hub, as it could learn from the Hub when defining priorities and launching calls. WHO commented that they are sometimes receiving requests from different stakeholders in participating in European calls (most recent ones: on AAL and on Horizon Europe Cluster 1 Health under topic HORIZON-HLTH-2021-ENVHLTH-02-02: Indoor air quality and health). According to the request received and expertise needed, there would be a possibility of adding the engagement to European mHealth Hub.

- **Service as focus on consolidating existing knowledge, spotting possible tensions and innovative ways beyond**

The possibility of the Hub to focus on consolidating existing knowledge, looking for certain aspects that are not necessarily addressed in the current regulations, spotting possible tensions and innovative ways beyond. There are certain situations in which mHealth proposals cannot go beyond regulations and good solutions cannot be fully implemented. Identifying those blockages could move further the mHealth services Agenda. The Hub has already undertaken this activity through several actions: KT3 through collecting best mHealth practices, KT1 through Assessment Frameworks analysis, WP5 through interviews and desk research regarding policies and regulations. The focus of the activities during this R&D phase have been to consolidate what seems to be these existing good practices. What might happen in the future under SA3 (Education, Networking and mHealth Advocacy) is community building, and is quite possible that as part of the community coming together could act as a place where further challenges, issues, and gaps in existing instruments are identified.

- **The Hub as a neutral convener versus taking a specific position**

A difficult choice is whether the Hub stays neutral. Will it produce documents that reflect or does the Hub take on advocacy calls? This is not decided yet, but good topic to further discuss. A possibility under membership services to the communities of practice, would be that the Hub without taking responsibility, could allow the community to mainstream such problems; There is a need to understand

if the scope of the current service areas is sufficient, and if they can account for different situations.

- **Branding of the future Hub services**

The Hub is the place to go if you want to get informed about the latest and best developments in mHealth. As there is a pressure towards sustainability, the consultancy aspect is emphasised in the overhead. The wording needs to be carefully considered so it does not result in a pushback.

- **Positioning of the future Hub**

The Hub needs to understand its relationship and future interactions with other initiatives that are going on. One such initiative is GHI (global initiative for interoperability), that contains 30 globally relevant governments, and they have different streams that work on iPS, standards registry and measuring interoperability of the MS that are members. Another initiative to be considered is the BHBM programme developed by WHO. What is it that the Hub offers in Europe which complements or takes BHBM programme forward?

- **The consultancy aspect of the future Hub – Position it as a primarily network of experts, emphasise service area 1 as capacity building.**

The consultancy aspect stands out as it is highlighted and positioned as the service number one. A suggestion would be to consider the Hub as advisor to the governments. It is a question of framing. There might be consultancy services offered, but under the approval of the Hub. The framing and the branding are the elements that will strengthen the Hub in the future. There are few models when thinking of offering expertise services to health ministries. A passive and simple model would entail a group of experts that would work commission-based and would offer a place to match-make. Another mode could be represented by a prime contractor on behalf of a network of experts with a revenue sharing model. Consultancy companies tend to do very little networking. The Hub needs to position itself primarily as a network of experts. The Hub is building a community of practice that is self-financed, and can capitalise on twinning, on getting people to learn from each other. There is a need to be clearer about SA1 as capacity building and offering links to experts but not actually implementing their agenda. The Hub's main strength and unique selling point is the peer community as a main strength.

PART II: TYPE OF ENTITY, ESSENTIAL CAPABILITIES, FUNDING SOURCES AND BUSINESS MODELS, DEFINING AND PREPARING THE TRANSITIONAL MODEL.

- **ITU foreword to the discussion**

The Hub was founded due to the need and desire to institutionalise the knowledge around mHealth, and implementing mHealth in a way that is trusted, neutral, not-for-profit, being a trusted advisor for countries, as they would like to learn, based on evidence and concrete experience. The Hub is not in competition with the private sector and tries to act in a way that is more neutral, not-for-profit advisory for MS. During the last year and a half (operational period of the Hub), the Hub started to create this identity. We have developed, compiling, aggregating existing knowledge. We started to put this in the service of countries. Creating this level of

experience, how to create a network and organise as a Hub to deliver these services. We received several types of proposals. The consortium - diversity and network to ensure diversity, community-based, could bring public sectors but also public organisations. During the last year and a half, we built the brand in terms of capacity of the Hub. That it would be easily consumed in this way. We need to think how we should position ourselves in the next phases. One of the most important things, Hub needs to move from EC project type to a different type of body, also in terms of governance. ITU/WHO do not want to govern the Hub forever. One of the big questions concerns the governance and the service portfolio. We don't want to appear as consultancy, but we need to have a balance between services that generate revenue, based on evidence, but also services that do not generate revenue and we need to consider future potential bottlenecks. The discussion needs to be expanded beyond WPs. We absolutely need a transition period as two years are not enough the full sustainability. That is why we suggested to write this letter, EU to consider a cost-extension for three years. We need to think of how we manage this period, we need a transition team, not only a WP4 Team. Others that are interested to be part of this team are welcomed.

Discussion on the different governance models proposed and criteria

- one suggestion was to consider the overall feasibility of the options as a criterion.
- The EU Agency might not be a feasible future option, from multiple reasons, one of them being that it might become easily politicised, especially for a bottom-up grassroots developments in mHealth to express their views. It is possible that national preferences would override the essential necessities of citizens in Europe.
- Between agility and trust there are several mechanisms. For example, WHO have several collaborating centres. If the institution would be endorsed by WHO as a collaborating centre can keep the light weight of management and develop a governance model that will be inclusive of members across Europe, and at the same time having official buy-in.
- WHO considers the Hub as a collaborating centre ++. That could alter the official buy-in score. Collaborating centres are usually universities. Not-for-profit is guaranteed.
- WHO is offering the idea of a global network of digital health hubs, where the ideal is to have a digital health hub in each region. The Hub would also fit as being a collaborative centre of all these Hubs (?)
- It was suggested that the European nutrition for Health Alliance could provide an interesting model. It operates in over 17 EU-countries, strategically linked essential stakeholders per country: https://european-nutrition.org/enha/.
- There might be easier and cheaper options, but maybe pressure in terms of costs would lead to a more successful outcome. There need to be some SME-like characteristics of the Hub in order to advance its' work.
- A good model might be a not-for-profit organisation, with a fixed structure of costs and employees, and a fully movable agile matrix of experts. For an SME-like structure, we need to define the SME, define the MVP and sell the first product.

Annex 10: mHealth Hub – ORCHA partnership SWOT Analysis

	ORCHA	European mHealth Hub
Strengths	• Catalogue of constantly updated solutions (Pro-active) • Constantly updated criteria covering all the assessment spectrum • Customized digital libraries (and maintenance thereof) • Market monitoring • MS Counselling • Customised training • Public educational events • Pricing support • Multi-stakeholder governance (e.g. prescription)	• Policy support • Integration in MS ehealth eco-system • Link with SDOs and other MS and EU eHealth • Policy bodies • Community of expertise • Use cases development • Training offers
Weaknesses	• Private business model • Lack of official recognition • Lack of (direct) link with MS initiatives	• Lack of immediate capacity to develop operational tools • Governance in the making • Business model to be created
Opportunities	• ORCHA: Operational arm of mHeath Hub • Official recognition • Development of new services (counselling)	• mHealth HUB: POLICY oriented • Short term visibility • Possibility to target priority areas • New training offers • New common projects
Threats	• Business model threatened • Conflict in coping a scaling up strategy • ORCHA not an EU entity	• Lack of convergence of interests • Loss of Independence • Mixed Governance

Annex 11: Identified funding opportunities

HEALTH WORK PROGRAMME

Uptake of technical specifications for "quality and reliability of health and wellness apps"

Europe is experiencing a fast growing market for Health and Wellness Apps. At the same time, concerns about the quality and reliability of apps have risen (for example, many health and wellness apps are being published on app stores without clinical evidence supporting the claimed benefits that they will deliver)77. CEN78, together with CEN/TC 251, ISO and IEC, is developing a new Technical Specification for 'Quality and Reliability of Health and Wellness Apps' together with a CEN/ISO 82304-2 health app quality label (capturing medical safety, usability, safety of personal data and technical quality of health apps).

The objective of the Technical Specification is to define quality and reliability criteria, which support app developers to design and users of apps to select better apps.

The specification is intended for use by manufacturers of health apps as well as by app checkers in order to communicate the quality and reliability of a health app.

However, once developed, there will be a need to bring together app developers, health and care system representatives, users (citizens/patients, health and care providers) and certification bodies in order to promote and stimulate the use and up-take of the health app quality label, building a digital ecosystem around a trusted mHealth label to support the integration and use of Health and Wellness Apps in the health and care system.

Projects are expected to address the following:

- Set up a structured dialogue on the uptake of the Technical Specifications between app developers, health and care system representatives, app stores, medical societies, patient organisations, users (incl. health and care professionals) and certification bodies, building a digital ecosystem around a trustable mHealth label.
- Co-create, develop and implement an action plan on the promotion of the mHealth label in the health and care system.
- Implement concrete actions on the integration and use of secure and qualitative Health and Wellness Apps, using the new label, in specific health and care settings, covering the entire European Union.
- Support and set-up an inclusive dissemination strategy to promote the use of the health app quality label (cfr. EU energy labels and EU Nutri-Score nutrition label) taking into account the different levels of digital health literacy among the involved actors.

“Smart Health Hub” (2022)

Projects are expected to contribute to the following outcomes:

- Accelerating adoption of digital tools for empowering patients and citizens to monitor their health status independently;
- Building a strong ecosystem of innovators, including, for example, SMEs, Research and Technology Organisations (RTOs), accelerators, incubators, European Digital Innovation Hubs (EDIH), European Reference Sites of the EIP-AHA83 and Knowledge Hubs, involving end-users
- Making European digital health companies, especially SMEs and mid-caps more sustainable and resilient through enhanced adoption of their innovations by public and private entities;
- Building a repository of digitally-enabled innovative solutions addressing all health related sectors, areas and segments, with particular focus on self-management and prevention.

Scope:

The EU has supported innovation of digital tools for better and more personalised treatment and self-monitoring of citizens and patients throughout Europe. However, adoption and deployment of digital health solutions in practice, both in the public health system and by private players remains low.

Building on the recommendations from the report of the Strategic Forum for Important Projects of Common European Interest84, coordination and support is needed to i) create a pan-European operational network as a mechanism (a European Smart Health Innovation Hub) that can assess and promote Smart Health initiatives; ii) stimulate the demand-side and the uptake of Smart Health products and services; and iii) support the development of Smart Health products and services.

The coordination and support action addresses the need to bring together different actors, working on innovative digital health solutions and to reinforce their collaboration, exchange and efforts on scaling-up digital health solutions across Europe.

Various repositories of digital health solutions, which are already deployable, exist across different projects and initiatives. It is necessary to integrate them into a European Digital Health Smart Innovation Hub, which will serve as a European reference platform for scalable digital health solutions, both for public organisations and private actors.

Projects are expected to address the following:

- Promote transfer and exchange of best practices (such as twinning activities) between different actors, such as SMEs, mid-caps, accelerators, incubators, RTOs, DIHs, EDIH, Reference Sites of the EIP-AHA and Knowledge Hubs – working on innovation of digital health solutions to exchange innovative practices, including training to end-users, e.g. citizens, patients, health and care providers,
- Promote scalability of digital innovation solutions by organising market places and pitching events to public health organisations and private actors,

- Integrating existing repositories into a sustainable European repository, serving as a reference of ready to market solutions (supply side) and public and private organisations adopting them (demand side), as well as best practices,
- Reinforce the European Smart Health ecosystem by enhancing collaboration and networking between the different actors working on digital health innovation across Europe.

"Supporting digital empowerment and health literacy"

European mHealth Hub has developed a wide network in Europe for wide spreading digital empowerment and health literacy. European mHealth Hub has developed a service portfolio which definitively aims at supporting digital empowerment and heath literacy.

ACTIVE AND ASSISTED LIVING PROGRAMME (AAL) CALL OF PROPOSALS 2021: "ADVANCING INCLUSIVE HEALTH & CARE SOLUTIONS FOR AGEING WELL IN THE NEW DECADE"

WHO Ageing Unit end-user and Coordinator of the AAL consortium. European mHealth Hub business partner which will help preparing a business plan to deliver the partners' solutions.

Key challenge: look if healthcare professionals can make sense from all the available data, and help professionals to take actions following the information from all the data gathered.

Objective: bring all this information together and put forward a solution in a unified framework following the already set up WHO concept on healthy ageing - intrinsic capacity, like this being able to combine different domains in one ecosystem in order to better understand the variability of each patient and variability over time.

Solution: filling in the gap of the component currently missing: an Intelligent healthcare ecosystem. It will be required to monitor the intrinsic capacity from the elder people and needed operational capacity to look at this intrinsic capacity. We will be building on existing tools and technologies (i.e. WHO apps such as ICO App ; existing technologies from WHO in which systems can build on), and we will be gathering the important characters in the different domains of intrinsic capacities that we need to measure

Strength of European mHealth Hub as partner:

Inside the 18 partners conforming European mHealth Hub, there are regional and local organizations awarded as AAL "Reference Site" status (these organizations have demonstrated the existence of comprehensive strategies to advance innovation and to understand and address the challenges of delivering health and care services to the ageing population. In the 2019 Call, six 4 stars reference Sites have been awarded a "Special recognition for excellence" for their outstanding work in driving regional innovation in active and healthy ageing, improving the quality of life of the ageing population, making health and social care delivery more sustainable and stimulating economic growth and competitiveness. These

Reference Sites include: South Denmark, Basque country, Andalusia, Catalonia, HANNN and Scotland. European mHealth Hub has some of them as partners.

Some of the European mHealth Hub partners have participated in the past on the relevant strategic developments of the European Innovation Partnership on Active and Healthy Ageing (EIP on AHA) including the Transformation of Health and Care in the Digital Single Market and work carried out through the Horizon 2020 WE4AHA CSA, particularly in the 3 horizontal initiatives, such as the Blueprint and the Innovation to Market (I2M) plan and MAFEIP.

This "Advancing inclusive Health & Care solutions for ageing well in the new decade" project proposal is a perfect opportunity for European mHealth Hub in order the European mHealth Hub Reference Sites partners to make progress by incorporating and improving Tools to identify gaps and opportunities for improvement, as well as develop an implementation plan. This will allow European mHealth Hub Reference Sites partners to continue challenge and benchmark themselves to ensure they are at the forefront in strategy and policy development and therefore contributing to the economic growth in their region and across Europe.

The strong network that European mHealth Hub has developed in Europe will be able to confront the aforementioned key challenge and objective by delivering the convenient solutions through an appropriate business plan.

BRAINSTORMING INPUTS FOR CURRENT DIALOGUE WHO EURO - EC FOR NEXT INSTRUMENTS AND FUNDING OPPORTUNITIES INSIDE THE *STRENGTHEN EFFECTIVE INNOVATIVE AND RESILIENT HEALTH SYSTEMS ROADMAP* THAT IS NOW BEING DEFINED BETWEEN WHO EURO AND EC SANTE C.

- Bringing up the work already done at WHO - EC collaboration on digital mental health and the place for European mHealth Hub
- Presenting the assets of our work to high level at WHO EURO /ITU/EC together with European mHealth Hub service portfolio, profiting from the started collaboration WHO HQ and EURO Mental and DHI - EC (very well defined and crisp concept note from WHO HQ and EURO Mental and DHI Teams with good desk research background and good complementary ideas sent to EC last year, see benefits for Europe and linkages with current EU initiatives on Digital and Mental Health that were written below)

Benefits for Europe and linkages with current EU initiatives on Digital and Mental Health

- *Creation of a **European Digital Mental Health Hub**, **linking with**:*
    - *Existing EU initiatives, such as European mHealth Hub, e-mental health innovation and transnational implementation platform North West Europe (eMEN), eHealth Hub*
    - *SMES/*Innovative technology companies*/EU Start-ups,* such as Monsenso, offering mHealth solutions to help optimise the treatment of mental disorders

- *'best practice' showcases and e-mental health product pilots that have been implemented in other EU projects*
- Previous EU projects on transnational policy for e-mental health, e-mental health policy around Europe, approaches to evidence-based research, implementation of e-mental health products into services, implementing e-mental health for clinicians, evaluation of e-mental health products, best practice examples and case-studies, such as Nevermind, MasterMind, or the AAL Programme solutions to support mental wellbeing of elderly people
- European Digital Innovation Hubs both, with the private sector and supporting governments in making their services and interventions more digital
- Health Promotion, Disease Prevention and Management of Non-Communicable Diseases (HPP) for knowledge sharing and support of exchange between countries in mental health
- European Reference Networks (ERNs) for the implementation/deployment of telehealth services at hospitals involved. Rare mental health conditions need from clinicians' interventions.
- Existent EU partnerships, such as Cofund on Health and Care systems and digitalisation for Communities/Hub Action and Country implementation, regarding how heath systems can be transformed, how can be scaled up innovation

- Boosting implementation of tools and programs into the European health and care systems
- Bringing research results towards the people and governments
- Boosting EU's preparedness for major cross border health threats and making sure health systems are resilient and can face epidemics and long-term challenges such as an ageing population and inequalities in health status. The *European Digital Mental Health Hub* with a strong/consolidated DMHP and telehealth/telemedicine services will strongly contribute to it
- Boosting and linking together EU programmes/instruments results' for bringing digital solutions to people and their integration into health systems in a sustainable way

UN COORDINATION MECHANISMS FOR DIGITIZATION OF HEALTH

UN has the capability of influencing the establishment of mHealth programmes in countries.
ITU Regional Office team for Europe is planning to get involved and do some outreach once Hub products will be available. Hub products could be taken and promoted in countries through UN Coordination mechanisms for the mHealth.

ITU Regional office together with country teams Have the capability to attract appropriate funding to support digital health programs. They can reach out to donors to roll out mHealth programs in the countries. This could represent a valuable source for scalability and sustainability of the Hub.

ITU engagement with Resident Coordinators in Europe region is for the following countries: Albania, Bosnia and Herzegovina, Georgia, North Macedonia, Moldova, Montenegro, Serbia, Turkey, Ukraine.

Countries with in-depth engagement are: Albania, Montenegro and Moldova

ITU Regional Office together with WHO representatives will set up one to one meetings with these countries teams to discuss possible programmes for digitization of health in the country and opportunities for cooperation. First such meeting is planned with North Macedonia for end of February. After preliminary discussions meetings are expected to be arranged between Hub and the country.

For this purpose the Hub already provided a two pager with promotional material on what this project backed up by the EU can offer in order to hook up the discussion with the governments.

ITU Regional office is looking Forward to make a concrete value proposition to the countries when the service portfolio will be more crystallised and business models developed by the hub. As donors are not interested in conceptualization, it is believed that with a “ready to go” programme for making the change in the health system there are high chances to catch interest from the donors.

ITU Regional is in a position to propose this value proposition for mHealth programs to the country teams.

Annex 12: Synergies and partnerships interviews with operational frameworks

List of interviews with operational frameworks and interviewees

Organisation	Interviewed	Date
DiGA	Julia Hagen (Digital health coordinator)	14 April 2021
EIT Health	Jan Philipp Beck (Chief Executive Officer)	18 February 2021
HL7 Europe	Catherine Chronaki (Secretary General)	25 January 2021, 3 February 2021
MedTech Europe	Michael Strübin (Director Digital Health)	4 February 2021
mHealth Belgium	Alexander Olbrechts (Business Group Leader)	20 January 2021
Osakidetza - Kronikgune	Nicolas Francisco González López (Osakidetza) Lola Verdoy (Kronikgune)	1 February 2021
ORCHA	Liz Ashall-Payne (Co-founder and CEO) Heather Cook (Associate director of partnerships) Tim Andrews (Co-founder and COO)	26 March 2021
Oulu Health – Finnish Digital Health hub	Guido GiuntiSatu Väinämö Jarmo Reponen Maritta Perala-Heape	4 March 2021
PCHA	Elinaz Mahdavy (Director of European Affairs & Partnerships) Petra Wilson (Managing director)	2 March 2021
SPMS	Samuel Jacinto (eHealth project manager)	27 January 2021
TicSalutSocial	Josuè Sallent (Director)	24 February 2021