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D4.3 Consolidated roadmap for mobile healthcare (mHealth)

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Abstract

This report develops the previously released deliverable D4.1 Consultation Document with each node described with its main attributes, including the outcomes of the consultation process, contextualised with a systemic view on mHealth.

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Executive Summary

Mobile Health (mHealth) solutions play an increasing role in healthcare and are considered likely to become more important during the next decade. Starting from a description of the State of play and trends (D2.1), the MovingLife project explored the current situation with regards to the deployment of mHealth solutions and described drivers and inhibitors for their further uptake. With the aim of establishing a wide use and acceptance of mHealth solutions for the year 2025 different scenarios have been developed (D3.2) illustrating the possible developments in this area. One of the developed scenarios has been adopted for elaborating a gap analysis that lead to 3 distinct preliminary roadmaps in the following areas: medical uptake; technologies and applications; and socio-economic factors (D4.1). D4.1 has been the reference document for the online consultation of several stakeholders with aim to take a broad perspective in the aforementioned areas.

This document reports an analysis of the collected input from the involved stakeholders as further insights to identify the needs and requirements that need to be satisfied in order to facilitate a deployment of mHealth solutions as in the future scenario. The result is three consolidated roadmaps, extending the preliminary roadmaps with additional elements and/or challenges¹.

The medical uptake consolidated roadmap

The roadmap on medical uptake illustrates the challenges that are and will be faced in the context of:

- *Patient empowerment and individualisation.* mHealth has a great potential to empower patients to be able to manage the care of chronic illness outside hospitals and clinics. This demands regulation and alternative care models in mHealth. Specific challenges are:
 - Acknowledge heterogeneity of patients.
 - Educate patients in the use of mHealth.
 - Individualism as key to integration.
 - Overcome differences in ability and motivation.
 - Patients should have the possibility to opt out of prescribed mHealth-based treatment for whatever reason.
- *Patient-doctor interaction.* A change in the patient-doctor relationship is expected. This calls for:
 - New skills and a redefinition of the role of the clinical staff in the healthcare ecosystem.
 - Courses in re-schooling clinicians and new training for future clinicians will need to be designed.
 - Universities will need help and guidelines from the European Union (or the National Education bodies) in order to be able to design courses that contribute to a cross boarder effort.
 - Healthcare staff needs evidence-based proof in order to trust new mHealth solutions.
 - Maximise the expected improvement of the quality and/or the efficacy of the healthcare professionals' work.
- *Medical guidelines.* Presently medical guidelines show big differences across but also within Member States. Therefore:
 - Minimum standards and templates, better education, and integrated care pathways are needed to facilitate the deployment of mHealth solutions.

¹ In the bullet points of the roadmaps, the black bullet points come from the preliminary roadmap, while the white bullet points emerged from the consultation process.

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- Reaching consensus in creating new guidelines for mHealth with local engagement and decisions at national level.
- *Personalized health systems.* At the moment health data is centrally stored within institutions. Data is not available across borders and in some European countries data is not even accessible across regions on a national level. Specific challenges in this area are:
 - Cross border accessibility of data, based on flexible and secure data storage and sharing platform, as the ones currently investigated in cloud computing approaches.
 - EU should consider standardizing the exchange of data and tagging data in order to improve safety for the patient.
 - Define ownership of the health data and the responsibility of a given healthcare professional to act upon these if necessary.
- *User acceptance.* The success of mHealth will be particularly determined by the trust of the users. Therefore, key future challenges will be:
 - Developing several points of access to health services.
 - Establish uniform regulations to increase trust.
 - Ensure usability and quality of mHealth solutions.
 - Fostering competition between mHealth solutions and other alternative ways to access treatment. This would eliminate less efficient and low quality solutions.
 - Involving mobile phone operators, mobile health companies, and call centres, which will have a crucial role in running Health solutions.

The Technology and Applications Consolidated Roadmap

The roadmap on technologies and applications outlines possibilities that can be used to tackle the existing challenges in the following areas:

- *Interoperability and standardization.* There are not widely adopted, interoperable standards (even for a generic Electronic Health Records) and software and hardwares (e.g. smart phones, medical equipment, etc.) does not work with each other. Therefore:
 - Implement neutral, trustworthy, transparent standards.
 - Semantic interoperability is an imperative (for both software and hardware) for the wide adoption of mHealth solutions.
 - Industrial standards associations, in strong cooperation with EU, National Healthcare Systems and National Governments, should stimulate and/or harmonize standardization efforts.
- *Security and Safety.* Many technical concerns are related to the secure storage and distribution of personal electronic health records, such as where they are stored. Specific challenges in this area are:
 - Cloud computing paradigms may represent an opportunity by enabling easy and fast access, standard base integration and interoperability among different healthcare systems, and collaboration among distinct healthcare actors.
 - Maintaining confidentiality and integrity of the information stored in all forms and ensuring data backup and recovery processes.
 - It needs to be improved the patient perception of the control over his/her health record in cloud solutions, as well as the patient satisfaction to e.g. enable storing/moving patient health record simultaneously in multiply devices.

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- *Apps as medical devices.* Applications for mobile devices (Apps) are a growing market and have started to enter the healthcare sector. Specific challenges in this area are:
 - The current legislation of the Medical Device Directive (MDD) does not sufficiently address this emerging market and in its current revision it is therefore advisable to take special care of this area.
 - Trustworthy certifications that make it simple and easy to verify, even for the patient, whether or not an application has been approved for medical use should become standard.
 - Responsibility to ensure the conformity of the Apps to the existing directive.
 - A new authority to perform market surveillance and certification issue is needed.
 - Apps as medical devices should affect only those solutions that have a direct effect on treatment or diagnosis.
 - mHealth service providers should revise their business models and focus on a few relevant Apps.
- *Connectivity and interferences.* Lack of connectivity or interferences could be a put off factor for final users thus potentially affecting the impact and user acceptance of mHealth. Specific challenges in this area are:
 - Ensure a ubiquitous broadband coverage.
 - Convergence of systems into integrated - and in some cases implantable - medical devices.
 - Decrease of energy required to operate medical devices.
 - Robust communication in short-mid range Wi-Fi technologies.
 - Medical Apps should be able to run without a connection, whenever the application allows it.
 - Extensive piloting actions are still needed to demonstrate their safety, as well as their actual effectiveness and reduction of costs with respect to existing non-invasive solutions.
 - The development of innovative technologies should be coupled with proper public awareness and education campaigns to address user acceptability.
 - Technology advances for robust communication should complement a sound regulatory framework in multiple directions (hardware and software).

In addition, the consultation process for this roadmap has been also used to prioritize the identified issues. According to many participants (50%), interoperability of both software and hardware is the main key for the wide adoption for mHealth solutions. Secondly, security-safety and Apps as medical devices are important themes (22% each). Finally, connectivity-interference is not seen as a priority in the short term (6%).

The Socio-economic factors Consolidated Roadmap

The roadmap related to socio-economic factors elaborates on the following themes:

- *Data protection and privacy.* Major concerns exist with regard to data protection and privacy, e.g. in relation to the exchange of data in mHealth. Legal safeguards for data protection and privacy will therefore have a crucial role in the future success of mHealth. In particular:
 - The development of a clear framework is needed, and one that is able to adapt quickly to future developments.
 - More specific guidance from EU is crucial, and additional communications directives or regulations could illustrate the application of the proposed changes for mHealth solutions.
 - Stronger emphasis on privacy by design is needed.

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- Higher amount of flexibility of data protection and privacy legislation is needed in order to respond to changes in technology
- *New actors in healthcare.* Healthcare will no longer be provided only by the traditional caregivers like nurses or physicians. Specific challenges in this area are:
 - Improving existing guidelines to address the complexity of new processes.
 - Harmonization of regulation concerning these new professions at the European level so that mHealth is able to operate across borders according to the demands of European citizens.
- Increasing importance of computer scientists.
- Changing role of physicians and nurses.
- The focus on profit might increase.
- Boundaries in healthcare are expected to become blurry due to a different perception of health and lifestyle.
- *Reimbursement schemes.* Reimbursement is of crucial importance for the success or failure of new technologies and innovations in healthcare. Specific challenges in this area are:
 - The acceptance of mHealth as a reimbursable act in all European healthcare systems is of pivotal importance.
 - A stronger cooperation of Member States in the reimbursement of cross border mHealth services, facilitated by the EU, will be needed to lead the way to an increased deployment of mHealth solutions in 2025.
- It is equally important to reorganise healthcare at national level.
- Focus on equity is necessary.
- *Inclusion and Ethical guidelines.* It should be noted that mHealth will be of importance in this area. In particular:
 - The realization of inclusive, patient-centred approaches will create a general base for the acceleration of mHealth.
 - Ethical guidelines concerning mHealth will help to increase the acceptance by safeguarding these issues but also by promoting patients' fundamental rights.
- Accessibility has to be guaranteed in financial terms as well as in educating care providers and patients in the use of new technologies.
- *Liability.* Liability varies enormously across different national systems. Specific challenges in this area are:
 - Liability needs to be, where possible, harmonized at the European level during the next years, in order to guarantee legal certainty for both providers and users of mHealth.
- *Interoperability of healthcare systems.* In addition to the issue of interoperability in a technical context, it should not be neglected that interoperability also plays a role in a socio-economic context. Specific challenges in this area are:
 - Coordination of therapies to facilitate interoperability.
 - Harmonisation of standards at national and European level.
 - A discussion about the definition of interoperability and interoperable healthcare systems is still needed.
 - Main advantages of mHealth in creating interoperable healthcare systems are:
 - Improving healthcare systems and reducing healthcare costs.
 - Increasing patient empowerment

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1 Introduction

The MovingLife project is a Coordination and Support Action that will deliver roadmaps for technological research, implementation practice and policy support with the aim of accelerating the establishment, acceptance and wide use of mobile eHealth (mHealth) solutions.

Starting from a description of the state of play and trends (D2.1), the MovingLife project explored the current situation with regards to the deployment of mHealth solutions and described drivers and inhibitors for their further uptake. With the aim of establishing a wide use and acceptance of mHealth solutions for the year 2025 different scenarios have been developed (D3.2) illustrating the possible developments in this area.

This document reports a set of consolidated roadmaps that elaborate possible routes from the state of play as existing in 2012 to the scenario outlined in 2025. The roadmaps cover the three areas of medical uptake, technologies and applications and socio-economic factors and build on the preliminary roadmaps that have been defined in D4.1 Consultation Document resulting from the performed gap analysis between the state of play and the chosen future scenario. D4.1 was the reference document for the online consultation with various different stakeholders, with aim to get a broad perspective on the aforementioned areas.

In the present deliverable, the collected input from stakeholders have been analysed and reported as further insights to identify the needs and requirements that need to be satisfied in order to facilitate a deployment of mHealth solutions as in the future scenario.

For the reader who is not familiar with mentioned deliverables or with the consultation process, we provide below a very synthetic account and contextualisation of the MovingLife project's achievements that form the basis of these consolidated roadmaps.²

1.1 Target audiences

The consortium envisages that this report will be useful to all those stakeholders directly involved in the implementation of mHealth as well as to any other relevant actors in the Health domain. Principally the consortium views the following groups of stakeholders as principal target audiences for the report:

- Primary stakeholders: i.e. patients and primary care givers, in particular patients with chronic health conditions that require management, patients who may be underserved by traditional medical community because of geography or immobility, private caregivers, e.g. family members or relatives.
- Secondary stakeholders: Professional users of mobile health technology solutions such as medical professionals, professional care providers, care homes and other service providers.
- Tertiary stakeholders: Suppliers of mobile health technology solutions, research organisations, public and private enterprises with a business in mobile technology (smartphones), enterprises with a business in telemedicine or telecare, providers of the IT infrastructure, hard- and software and/or service provision.
- Others: Media, employers, policy-makers, public administrations, civil society organisations, standardisation organisations, social and private insurance companies, supporters of mobile health technology solutions.

² The mentioned deliverables can all be downloaded from MovingLife's website at www.moving-life.eu

This list is by no means exhaustive and it represents those that the project consortium believes will potentially find value in the contents of this report.

1.2 State of Play

In D2.1 State of Play in Mobile Healthcare, MovingLife produced a study of the state of the play and trends in the following areas:

- Technologies related to mHealth and their Applications;
- Medical and Clinical Guidelines;
- User Acceptance, Security and Privacy;
- Regulatory and Legal Frameworks.

The work has been carried out using environmental scanning in the four aforementioned areas, two dedicated workshops (one for the Medical and Clinical Guidelines and one for the Regulatory and Legal Framework) and a number of interviews with relevant experts in India and Brazil in order to go beyond a purely European perspective. As a result, we have analysed and synthesized the above mentioned areas to put forward a framework for understanding the overall key trends, inhibitors and drivers which have an impact on the current and future state of play in mobile healthcare. For each target area, a summary of the key findings is presented as the contextualization of the respective consolidated roadmaps.

1.3 The future scenario

In D3.2 Vision Scenarios in Mobile Healthcare, four scenarios were envisaged in order to reflect the possible future visions. The scenarios were developed using the well-renowned IDON scenario technique. A vision scenario workshop was held in January 2012 where different stakeholders discussed their perspective on the trigger question “How will mHealth applications and solutions be used in chronic disease management in 2025?” As a result from the workshop, four alternative but equally viable vision scenarios were developed. In order to create the roadmaps as guidance towards mHealth in 2025, the MovingLife consortium chose to focus the gap analysis on only one of these scenarios, namely the scenario called “There must be an app for that!”. This scenario depicts a future with widespread use and acceptance of mHealth. The scenario is reported below.³

1.3.1 There must be an app for that!

Healthcare delivery has become digital and mobile; eHealth and mHealth technologies and applications are vital tools for how, when, where and by whom healthcare is delivered.

mHealth is enabled by the existence of wireless networks and mobile platforms that support full interoperability of all mobile technological solutions that fulfil European standard requirements.

Another important hurdle, namely how doctors are reimbursed, has been overcome by the implementation of clearly defined mHealth payment models combined with a “pay for performance” model. Doctors get paid based on the number of different mHealth services they offer and on the

³ Full storylines have also been developed for the four scenarios and can be downloaded at www.moving-life.eu

basis of how on the number of patients treated using mHealth solutions and/or applications. While there is a distinction between apps prescribed by the doctors and apps that patients download privately, this payment model also compensates doctors when patients present data from their non-prescribed apps during the consultation.

The overall saturation of smartphone and off-the-shelf apps for everything and anything imaginable has also reached the healthcare system and how patients themselves deal with their medical condition. Using health related apps has become a way of life and patients want apps that respond precisely to their individual needs. Mobile apps developers have now become important stakeholders in the healthcare eco-system.

mHealth is not only used to support and improve the care for the individual, it is also employed for public health purposes. Traditional direct targeted Text Messaging for the purpose of general health education and information has been taken a step further. Today, anyone who has downloaded the public health service app on their smartphone will receive an automatic text message informing them of the presence of communicable diseases in the area. The same app allows public health authorities to receive data from users' smartphone every time the user enters or leaves an affected area.

Patient and clinician reservations and concerns towards the use of mHealth services and application have been overcome by the implementation of trustworthy certifications which are in place across Europe. This makes it simple and easy to verify, even for the patient, whether an application has been approved for medical use. In addition, data protection and data management regulations have been adopted, enabling the use of mHealth services and applications without jeopardizing the protection of personal and medical data.

In medical practice, mobile technologies and applications have become embedded in patient-centred disease management and flexible care models, which have been able to compensate for the diminishing clinical personnel resources. In fact, patients, especially chronic patients who have particularly high needs and requirements concerning continuous care, hardly even perceive or experience the lack of medical staff. On the contrary, patients feel more connected to their doctor and more actively involved in managing their condition when they have to actively use mobile applications to monitor, record, and transmit medical and personal data.

In addition, simple mobile apps make it possible to collect and record other data than simply those directly connected to the condition in question which strengthen the holistic care model approach. The patient's experience, lifestyle and well-being are all taken under consideration and different apps can provide support for any of these issue. This could be air pollution data for asthmatic patients carrying a GPS-enabled device which records where and when they use their inhaler. The data can then be shared with other users and a map showing "polluted areas" can be generated. In this way, asthmatic patients can either avoid those particular areas or take their precautions if they have to enter them. In many ways, these types of applications enable citizen-centred surveillance of health risk factors similar to that employed by the state for public health warnings.

While the vast majority of patients readily embrace mHealth services and applications, patients living in remote areas actually do not have a choice. The scarcity of human resources, the deployment of mobile platforms, wireless networks and technological solutions make mHealth the obvious solution to improve the provision of care for people in remote areas. In addition to the traditional features of remote care and monitoring, an increasing number of unskilled health workers cover health needs in remote areas. Mobile applications and platforms support these workers in making skilled decisions and providing treatment and care.

1.4 Towards the Consolidated Roadmaps

As a first step, three preliminary roadmaps based on an analysis of the gap between the “As-Is” situation (the State-of-play document) today and the envisioned “To-Be” situation (the scenario storyline) have been developed. The three preliminary roadmaps are presented in the deliverable D4.1 Consultation Document and have been used as starting point for the consultation process. In summary, each preliminary roadmap describes the gaps that have been identified (as key elements of the future scenario that currently are not yet sufficiently developed), and for each gap, the key future challenges (according to our analysis) to fulfil such a gap have been defined.

The consultation process involved 45 participants, with the following background:

- 26 Academic/Research
- 8 Health Care Professional
- 6 Health Care Researchers
- 4 Industry / Service Providers
- 1 Other

In terms of country participation, we have had the following distribution:

- 4 Belgium
- 1 Brazil
- 5 Denmark
- 1 Estonia
- 3 Germany
- 1 Ireland
- 7 Spain
- 1 Turkey
- 8 United Kingdom
- 6 Other

The online consultation was based on 28 questions (which were a mix between open and closed questions) aimed at validate and provide further information on the identified future challenges, and thus produce the consolidated roadmaps. The consultation questions are provided in the annexes of this report.

A consultation report, including the scenario, was circulated to an extensive list of stakeholders. Stakeholders were identified during the course of the project and the list has been maintained by the consortium with the involvement of all partners. Stakeholders were asked to read the consultation report and then directed to an online set of questions created and hosted on SurveyMonkey. In total the consultation was kept open for two weeks. An initial invitation letter was followed up with a second reminder email halfway through the consultation.

The consultation questions were as with the roadmap and state of play reports broadly divided into three broad areas. These were questions on technical, medical and social/legal aspects. Questions were collaboratively developed by the consortium and reflected key issues identified in the scenario and consultation document. The consultation dependent on how much respondents contributed in their own words took 30-60mins to complete. At the beginning of the consultation exercise some respondents expressed a wish to complete the consultation offline. As a result an offline word-version was circulated to these respondents and provided to partners in the project should any stakeholders request an offline version from them.

As noted above questions were a mix of closed and open questions. The majority of closed questions had however a text box where respondents were encouraged to comment further and to provide more details on their answers. The majority of closed questions were also ranking questions where stakeholders were asked to rank or indicate key issues discussed in the consultation document and scenario. Stakeholders were also asked to provide demographic and contact details (if they consented to being contacted by the project), the results of which have been presented above.

Online results to the consultation were stored and produced utilising the tools provided by SurveyMonkey. As a number of stakeholders responded using an offline version a master result file was produced incorporating online as well as offline responses. The analysis of the results is presented in this report in the analysis conducted in the ‘further insights’ section.

The limitations of the consultation exercise are for the consortium primarily linked to a potentially low number of responses. This was due to two reasons. Firstly the timing of the consultation exercise, due to the constraints of time and the DOW, meant that the initial email was sent during what is a traditional holiday period for many stakeholders. Responses during this initial period were low and infrequent. Internally the consortium agreed to extend the initial deadline and a reminder email was sent to the list of stakeholders. Consequently an increased rate and number of responses to the exercise was generated. As with all consultation exercises more time would have been desirable and would have increased the number of responses but this was unfeasible given time constraints on the project. Secondly online consultation exercises have their own inherent limitations in respondents committing time to replying to the consultation, which in this case was compounded by stakeholders needing to read and digest material in the form of a consultation document. Again more time may have mitigated against this.

In addressing the limitation one key factor to also consider is the relative newness of mHealth as a topic. While arguable mHealth is set to grow in importance currently amongst a large number of stakeholders involved in healthcare or health services it is a relatively little known area. As such, taking this into account, our respondents were nearly all those involved in pushing, setting or responding to the mHealth agenda. The insights gleaned from these stakeholders are particularly valuable and we set out their contribution as recorded by the consultation exercise in the “Results of the consultation process” section of this report.

In the following, we present the 3 roadmaps structured along the following four sections:

- *Contextualisation:* Where we briefly recall the key findings in terms of current development;
- *Identified gaps and preliminary research themes:* Where we report the key findings of the preliminary roadmap;
- *Results of the consultation process:* Where we report the key input from the consultation process.
- *Consolidated Roadmap:* Where we extend the preliminary roadmap with future insights emerging from the previous section, and thus obtain the consolidated roadmap.

2 Medical uptake Roadmap

This roadmap elaborates on aspects related to the medical uptake of mHealth solutions such as the empowerment of patients, the patient-doctor interaction, the application and use of medical guidelines, the opportunities and challenges of personalized health challenges and user acceptance.

2.1 Contextualization

Originally the task was scoped at “medical and clinical guidelines”, but these two terms (medical and clinical) more or less substitute each other. It also soon became clear, that mHealth integration in clinical guidelines is not an absolute indicator of integration in established healthcare services. Thus we use medical uptake in a broad sense in which different levels of uptake can be identified and the term “medical” also refers to the point of view of the clinician or healthcare provider. Medical uptake must signify the degree of acceptance within the established healthcare system.

In our investigations the main focus was mHealth technologies that are being used by a patient (or a healthcare professional) outside an authorised healthcare clinic/location. We found an increasing amount of clinical studies and randomized trials that examine the consequences of mHealth intervention. To support these types of activities are of paramount importance to increase the implementation of mHealth in established healthcare systems. We have found very few clinical guidelines that support mHealth use by healthcare professionals or their patients (when still submitted in a professional healthcare provider relationship). This fact can mean either that the mHealth solutions do not fit into the established clinical guideline framework at all or that the mHealth solutions are simply too immature to be integrated into these. The argument from the expert workshop⁴ was that it depends on the type of mHealth solution; if it is radically changing the care model and the responsibility between the provider and the patient, the need for integration into guidelines will be bigger.

The actual context in this area can be summarised in terms of the following Trends (Table 1) and Drivers and Inhibitors (Table 2), which respectively feed and limit the identified trends.

Table 1 - Trends in Medical Uptake

Trends	
<i>Patient empowerment</i>	How mHealth applications enhance patient empowerment, support patient self-management and also empower carers and other medical professionals is a key issue. As we explore in the project, empowerment is often a central objective of mHealth deployment in how control and decision-making is embedded within strategies supporting patient self-management. Patient empowerment tends to put the patient in a central, active role as opposed to a passive recipient of healthcare services. Patient empowerment through mHealth solutions could lead to more work for the professional interpreting information and statistics for the patient. Therefore the “small things” should be taken care of by algorithms etc. in smartphones. This means that patient education is an important part of the patient empowerment trend. This fits well with several lines of thinking with mHealth, and mHealth may to some extent be seen as the ICT support for this trend.
<i>Consumerism in healthcare</i>	As a parallel trend to patient empowerment, the growing consumerism in healthcare is putting patients at the centre when it comes to delivering services. Technology innovation is facilitating this trend. Even in countries with publicly provided healthcare, the trend is pushing the boundaries of the traditional roles of the patient and the healthcare professional. Another element of consumerism which will probably promote wider use and integration of mHealth solutions is represented by the consumer health apps. If a patient or citizen is using

⁴ The MovingLife Pan-European Workshop on Medical Uptake of Mobile Health Solutions, 5 December 2011, Brussels.

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	an app to track their health, it is likely that they will seek to include this information during visits to their general practitioner (GP) or during hospitalisation. When the number of such requests reaches a certain point, direct inclusion through either import/export data options or use of approved applications with integration into the Personal Health Record or the eHealth system of the GP seems inevitable. Furthermore, if patients realise that using an app to closely monitor a condition can reduce the number of routine visits to e.g. the GP, there is very likely to be an immediate demand for the apps.
<i>Healthcare expenditure reduction:</i>	mHealth may be a means of providing cheaper healthcare to more individuals. In particular, the new technologies (e.g. 4G) can make monitoring, consulting and healthcare more flexible and convenient (e.g. enabling the exploitation of both mobile telecommunication and multimedia technologies).

Table 2 - Drivers and Inhibitors in Medical Uptake

Drivers
<i>Individuals want more control over their healthcare.</i> This is in terms of where they access healthcare and through what medium healthcare is provided to them.
<i>Growing demand for more integrated care pathways</i> and patients who prefer or want remote monitoring: For example, Danish patients are continually experiencing the healthcare system as being built up in “silos” and this may be relevant for other EU patients as well. Many healthcare systems lack integration between deeply specialist therapeutic areas, making them prone to delivering a staccato healthcare service to the citizens when we look at the treatment of the patient over time. Patient organisations are raising awareness about this inappropriate way of delivering healthcare services not just from a service perspective but also because the deep specialisation has morbid consequences for e.g. the chronically ill with several illnesses. This demand for more integrated care pathways and care models naturally increases the demand for uniform healthcare information in different care spaces.
Inhibitors
<i>Inertia of public healthcare services.</i> For public healthcare service systems, patient empowerment constitutes a change in paradigms and in particular necessitates reorganisation. This inertia of public healthcare services at individual level as well as organisational level constitutes an obstacle to mHealth uptake.
<i>Lack of cost/payment models:</i> In particular, lack of analysis of effectiveness and cost-effectiveness of mHealth applications.
<i>The doctor's organisations:</i> If mHealth is seen as too great a transferral of power or loss of authority, resentment can arise. Furthermore, if doctors believe that mHealth solutions will require them to monitor all information extracted then resentment will quickly become evident. It is therefore important to emphasise algorithms and graphical representation as tools to lessen the perceived burden of huge amounts of data. If mHealth is seen as easing tasks and supplying valuable information, then support may be achieved. Should mHealth solutions provide a direct, tangible advantage to doctors, they are very likely to embrace mHealth, which could also constitute an improvement in quality for their patients. There may be resistance amongst healthcare professionals and providers in giving more control to individuals, whether these are patients or those assisting in the provision of care for patients.

Finally, our investigation clearly illustrates that the current state of play for medical and clinical guidelines dealing with mHealth is not developed or formulated to the same degree as other technologies (such as medical devices) or applications derived from eHealth solutions. Therefore, mHealth represents a number of major potential changes to the delivery and practice of healthcare. In particular, the following key findings need to be carefully taken into consideration:

- mHealth does not for the most part fit into traditional or current methods of assessing the clinical utility of treatments or technologies.
- mHealth may transform the practice and delivery of healthcare. In doing so however there may be resistance or rejection amongst healthcare professionals and patients. Trust is an essential prerequisite for the success of mHealth.
- As mHealth constitutes a potential restructuring of healthcare spaces and delivery, the trajectory of how technology develops is tested and then implemented will diverge from current health technology assessment and evaluation models.

- mHealth devices and services are positioned to address some of the most problematic issues facing healthcare delivery in the EU, such as the treatment of chronic diseases whether associated with lifestyle or an ageing population.

2.2 Identified gaps and preliminary research themes

From the analysis of the status of play outlined above, the following main elements have been mapped to the target scenario described in Section 1.3.1, in order to identify existing main gaps:

- Patient empowerment and individualisation
- Patient-doctor interaction
- Medical guidelines
- Personalised health systems
- User acceptance

As a result, the following table summarises the emerged research themes (i.e. gaps to be fulfilled) for each selected element, which will be detailed in the following sub-sections.

Table 3 Medical Uptake Preliminary Roadmap

GAP	Preliminary Research Themes
Patient empowerment and individualisation	<ul style="list-style-type: none"> • Acknowledge heterogeneity of patients • Educate patients in the use of mHealth • Individualism as key to integration
Patient-doctor interaction	<ul style="list-style-type: none"> • Redefinition of role of clinical staff • Education of healthcare providers
Medical Guidelines	<ul style="list-style-type: none"> • European standards and templates for medical guidelines • Integrated care pathways • Training of clinicians
Personalised health systems	<ul style="list-style-type: none"> • Cross-border accessibility of data • Standardisation of data exchange • Define ownership of data
User acceptance	<ul style="list-style-type: none"> • Developing several points of access to health services. • Establish uniform regulations to increase trust • Ensure usability and quality

2.2.1 Patient empowerment and individualisation

The overall saturation of smart phone and off-the-shelf apps has reached the healthcare system. Using health related apps has become a way of life and an increasing number of patients want apps that respond precisely to their individual needs.

Future challenges:

- *Acknowledge heterogeneity of patients, Educate patients in the use of mHealth and Individualism as key to integration.* mHealth has a great potential in empowering patients to manage their own chronic disease outside hospitals and clinics. However, this calls for certain

technical skills in order to be able to upload the right data at the right time and place and to communicate with the healthcare staff remotely. However language, culture and technical knowhow vary from country to country and within countries. Individualisation in the usage of mHealth is therefore a key element in successful integration. Segmented education of European citizens in handling their own disease through mHealth, e.g. patient schools, could impose the integration of mHealth.⁵ Furthermore, some patients may refuse treatment through mHealth methods for various reasons. This will result in a demand for regulation and alternative care models to mHealth to be available.

2.2.2 Patient-doctor interaction

Mobile technologies and applications have become embedded in patient-centred disease management and flexible care models compensating for the diminishing clinical personnel resources. Mobile applications and platforms support unskilled workers in making skilled decisions and providing treatment and care.

Future challenges:

- *Redefinition of role of clinical staff and Education of healthcare providers.* Clinical staff can no longer rely on real time communication and physical examination⁶ of the patient when ‘out-monitoring’ the patient using mHealth. Furthermore, patient empowerment and unskilled workers are doing what doctors do today. This calls for new skills and a redefinition of the role of clinical staff in the healthcare ecosystem. Courses in re-schooling clinicians and new training methods for future clinicians have to be designed in order to handle the new type of tasks and skills in monitoring a patient from a far. Universities and other teaching institutions will require guidance from the European Union in order to be able to design suitable training that will contribute to a cross border effort.

2.2.3 Medical guidelines

In order to reach the point where eHealth and mHealth are effective tools for how, when, where and by whom healthcare is delivered, clinical staff will need guidelines to support and standardise their usage of technology, especially when mHealth is radically changing the care model and the role and responsibilities of healthcare providers and patients.

Future challenges:

- *European standards/templates.* Today guidelines and how they are implemented differ from region to region and from country to country. Furthermore, guidelines today often focus more on clinical procedures than the means by which results or data are communicated⁷. This raises the demand for a minimum European standard or template, which explain how patients can expect to be treated in other European countries. At the same time the standard or template will guide the clinicians in giving the needed treatment remotely. The template or standard should include how to ‘sense’ the patients remotely.

⁵ Asymmetry in network coverage and Internet access is also a great obstacle when dealing with patient empowerment – this is treated under ‘Technology’.

⁶ We only focus on treatment and not diagnosing in this project, however continuous diagnosing and treatment cannot entirely be separated.

⁷ State of Play and Trends, p. 46.

- *Integrated care pathways.* Many healthcare systems lack integration between deeply specialist therapeutic areas, making them prone to deliver isolated healthcare services to the citizens.⁸ More integrated pathways and care models increase the demand for uniform healthcare information in different care spaces.
- *Education of healthcare providers.* In order to raise the awareness and acceptance of mHealth, clinicians need further training. Universities and other teaching institutions should be provided with impetus to achieve this.

2.2.4 Personalized health systems

When mHealth data protection and data management regulations have been adopted it will enable the use of mHealth services and applications without jeopardizing the protection of personal and medical data.

Future challenges:

- *Cross-border accessibility of data, Standardisation of data exchange and Define ownership of data.* Today health data tends to be centralized at the regional or Member State level. Data is however not readily available across borders and in some European countries data is not even accessible across regions. In the future, both patients and clinicians should have the possibility to access and upload data across borders. This will likely demand flexible and secure data storage and sharing platforms such as cloud computing. Data will follow the patient when he travels travelling from hospital to hospital, region to region, country to country. Furthermore, the EU should consider standardizing the exchange of data and tagging data in order to secure the patient. It is crucial to define ownership of the health data and healthcare professionals' responsibilities and course of actions when receiving a patient's health data through the means of mHealth.

2.2.5 User acceptance

In the scenario patients feel more connected to their doctor and more actively involved in managing their condition when they have to actively use mobile applications to monitor, record, and transmit medical and personal data. This is in contrast to what is happening today.

Future challenges:

- *Developing several points of access to health services.* Both patients and clinicians fear that technical complications will occur at crucial times. Several points of access are therefore of great importance when establishing user acceptance. An example of a potential solution could be where a patient cannot get through to his GP and is consequently automatically re-routed to a national or European call centre.
- *Establish uniform regulations to increase trust.* Trust can also be gained through uniform laws and regulations across borders in how to handle patient data and securing privacy issues technically.
- *Ensure usability and quality of mHealth solutions.* If mHealth solutions provide a direct and tangible advantage to doctors they are likely to embrace mHealth. It is therefore important to emphasise algorithms and graphical representations as tools to reduce the perceived burden of huge amounts of data rather than tools that monitor all the information that can be extracted from

⁸State of Play and Trends, p. 20.

mHealth solutions.⁹ Healthcare Technology Assessment (HTA) and clinical trials should be used not only to validate the usage of a certain mHealth technologies but also to emphasize the ease and the improvement in treatment when using the technology. The intuitive benefit of mHealth will possibly impose a cultural change and require a ‘leap of faith’. Nevertheless, it is important to communicate the results of successful clinical trials and HTA to all European countries.

2.3 Results of the consultation process

In line with the preliminary roadmap the survey questions during the consultation process have focused on the identified main gaps associated with Medical Uptake in mHealth, i.e. patient empowerment and individualisation, patient-doctor interaction, medical guidelines, personalised health systems and user acceptance. These gaps have not been prioritised because a prioritisation would not show *how* the gaps differ in value to the different stakeholders. The gaps are judged to be too different in nature to be equated.

The results the consultation process confirmed the key significance of the identified gaps in the preliminary roadmap related to the Medical Uptake in mHealth. The respondents ask for more training of healthcare professionals and patients, campaigns, integration of mHealth with new and existing pathways, less administration, balancing data protection and privacy rights with technological innovation and several points of access. Moreover, the consultation process has resulted in acquiring additional aspects of the identified gaps, which nuances the final roadmap.

Subsequently, the outcomes of the consultation will be summarised according to the identified gaps grouped in further insights for the consolidated roadmaps.

2.3.1 Patient Empowerment

- *Overcome differences in ability and motivation:* To avoid that differences in language, culture, religious belief, age, level of education or technological know-how become barriers for using mHealth technologies, the stakeholders suggest the following two initiatives:

- extensive training for healthcare professionals and patients
- public awareness campaigns

Training should be understood in a broad sense. Patients and healthcare staff should receive training in how to use mHealth technologies and how to benefit from mHealth. Also, be beneficial to explore the possibility of setting up training within existing patient groups where experienced mHealth users (patients) could train other patients. When it comes to campaigns, the information is recommended to be targeted both patients and non-patients also taking into account factors such as different levels of IT literacy, ethnicity, and age.

When all this is said, it seems like a large group of the respondents also believe that the positive effects from mHealth are easy to grasp for patients. One of the explanations is that mHealth is expected to respond to patient unique needs and this in turn drives the patients demand for Apps. Another explanation is that mHealth solutions can become drivers to endorse patient empowerment in remote and/or depressed areas. Apps are compact knowledge platforms, which can reach a huge amount of people and this makes it possible to distribute health (medicine) technology in spite of language, education and technological know-how.

- *To opt out of a prescribed mHealth treatment.* The majority of the respondents believe that the patients should have the possibility to opt out of prescribed mHealth treatment. With ordinary treatment it is possible for patients to opt out of a prescribed treatment no matter which technology is involved. Patients should be free to accept or refuse treatment as they are today.

⁹State of Play and Trends, p. 17.

Making mHealth services the only option will not actually guarantee that all patients will accept and use it.

2.3.2 Patient-doctor interaction

- *Healthcare staff needs evidence-based proof in order to trust new mHealth solutions.* As highlighted in the preliminary roadmap, to support professional usage of mHealth solutions the following two actions are deemed necessary:

- Training for healthcare professionals (post education).
- Changes in curriculum at universities and other teaching institutions.

However, some of the respondents describe healthcare professionals as rather conservative and reluctant to change. Therefore, the training should not only focus on how to use mHealth technologies (technical aspect), but also on how to integrate the mHealth solutions in the entire care path (organisational aspect). One respondent calls it a cultural change and not only a change in technical competencies, while one respondent also suggests that a pull mechanism from patients also can motivate healthcare staff to use mHealth. In other words, staff needs evidence-based proof in order to trust that new mHealth solutions actually can improve treatment and care.

- *Maximise the expected improvement of the quality and/or the efficacy of the healthcare professionals' work.* The point above calls for more longitudinal studies in mHealth solutions. In particular, it is important that the healthcare professionals experience the new mHealth solutions as real support to their work rather than an administrative burden and they should feel that the quality and/or the efficacy of their work have to become improved with the implementation of mHealth solutions. Thus new courses and e-training should be very closely related with daily practice. Another important input from the respondents is that post education courses will only be effective if the legal framework, IT infrastructures and reimbursement models (both on a national and EU level) also are being taken into consideration. Otherwise the staff will lose their incentives to treat patients from other nations as it will become too difficult to deal with patients from other nations.

2.3.3 Medical guidelines

- *Reaching consensus.* Creating new guidelines for mHealth is highly recommended by the respondents. It is also emerged that local engagement and decisions at national level are key when it comes to reaching consensus and agreement on medical guidelines that meet the existing standards and match the cultural contexts of countries across the EU. In fact, European Level Action to promote guideline adoption in clinical practice is almost just as important as long as the local level is taken into consideration as well. Besides the national level, local actors such as doctors, health-care professionals and hospitals/clinics should be involved in the development and implementation of guidelines to mHealth solutions. It is worth to highlight that respondents state that clinical trials are not the way to achieve more transparency regarding the quality of the mHealth solutions nor the way to create guidelines for how to use mHealth solutions in treatment. New evidence based methods need to be developed in order to evaluate the usage of mHealth and to develop guidelines in how to use mHealth.

2.3.4 Personalised health systems

According to the consultation process, the identified gaps can be prioritized as follows (from the most important to the less important):

1. Balancing data protection and privacy rights with technological innovation
2. The general use of privacy by design
3. The lack of flexibility of data protection legislation in order to adapt to rapid changes and new developments

4. The speed of the developments in mHealth technologies
5. The uncertainties with regard to the implications of new rights in data protection for mHealth
6. The application of new rights in the context of mHealth

One interpretation of the prioritisation is that data protection and data management regulations should become adopted, enabling the development and use of mHealth services and applications without jeopardizing the protection of personal and medical data. This calls for more flexible and secure data storages and sharing platforms, as already highlighted in the preliminary roadmaps.

2.3.5 User acceptance

The majority of the respondents confirmed that it is crucial to have several points of access to the right healthcare professionals in order to establish user acceptance (and trust) of mHealth solutions. E.g. the patients should also meet his or her healthcare professional face-to-face and offline on a regularly basis if needed. However, according to the stakeholders, other factors are essential too in gaining user acceptance. In particular:

- *Competition between mHealth solutions and other alternative ways to access treatment could also establish trust.* Competition will eliminate the less efficient and poor quality solutions. Furthermore, those professionals that are fond of technology and aware of its possibilities may be cornerstones to reach the patients. Such role models could also reduce patients' and other healthcare professionals' scepticism towards mHealth.
- *Mobile phone operators, mobile health companies, call centres will also have a crucial role in running the mHealth solutions.* This calls for a new collaboration between specialist healthcare staff and the telecom-industry.

2.4 The consolidated roadmap

The table below synthetically provide a snapshot of the proposed roadmap for the Medical Uptake area in terms of the preliminary research themes associated to the gaps and of the further insights emerging from the consultation process.

Table 4 - Medical Uptake Consolidated Roadmap

GAP	Preliminary Research Themes	Further Insights
Patient empowerment and individualisation	<ul style="list-style-type: none"> • Acknowledge heterogeneity of patients • Educate patients in the use of mHealth • Individualism as key to integration 	<ul style="list-style-type: none"> ○ Overcome differences in ability and motivation. ○ Patients should have the possibility to opt out of prescribed mHealth-based treatment for whatever reason.
Patient-doctor interaction	<ul style="list-style-type: none"> • Redefinition of role of clinical staff • Education of healthcare providers 	<ul style="list-style-type: none"> ○ Healthcare staff needs evidence-based proof in order to trust new mHealth solutions. ○ Maximise the expected improvement of the quality and/or the efficacy of the healthcare professionals' work.
Medical Guidelines	<ul style="list-style-type: none"> • European standards and templates for medical guidelines • Integrated care pathways • Training of clinicians 	<ul style="list-style-type: none"> ○ Reaching consensus in creating new guidelines for mHealth with local engagement and decisions at national level.

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Personalised health systems	<ul style="list-style-type: none"> • Cross-border accessibility of data • Standardisation of data exchange • Define ownership of data 	
User acceptance	<ul style="list-style-type: none"> • Developing several points of access to health services. • Establish uniform regulations to increase trust • Ensure usability and quality 	<ul style="list-style-type: none"> ○ Fostering competition between mHealth solutions and other alternative ways to access treatment. This would eliminate less efficient and low quality solutions. ○ Involving mobile phone operators, mobile health companies, and call centres, which will have a crucial role in running Health solutions.

3 Technologies and Applications Roadmap

The deployment of mHealth solutions does not only offer great opportunities, but also poses significant challenges. This is particularly true with regard to technological requirements and developments. This roadmap therefore illustrates requirements in the area of technologies and applications in terms of connectivity and interferences, interoperability and standards, security and safety and the medical device framework.

3.1 Contextualization

Central to mHealth architectures is the mobile channel of delivery and assorted ways in which health can be delivered through that channel. The key is the use of protocols (e.g. IP, GSM, 3G, mid-short range wireless technologies, etc.) to communicate over a mobile network and thus provide features such as:

- Remote access to healthcare services or more efficient healthcare management (for example appointment reminders, treatment adherence, maternity management, SMS consultations, etc.)
- Non-clinical healthcare information and scheduling (for example appointments, health diaries, etc.)
- Clinical services using medical measurement devices to monitor the patient's health parameters (for example remote heart monitors, remote blood glucose monitors, etc.).

In addition, there is a growing emphasis on technical considerations in relation to the device itself – whether it is the phone itself or the extent to which it can connect to medical devices (or even whether the medical device itself is connected through the mobile network). In fact, mHealth solutions can either be embedded in cases where the mobile connectivity is closely coupled and integrated into medical devices and services, or non-embedded in cases where the mobile device is used as a user interface onto remote services.

The actual context in this area can be summarised in terms of the following Trends (Table 5) and Drivers and Inhibitors (Table 6), which respectively feed and limit the identified trends.

Table 5 - Trends in Technologies and Applications

Trends	
<i>Diffusion of mHealth applications</i>	mHealth applications used to improve or offer new ways to deliver personalised healthcare.
<i>Smartphone Apps</i>	Off the shelf Apps for smartphones aimed at the end-user (patient). Many Apps have a free basic version or cost less than USD (\$) 1 to download. The free version can often be upgraded to a paid version with more and additional sophisticated features. There are more than 5000 health related Apps to choose from and with different features, which allows the consumer to choose exactly what he wants. The Apple App store has made it easy for application developers to gain access to consumers and developers who have also thus gained a greater revenue generated by App downloads. Also, the Apple app store has made it easy for the consumer to browse available Apps. Especially younger consumers have embraced the App trend. Smartphone applications are also aimed for the use of physicians. There is an increase in the growing number of physicians who use smartphones and/or tablets.
<i>WBAN diffusion</i>	Serious technological evolution within sensors and radios are in progress. This evolution will bring us a variety of wireless, wearable mHealth sensors for improving the patients' quality of Life. The growing use of smart phones and other wireless portable devices will facilitate a BAN using wireless or wired wearable sensors. Wide adoption of wireless sensor and actuator devices with lower size and higher physical compatibility to human tissues. In most cases such devices are wearable (in some cases already commercial), but first implantable devices are in testing phase.
<i>PAN for more advanced</i>	Many projects/solutions adopt PAN technologies, such as IEEE 802.15, Bluetooth, Zigbee,

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<i>applications</i>	to interconnect/combine a BAN to (a) other devices in the environment (e.g. for fall prevention/detection) and (b) external servers/devices via a home gateway (e.g. PC/Mobile/TV). Domotic solutions are diffused in this area.
<i>WAN for connecting to remote back-ends</i>	WAN; connectivity in the wide-area network domain is mostly based on using the Internet, hosted accessibly through different access networks: (a) landline based: ADSL, CATV cable, and fibre-optic to home; (b) wireless/mobile (GSM/GPRS, EDGE and UMTS and future technologies as developed, e. g. by 3GPP), wide-area wireless broadband networks like WiMAX.
<i>End user devices</i>	This area is dominated by the increasing diffusion of smartphones and tablet PCs, which combine WAN connectivity, larger screen size and ease of interaction for older adult users and in general higher computational performances that will enable more advanced and interactive solutions/application, e.g. including video conferencing communications.
<i>Adoption of existing security solutions</i>	The level of security around mHealth solutions is largely driven by regulatory requirements and local expectations of personal security and personal privacy. It is unlikely that mHealth requires completely new technology approaches/solutions, but it will be important to remove any unnecessary regulatory barriers and ensure legal certainty.
<i>Easy authentication systems</i>	Advanced authentication systems may develop in the future that are easier to use, e.g. NFC, Lab on Chip, etc.

Table 6 - Drivers and Inhibitors in Technologies and Applications

Drivers
<i>Global dissemination of mobile devices.</i> Proliferation of new devices that can enable mHealth services to be deployed (i.e. smartphones). Continued improvement of the technologies for mobile devices. Continued reductions in the costs of these devices. Smartphones will offer more advanced multimedia functions, such as video, web browsing, and health-related software applications.
<i>Increasing broadband network availability.</i> Broadband communication is becoming more and more available at home, but also on portable equipment.
<i>Increasing Networking capacity and Convergence of networks.</i> The future use of 4G mobile systems will enable video and multimedia communication between homes and the outside world and will focus on seamlessly integrating the existing wireless technologies including GPRS, 3G, wireless LAN, Bluetooth, and other newly developed wireless systems into IP-based core network of heterogeneous access networks.
<i>Convergence of systems.</i> The latter will mainly refer to integrating mobile connectivity into bio-medical devices to enable advanced remote monitoring, rapid diagnosis and on-going management of health, such as the so-called System-On-Chip (or Lab-on-Chip), which will integrate all the functions of a modern computer or electronic system on to a single substrate chip.
<i>Maturity of short and mid-range communication technologies and protocols.</i> Networks protocols for near field communication (even up to 100m) are emerging e.g. ZigBee, Bluetooth, near-field communication, RFID, and even simplified Wi-Fi. RFID capable devices, including Near Field Communication (NFC), Electronic Product Code (EPC), etc.) which will penetrate daily life.
<i>Concepts of context awareness.</i> In the future eHealth systems may have awareness of the presence of a user, location, devices and date/ time, etc. This requires presence-detection capabilities.
Inhibitors
<i>Interoperability.</i> At the moment, interoperability is an important inhibitor. There is a need for better collaboration. There is a current deficiency in interoperability amongst devices and applications, including totally closed systems, limiting the pace of development and reducing competitiveness. Currently the Apple platform and the Android based smartphones offers almost the same capabilities, but they are based on different operation systems. Therefore the applications must be developed separately for the two systems. Most of the investigated R&D projects and commercial solutions include the development of new families of wearable and contactless sensors.
<i>Lack of standards.</i> There is no single standards organisation that covers the complete needs of mobile health. Mobile health architectures in the market today must make use of a wide range of technical components, each with potentially overlapping or missing standards. However, some organisations, such as the Continua Health Alliance and the Integrating the Healthcare Enterprise (IHE), are addressing this issue by providing interoperability guidelines that group standards together into profiles, combining data standards, security standards, messaging standards and transports together into a single certifiable solution (see figure and table below).

Lack of a reference architecture. A reference architecture for mHealth does not exist yet (most of the current solutions have been developed as closed, end-to-end systems)

Finally, from our investigation it emerges that research is diverse in terms of focus and outcomes in technological development. This, as our review demonstrates, ranges from readily available apps to large integrated projects funded at national and EU level. This diversity reflects the observation that mHealth while building on successful eHealth and other technology related drives in healthcare provision and delivery remains an emergent and rapidly developing field. In particular, the following key findings need to be carefully taken into consideration:

- mHealth technologies and applications are diverse and range across a variety of technological fields in their development and implementation. They also address a wide variety of healthcare needs and demands.
- Current smartphone technologies are leading the way in pushing mHealth applications and services and their continued rise in use provides a framework for mHealth delivery.
- Network technologies (WAN, PAN) are fundamental elements of mHealth devices, applications, services and delivery. Continued technological development and evolution in these fields will further drive and support the development and implementation of mHealth. The need to consider which spectrum frequencies will be used remains an open question, for example in the case of MBANs in the US the FCC is due to issue guidelines in April/May 2012.
- There is a considerable lack of standardisation which means interoperability between devices and systems is currently limited. Standardisation is essential for the future success of mHealth.
- There is a lack of regulation from a technical perspective as to how mHealth applications and devices fit into healthcare technology and services. Harmonisation of legal and regulatory frameworks is essential for the future success of mHealth.

3.2 Identified gaps and preliminary research themes:

From the analysis of the status of play outlined above, the following main elements have been mapped to the target scenario described in Section 1.3.1, in order to identify the existing main gaps:

- Connectivity-interference
- Interoperability-standards
- Apps as medical devices
- Security and safety.

As a result, the following table summarises the emerged research themes (i.e. gaps to be fulfilled), for each selected element, which will be detailed in the following sub-sections.

Table 7 Technologies and Applications Preliminary Roadmap

GAP	Preliminary Research Themes
Interoperability - Standards	<ul style="list-style-type: none"> • Implement neutral, trustworthy, transparent standards • Make semantic interoperability an imperative
Security and Safety	<ul style="list-style-type: none"> • Use of cloud computing paradigms to ensure easy and fast access to data and interoperability between healthcare systems • Enforce a greater degree of administrative control of data

Apps as medical devices	<ul style="list-style-type: none"> • Include Apps in the revision of the MDD framework • Implement trustworthy certifications
Connectivity- Interface	<ul style="list-style-type: none"> • Ensure ubiquitous broadband coverage • Convergence of systems into medical devices • Decrease of energy need of medical devices • Robust communication in short-mid range Wi-Fi technologies

3.2.1 Connectivity – interferences

mHealth proposes solutions that set patients and healthcare professionals free from delivering and/or receiving healthcare at a geographically fixed point. Therefore, the future of mHealth is intrinsically related to the development (improvement) and diffusion of wireless networks and technologies.

Future challenges:

- *Ubiquitous European broadband coverage:* Connectivity in the Wide Area Network (WAN) domain is currently mostly based on using the Internet, hosted accessibly through different access networks: Landline based (ADSL, CATV cable, and fiber-optic to home) or Wireless/Mobile networks (GSM/GPRS, EDGE and UMTS and emerging technologies, such as WiMax). Next steps will mainly be:
 - The actual deployment and use of 4G mobile networks. 4G will enable video and multimedia communication between homes and the outside world and it will focus on seamlessly integrating the existing wireless technologies (including GPRS, 3G, wireless LAN, Bluetooth, and other newly developed wireless systems) into IP-based core network of heterogeneous access networks.
 - The take up of satellite solutions in peripheral regions (with no prospect to get terrestrial connectivity in the short/medium term), by leveraging existing European satellite networks (e.g. HYLAS and KA-SAT) and stimulating the satellite industry to develop ultrahigh capacity systems.
 - The progression of new standard releases beyond 4G (e.g. 5G). These new standards would enable full support for ubiquitous computing. In other words, the user will be simultaneously connected to several wireless access technologies and seamlessly move between them.
 - Higher bandwidth by adopting cognitive radio technologies (in this approach different radio technologies share the same spectrum efficiently by adaptively finding unused spectrum and adapting the transmission scheme to the requirements of the technologies currently sharing the spectrum) and accessing to IPv6 protocol.
- *Convergence of systems (intelligence, communication and bio-systems) into medical devices:* This will enable advanced remote monitoring, rapid diagnosis and on-going management of health. As an example, the so-called System-On-Chip (or Lab-on-Chip) will integrate all the functions of a modern computer or electronic system on to a single substrate chip. This will require R&D for the miniaturization of sensors and related hardware, implantable in vivo monitoring chips, new, smart multi-frequency band antennas, integrated on-chip and made of new materials, integration of capabilities such as context-awareness and pre-processing of the measured signals.
- *Robust communication in short-mid range Wi-Fi technologies:* In Personal Area Network (PAN) contexts the connectivity, communication and data exchange from PAN devices between each other and with one or more devices in the LAN network is realized (mature standards are

available such as IEEE 802.15, Bluetooth, Zigbee). The problem that can occur with such an array of devices in existence is that they have the potential to interfere with each other's operation. There is a need for regulation to control, on the one hand, the emission of Electromagnetic Interference (EMI) from such devices and, on the other, the resistance of devices to the EMI of other devices. This means to quickly implement systems within Europe while avoiding harmful interference with other services and systems whilst providing spectrum allocation similar to that provided elsewhere in the world. The ECC has recently been presented a proposal to designate frequencies in the range 2360-2500 MHz as a suitable designation for MBANs to be used in hospitals, at home or by ambulances.

- *Decrease of energy required to operate medical devices:* The world is brimming with cell phones, static and mobile sensors, and in general devices with sensing and computing resources that poses problems in terms of promoting sustainable global levels of energy consumption. Therefore, the issues such as energy harvesting and low-power chipsets are central to the development of mHealth. The target will be the achievement of zero level of entropy where the device is able to harness its own energy or can share its duties with other interconnected devices (opportunistic computing).

3.2.2 Interoperability - standards

Currently, there is a deficiency in interoperability amongst devices and applications, including totally closed systems, limiting the pace of development and reducing competitiveness, whereas, in terms of standards, there is no single standards organisation that covers the complete needs of mHealth¹⁰. It is worth highlighting that standards are not only useful to address interoperability (although it is an important aspect). In fact, standards can be used by manufacturers to demonstrate compliance with the MDD's essential requirements. This makes the task of manufacturers easier as available standards mean the availability of clear roadmaps to follow.

Future challenges

- *Making standards that are open and foster the following features: interoperability, neutrality, trustworthiness, transparency in governance, protects privacy and fundamental rights of users, security, liability and accountability* (chains of responsibility should be clearly established and remedies must be available). Standards for interoperability need to address issues at different levels: radio access level (this is related to the appropriate frequency allocation and harmonization introduced in point 3), protocol level and semantic level.
- *Semantic interoperability* could become an imperative for the mHealth providers and requestors to communicate meaningfully with each other despite the heterogeneous nature of the underlying information structures. This is aligned with the future developments in the 'Internet of Things' context, where devices will be able to autonomously negotiate the communication protocol on the base of a combination of context independent shared information models, coupled with context specific information specializations.

3.2.3 Apps as medical devices

Using health related apps will become a way of life and patients will want apps that respond precisely to their individual needs. Already now, there are more than 5000 health related Apps to choose from

¹⁰ Some organisations, such as the Continua Health Alliance and the Integrating the Healthcare Enterprise (IHE), are currently addressing this issue by providing interoperability guidelines that group standards together into profiles, combining existing data standards, security standards, messaging standards and transports together into a single certifiable solution.

with different features. These allow the consumer to choose exactly what they want. One might well ask the question whether these apps are medical devices and if they do purport to carry out a medical function. Of the thousands of apps now available for download many are of a possible medical or quasi-medical application. This poses the question to what extent these apps should be classified as a medical device and thus subject to the regulatory regime of the Medical Device Directive (MDD). However, the correct application of MDD regulation would in reality mean that the apps in question would have to undergo the full regulatory procedure for each and every phone they were to be used with, and this would likely have a big and very much inhibiting impact.

Future challenges

- The main challenges are related to the need for the *MDD to be reframed in a way that will allow it to correctly regulate mobile phone apps*, a potentially important source of future innovation in mHealth. At present many such apps are partially caught by the definition of a medical device, but they are not compliant with the framework's essential requirements.
- Patient and clinician reservations and concerns towards the use of mHealth services and applications could be overcome by the *implementation of trustworthy certifications that make it simple and easy to verify*, even for the patient, whether an application has been approved for medical use. The CE mark is a highly defined symbol which expresses a declaration of conformity of the device and thus it could be embedded into the software and opportunely reveal to users in its correct form (i.e. its correct dimensions and indicating that it applies to the device in question under the MDD) when downloading an app, together with the instructions for use of medical devices.

3.2.4 Security and safety

The recent directive on data protection¹¹ requires Member States to ensure that individuals seeking healthcare in another Member State are entitled to receive at least a copy of their health records or to have remote access to them from the Member State of Affiliation. This represents an important step in the provision of a truly mobile system of healthcare. Indeed, access rights to one's personal record means that individuals should be able to obtain medical treatment in other Member States that can be precisely tailored to their needs given their specific medical history. This will be important for individuals who use mobile devices or methods of accessing healthcare as it will mean that they should in theory be able to rely upon such devices even if they cross Member State frontiers. It also means that individuals should be able to utilise the services of different medical professionals in different Member states in a co-ordinated manner if they wish.

Future challenges

The main challenges, from a technical perspective, are mainly related to the secure storage and distribution of personal electronic health records. This will include notably the question of where such data is stored. Will this be in a mobile or a central repository? How can data be accessed by different doctors in different countries? In particular:

- *Cloud computing paradigms* may represent an opportunity by enabling easy and fast access, standard base integration and interoperability among different healthcare systems, collaboration among distinct healthcare actors (e.g. companies offering similar services and share data with the consent of patients to improve service), scalability, and increased customer service quality. However, other important aspects need to be carefully taken into consideration and addressed,

¹¹ Directive 2011/24/EU, Article 5(d).

such as maintaining confidentiality and integrity of information stored in all forms and ensuring data backup and recovery processes in case of system breakdown are of paramount importance and allow no half-measures.

- *Enforcing a greater degree of administrative control over all channels of operation is not optional anymore and requires rigorous monitoring.* In fact, it is imperative that information stored in data stores is available through the right channels and to the right parties. Moreover, some legacy applications used by healthcare organizations may require a high degree of customization to access the cloud and thus does not offer immediate benefits. Finally, multi-language issues of stored data should be addressed (e.g. using a second language, such as English, to at least tag contents).

3.3 Results of the consultation process

In the Technology and Applications area, the consultation process allowed us, on one hand, to enforce/validate the identified research themes and, on the other hand, to prioritize the identified issues. In fact, although most of the consultation participants (75%) considered the list of the identified technology challenges complete, some additional aspects/elements emerged from the consultation process, as reported below.

3.3.1 Interoperability-standards

There are not enough standards (even for a generic Electronic Health Record), and software and hardware (smart phones, medical equipment, etc.) usually do not work with each other. To address this:

- *Industrial standards associations, in strong cooperation with EU, National Healthcare Systems and National Governments, should stimulate and/or harmonize standardization efforts.* Starting from intra-nation and cross-nations piloting activities (to identify the real issues of the harmonization process), existing Industrial standards association or joint efforts (e.g. Continua Alliance) should take the lead and they should be continuously confronted with clear targets under the monitoring of EU and national healthcare systems¹². If targets are not reached, regulatory requirements should be implied by EU according to a clearly communicated roadmap.

3.3.2 Security-safety

Although some concerns about privacy and ownership of health data stored in the cloud still remain, cloud solutions are key to wide international deployment of mHealth applications. Indeed, as mHealth is based on mobility, connections between patients and systems can occur anywhere, anytime.

- *What needs to be improved is the patient's perception of control over his/her health record in cloud solutions, as well as the patient trust in e.g. storing/moving his/her patient health record simultaneously in multiply devices.* While patients may perceive that they have greater control of who has access to their health data if he/she keeps his/her health records in one specific device, there is also a high risk of losing all data if the device is stolen or lost. In other words, the decentralised solution has built-in safety, but it is also not secure (enough). Moreover, much of what could be done in mHealth cannot be done with a decentralised solution. Local data storage adds complexity to operations and put interoperation, availability and security measures under local administration. This is directly translated into high costs and vulnerability.

¹² The actual national reference body could be different from country to country, for example in Denmark where the healthcare system is based on public funding (taxation) the national government will have stronger power than in countries where health care system based on private insurance.

3.3.3 Apps as medical devices

According to the outcomes of the consultation process, there are two main legal aspects to be taken into consideration and clarified:

- *Responsability to ensure the conformity of the Apps to the existing directive.* Although it is still open to discussion if both the app developer/designer and the app distributor as responsible for ensuring conformity - since both include the Apps in their business - the MDD (as well as the EN ISO 62304) is about software development processes. Therefore, Apps developers should follow the MDD directives. It is also worth to highlighting that apps which do not interfere with treatment or diagnosis should not need to be MDD complaint, and the MDD process for those apps that have medical uses should be revised to certify the app software and not the device they are installed on.
- *A new authority to perform market surveillance and certification issue.* There must be regulatory bodies involved, more or less similar to the (mainly national) rules or laws regarding the development of medical devices. In particular, a new institution could be created to be responsible for inspection. For example, the creation of a CE-label, as suggested in the roadmap, is a feasible way. This may be enforced/complemented by EU actions (Directive or Regulation), consumer legislation with trading standards monitoring compliance, self-regulation and reporting by industry and International Codes of Conduct.

In addition, as a confirmation of what we have reported in our state of play analysis, the involved stakeholders highlighted that the huge number of health Apps creates confusion among consumers, as well as among domain experts as to what is required to regard apps as medical devices. To overcome this situation the following suggestions could be taken into consideration:

- *Apps as medical devices should affect only those solutions that have a direct effect on treatment or diagnosis.* Apps should demonstrate their potential to positively impact on the patient's treatment and, simultaneously, they should be designed to place the patient in the centre of the process, giving him a full control over the application and guaranteeing his/her privacy.
- *mHealth service providers should revise their business models and focus on a few relevant Apps.*

3.3.4 Connectivity-interference

The consultation process highlighted that, among the four identified gaps, the broadband deployment could not be a priority in the short term. Indeed, with the exception of image-based applications, other interchange of data does not need high connection speed. In addition, the current penetration of smartphones makes possible to have the technology seamlessly available in geographic terms. Nevertheless, there are obvious differences among technology adopters, and some segments of population could be excluded from the use of mHealth due to their problems to access mobile technologies. For example, there are huge differences between the likes of rural UK and even rural Italy - primarily in terms of availability (the best availability and take up seems to be in the North-West of the EU and progressively deteriorates in the South and East). Therefore, the foreseen take up of satellite solutions in peripheral regions may represent an opportunity to fulfil this gap. However, as a useful suggestion, we would consider in our roadmap the following aspect:

- *Medical apps should be able to run without a connection, whenever the application allows it.* This includes the possibility for “mobile medical devices” to cache locally data when connection is not available (or not necessary), and, in a second stage, push data to the remote backend when the connection is available.

In the field of converge of systems (intelligence, communication and bio-systems) into medical devices, the following additional aspects emerged:

- *Extensive piloting actions are still needed to demonstrate their safety, as well as their actual effectiveness and reduction of costs with respect to existing non-invasive solutions.* In fact, at this

stage, implantable devices still pose a greater risk and are significantly costlier to develop, produce and sell than apps or external monitoring devices.

- *The development of innovative technologies should be coupled with proper public awareness and education campaigns to address user acceptability.* Otherwise patients will be reluctant to engage. For example, one barrier is that some patients may feel it will threaten their identity and independence or may fear of being manipulated or controlled by others. To address these issues, simple rules/solutions should be taken into consideration:
 - All treatments are offers.
 - Clear and transparent guidelines are needed.
 - Implantable devices would have to be very user oriented and user-friendly.
 - Improved reliability of the devices. Implantable devices will not be a problem as long as they last for at least a year without needing any attention and will work reliably over that time. Any shorter time will be a problem.
 - Creation of an European registry of mHealth devices implanted in people

In order to assure robust communication in short-mid range Wi-Fi technologies an adequate regulatory framework still represents a priority. However, in the long term, regulatory framework is not a sufficient solution to interference issue. Therefore:

- *Technology advances for robust communication should complement a sound regulatory framework in multiple directions (hardware and software).* For example the following technologies have been highlighted: new class of communication (hardware) modules should be embedded in medical devices; new dedicated connectivity protocols/standards should be developed; software solutions that dynamically allocate spectrum.

3.3.5 GAPS prioritisation

According to the consultation process, the identified gaps can be prioritized as follows (from the most important to the less important):

1. *Interoperability-standards.* Interoperability of both software and hardware is a key requirement for all mHealth solutions. In particular, the biggest barrier seems to be getting suppliers to stop insisting on selling hardware and software bundled together, and instead to be prepared to sell the software only.
2. *Security-safety and Apps as medical devices.* These aspects are key to establish a broad acceptance of all technologies. In particular, the security-safety is core to all medical related services and products and in principle would not need additional prioritization. However, at the moment saving lives is a more important issue than security and safety, and there are a lot of simple mHealth solutions where security and safety are not required features.
3. *Connectivity-interference.* In a second stage (e.g. once the system is acknowledged as being safe and considered as a medical device) lack of connectivity or interferences could be annoying for the user which could prevent the impact of mHealth. However, connectivity interference affects only part of the solution spectrum, and is object of research by the telecom industry for numerous other reasons (such as interference between WiFi, RFID and Bluetooth enable devices in retail).

3.4 The consolidated roadmap

The table below synthetically provide a snapshot of the proposed roadmap for the Medical Uptake area in terms of the preliminary research themes associated to the gaps and of the further insights emerging from the consultation process.

Table 8 – Technologies and Applications Consolidated Roadmap

GAP	Preliminary Research Themes	Further Insights
Interoperability - Standards	<ul style="list-style-type: none"> Implement neutral, trustworthy, transparent standards Make semantic interoperability an imperative 	<ul style="list-style-type: none"> Industrial standards associations, in strong cooperation with EU, National Healthcare Systems and National Governments, should stimulate and/or harmonize standardization efforts.
Security and Safety	<ul style="list-style-type: none"> Use of cloud computing paradigms to ensure easy and fast access to data and interoperability between healthcare systems Enforce a greater degree of administrative control of data 	<ul style="list-style-type: none"> It needs to be improved the patient perception of the control over his/her health record in cloud solutions, as well as the patient satisfaction.
Apps as medical devices	<ul style="list-style-type: none"> Include Apps in the revision of the MDD framework Implement trustworthy certifications 	<ul style="list-style-type: none"> Responsability to ensure the conformity of the Apps to the existing directive. A new authority to perform market surveillance and certification issue is needed. Apps as medical devices should affect only those solutions that have a direct effect on treatment or diagnosis. mHealth service providers should revise their business models and focus on a few relevant Apps.
Connectivity- Interface	<ul style="list-style-type: none"> Ensure ubiquitous broadband coverage Convergence of systems into medical devices Decrease of energy need of medical devices Robust communication in short-mid range Wi-Fi technologies 	<ul style="list-style-type: none"> Medical Apps should be able to run without a connection, whenever the application allows it. Extensive piloting actions are still needed to demonstrate their safety, as well as their actual effectiveness and reduction of costs with respect to existing non-invasive solutions. The development of innovative technologies should be coupled with proper public awareness and education campaigns to address user acceptability. Technology advances for robust communication should complement a sound regulatory framework in multiple directions (hardware and software).

4 Socio-economic Factors Roadmap

The following section outlines a consolidated roadmap of the necessary evolution of the various socio-economic components towards a vision of mHealth in 2025. This includes an analysis of issues of data protection and privacy, liability, ethics, inclusion, the provision and reimbursement of healthcare and the interoperability of healthcare systems. The intention is not only to outline a vision of the future but also to illustrate the requirements of the different actors and the environment itself in order to achieve a high acceptance and use of mHealth solutions.

4.1 Contextualization

In this roadmap two main areas have been taken into consideration: (i) end-users perspectives in mHealth initiatives and (ii) regulatory and legal frameworks.

(i) End-users are central to mHealth initiatives. However the term end-user subsumes a number of differences in the experiences, needs and expectations of different categories of end-users. MovingLife focuses on two categories of end-users:

- End-users who are the recipients of care or are caring for themselves
- End-users who are the providers of care, including medical professionals as well as those supporting recipients of care, such as family or friends.

The end-user perspective considers specific end-user issues in mHealth applications used for chronic disease management. This requires consideration of a particular set of end-user needs, expectations and demands in the deployment of mHealth applications. However, while there are some specific concerns the majority of these can be extrapolated to a general framework for conceptualising the key issues involved for end-users of both types in other mHealth applications.

(ii) Health is a matter of fundamental importance in European societies, both as a fundamental right and as an element in the productive workforce of an economy. New mHealth technologies promise improved quality of life for patients suffering from a range of diseases. At the same time, however, they pose significant challenges for governments, healthcare providers and patients. Considerations of ethical and legal implications that the development and proliferation of new mHealth technologies have for people and/or patients should always be underpinned by the recognition of fundamental rights and legal obligations, either positive or negative. This means that the diffusion and application of mHealth must not impair fundamental rights and should contribute to the values they embody. In the context of mHealth a special focus should be on the right to healthcare itself, the right to access to information, the right to privacy, and the right to data protection.

The actual context in this area can be summarised in terms of the following Trends (Table 9) and Drivers and Inhibitors (Table 10), which respectively feed and limit the identified trends.

Table 9 - Trends in Socio-economic factors

Trends	
<i>Revision of the Medical Devices Framework</i>	The European Medical Device Framework is currently under revision. New developments like the increasing use of mobile phones for medical purposes require an adaptation of the directives.
<i>Allocation of spectrum frequencies for medical use</i>	The allocation of spectrum for medical use is limited. However, the opportunities of allocation spectrum specifically for medical use with mBANs are being debated.
<i>Proposal for a new European Data Protection Framework</i>	The proposed changes are introducing a right to be forgotten and also a right to data portability. These are important issues that will have to be taken into account in the design of mHealth services and in data processing in mHealth.
<i>The network society</i>	mHealth is able to be realised by the tremendous changes which have occurred as a result

D 4.3 Consolidated roadmap for mobile healthcare (mHealth)

	of technological developments in modern societies. ICTs, networks and related devices have radically transformed other areas of human activity and they have the potential to do the same for medicine and healthcare. This affects those using or consuming health services and mHealth can be said to be a part of this in allowing users to combine their mobile world with their healthcare.
<i>mHealth as a concrete example of Social innovation</i>	Social innovation is emerging as a policy goal tackling problems associated with economic difficulties across the EU. Social innovation is innovation which is social in its ends and social in its means.
<i>Remote monitoring is becoming more and more popular</i>	Remote monitoring of health data such as blood pressure, blood glucose level, weight etc.

Table 10 - Drivers and Inhibitors in Socio-economic factors

Drivers	
<i>Individuals want more control over their healthcare:</i>	This is in terms of where they access healthcare and through what medium healthcare is provided to them.
<i>Growing demand for more integrated care pathways and patients who prefer or want remote monitoring:</i>	For example, Danish patients are continually experiencing the healthcare system as being built up in “silos” and this may be relevant for other EU patients as well. Many healthcare systems lack integration between deeply specialist therapeutic areas, making them prone to delivering a staccato healthcare service to the citizens when we look at the treatment of the patient over time. Patient organisations are raising awareness about this inappropriate way of delivering healthcare services not just from a service perspective but also because the deep specialisation has morbid consequences for e.g. the chronically ill with several illnesses. This demand for more integrated care pathways and care models naturally increases the demand for uniform healthcare information in different care spaces.
<i>Realization of the right to health:</i>	The realization of the right to health can extend to modern technologies. mHealth might therefore play a role in it. Striving for a realization of this right might include an increased demand of mHealth technologies and services.
<i>Internet access as a fundamental right:</i>	Recently, there is an increasing interest in the access to internet as a fundamental right. Laws like the HADOPI law in France led to increased public interest.
<i>Cross Border Reimbursement:</i>	Cross border reimbursement makes mHealth an opportunity for those crossing border for work, holidays, etc.
<i>Focus on Corporate Social Responsibility:</i>	A stronger focus on the field of CSR is likely to bring changes with regard to the current conduct of business. This might also influence the area of mHealth. The concrete development is not foreseeable. Many of the developments do rely on international not on European documents.
Inhibitors	
<i>Ageing society:</i>	The ageing society can be an inhibitor due to the fact that mHealth is not easily understandable and accessible for older people. Older individuals may not be able to realise the full potential of some mHealth solutions and services.
<i>Social inequalities:</i>	Education and economic status play an important role. mHealth might shift costs onto individuals. While those able to pay may benefit from mHealth solutions and services, those who are not able to afford to pay, either for services or devices may suffer exclusion from a mHealth enabled future. Those who would be involved in social innovation are already facing a number of pressures in the current economic and financial climate. These include patients, families, support groups and other providers of informal care. These groups may not be able to deliver the goals of social innovation as it pertains to health adequately.
<i>Digital divide:</i>	The digital divide exists in Europe not only with regard to different age groups. For example, there are large differences in the availability of broadband in different countries or regions and in the usage of different age groups.
<i>Accessibility:</i>	Accessibility is often limited regarding connectivity and content. Accessibility is linked to the digital divide and the ageing society.
<i>Data protection:</i>	Data protection as inhibitor has two main aspects. First, companies might not be willing to comply with the strict requirements with regard to medical data and therefore not engage in this area. Second, users lack trust in the current data protection regime. Data protection is linked to notions of trust and privacy.

D 4.3 Consolidated roadmap for mobile healthcare (mHealth)

<p><i>Privacy and Security issues:</i> The privacy and security issues concern the handling of healthcare information. This is sensitive data which cannot and may not be distributed or transferred without encryption or a record being kept of who accesses the data. An argument put forth at the expert workshop was that the systems that are developed today define what data is private and what is not – it should be the other way around. The user should define it and be able to remove stored data themselves. Generally the medical uptake awaits the development in the healthcare consumer market (i.e. healthcare services developed by private providers without legal healthcare authority), where the uptake of smartphones is moving fast and the speed of the software development (especially the application development) is pushing the boundaries of what can be done in the clinical world. At the same time, clinicians (doctors, nurses and other healthcare professionals) are illegitimately or legitimately using their own consumer devices (iPhones or android smartphones etc.) with medical apps installed for clinical purposes (Springer Publishing, 2011). In order to assure, that the security level is appropriate for the entire system, all the parts of the system must obtain the same security level. The Smartphone must include the same security level, and the application must be developed in accordance to this. Privacy is related to data protection and trust.</p>
<p><i>Trust:</i> The uptake of mHealth solutions highly depends on trust. At the moment this trust is often lacking.</p>
<p><i>Liability:</i> Unclear regulations on liability might inhibit the uptake of mHealth.</p>
<p><i>Increasing responsibilities and obligations for enterprises:</i> A stronger emphasis on Corporate Social Responsibility might limit the willingness of enterprises to involve in certain business because of the high obligations they have to fulfil. New requirements in the context of business and human rights increase the likeliness of consequences for misconduct. Enterprises have to meet increased moral and ethical requirements.</p>
<p><i>Requirements of the MDD:</i> The necessity to fulfil the requirements of the MDD might decrease the willingness of companies to get involved in the medical field. This is especially true for potential app based applications using smart phones.</p>
<p><i>Lacking harmonization of radio spectrum:</i> A lack of the harmonization of current radio spectrum policies limits the cross border use of mHealth.</p>
<p><i>Boundaries of MDD:</i> Convergence of networks and systems will further highlight one of the central issues in future medical devices: where does the boundary lie between a medical device and the communications infrastructure it uses, and how is that interface to be regulated?</p>
<p><i>Lack of Reimbursement regulations:</i> Limited reimbursement for mHealth and unclear regulations (particularly in a cross border context) can limit the uptake of mHealth.</p>

Finally, our investigation of the current state of play demonstrates that attitudes, experiences or issues and challenges related to the issues of user acceptance, security and privacy remain unclear and underdeveloped. Similar conclusions were made in relations to medical uptake issues. In contrast, current regulatory and legal frameworks already influence and have an impact on other technological fields, applications or services, and will therefore probably be robust enough to deal with the issues highlighted in the mHealth technologies and applications state of play. In particular, the following key findings need to be carefully taken into consideration:

- User experiences have mainly been limited to small scale pilot projects as large scale deployment of mHealth has not been realised yet.
- mHealth can be an important tool for greater patient empowerment but this must be balanced against the risks associated with safety and security issues.
- Privacy is not only about data protection; end-users may be affected by other types of privacy issues associated with mHealth. These need to be considered as mHealth moves from pilot to large scale deployments.
- mHealth has the potential to revolutionise healthcare practice and delivery in the 21st century. While regulation often lags behind current EU reforms of its data protection regime and medical devices framework, there is increasing awareness that new developments in ICTs (in health care and other sectors) requires new regulatory frameworks to adequately protect EU citizens.

- Consumerism in healthcare supports patient empowerment and mHealth is potentially at the forefront of this trend. This however requires robust legislative and regulatory frameworks to guarantee the protection of individuals as patients and as consumers.
- Liability issues are unclear (i.e. who might be responsible when accidents occur) and this is a considerable regulatory challenge to be addressed for mHealth in the EU.
- Healthcare financing and reimbursement is fragmented and varied across the EU. Regulatory and legal frameworks in the medical context are also often substantially different. Harmonisation may be difficult but a lack of it may represent a significant regulatory and legal hurdle for mHealth providers and developers.

4.2 Identified gaps and preliminary research themes:

From the analysis of the status of play outlined above, the following main elements have been mapped to the target scenario described in Section 1.3.1, in order to identify the existing main gaps:

- Data protection and privacy
- New actors in healthcare
- Inclusion and ethical guidelines
- Liability issues
- Interoperable healthcare systems.

As a result, the following table summarises the emerged research themes (i.e. gaps to be fulfilled), for each selected element, which will be detailed in the following sub-sections.

Table 11 Socio-economic factors Preliminary Roadmap

GAP	Preliminary Research Themes
Data protection and privacy	<ul style="list-style-type: none"> • Development of a clear framework • Guidance on applicability of new developments in data protection to mHealth • Stronger emphasis on privacy by design
New actors in healthcare	<ul style="list-style-type: none"> • Improving guidelines • Harmonisation of regulation concerning new profession
Reimbursement schemes	<ul style="list-style-type: none"> • Recognition of mHealth/eHealth as a reimbursable act • Stronger Cooperation of Member States
Inclusion and ethical guidelines	<ul style="list-style-type: none"> • Use mHealth to guarantee accessibility of healthcare • Establish and promote ethical guidelines
Liability issues	<ul style="list-style-type: none"> • Harmonisation of liability at European level for both healthcare providers and users
Interoperable healthcare systems	<ul style="list-style-type: none"> • Harmonisation of standards at national and European level • Coordination of therapies

4.2.1 Data protection and privacy

Data protection and privacy are considered as crucial factors for the success of mHealth. Related to the trust of users their importance should not be underestimated. At the moment, European data protection legislation is under revision and a new regulation bringing further harmonization on this issue is expected to come into force in 2014.

Future challenges

Main challenges in this area are related to sufficient legal safeguards protecting the data and the privacy of users of mHealth solutions. European frameworks on data protection exist. However, they do not always suffice modern developments and technologies. Therefore:

- *The development of a clear framework is needed.* The new proposed regulation by the European Commission needs to establish a better framework that is flexible enough to adapt to new developments. Whereas traditional principles like data minimization with its limitation of purpose and the request of data quality continue to exist, new rights enter the stage. It appeared that the current data protection legislation at EU level does not offer sufficient protection for the users of modern technology. The introduction of a widely appraised ‘right to be forgotten’ and the ‘right to data portability’ shall increase the rights of users with regard to deleting their data.
- *More specific guidance from EU is crucial.* Since the implication and the applicability of the possible changes in EU data protection legislation are still unclear the exact changes that are to be expected cannot be predicted yet. Innovative approaches in data protection and privacy are required to be able to respond to the fast development of technologies. This goes beyond the possible changes by the proposed directive in 2014 but requires constant attention to new developments. The EU therefore needs to clarify how these new rights will be outlined and applied in the context of mHealth. More specific guidance is crucial, and additional communications or directives could illustrate the application of the proposed changes for mHealth solutions.
- *Privacy by design* should be a main principle for future developers and designers of new technologies and for data controller. To be able to face the changes in the healthcare market, privacy and data protection legislation need to be flexible in order to protect the rights of users without limiting further advances. Finding a balance between those demands will be one of the challenges that will determine the success of mHealth.

4.2.2 New actors in the provision of healthcare

With the increasing importance of mHealth solutions new actors will enter the stage. Healthcare will no longer only be provided by the traditional caregivers like nurses or physicians. The changes make it inevitable that other actors play a constantly growing role. Today, advice via mHealth technologies is no longer only given by traditional caregivers. The further deployment of mHealth solutions will lead to the rise of new professions.

Future challenges

The main challenges include that an increasing number of stakeholders might impact transparency. Issues like ownership of data already impact the deployment of mHealth. With the increase of actors this topic will become more important. Furthermore, new actors require new commitments with regard to decision-making processes.

- Hence, *the increasing complexity of these processes does not only call for improved guidelines* but might also mean that in the future voluntary commitments to, for example, mediation or corporate social responsibility will get a more prominent position.

- There will likely also *need to be a certain level of harmonization of regulation concerning these new professions* at the European level so that mHealth is able to operate across borders according to the demands of European citizens.

4.2.3 Reimbursement schemes

Reimbursement is of crucial importance for the success or failure of new technologies and innovations in healthcare. Decisions taken by national bodies influence the uptake of mHealth. At present, some member state's social security systems do not recognize acts of e-Health or mHealth. The acceptance of mHealth as a reimbursable act in all European healthcare systems is therefore of pivotal importance. The development of mHealth solutions will then be able to utilize the economies of scale that such funds offer. Whilst the role of the EU to force the implementations upon states is limited, ample scope exists for research, recommendations and guidelines to be produced at the European level.

Future challenges

Even though the role of the EU has produced important legislation in the last years on cross border reimbursement several challenges remain. The organization of healthcare is the sovereignty of the Member States. The EU has only limited influence. This leads to different reimbursement schemes in the Member States. These differences are one of the main inhibitors for cross-border healthcare and accordingly also a constraint to the deployment of mHealth which is likely to offer enormous cross-border potential. Despite the EU gaining competence in this area it is not believed that this division will be overcome in the near future.

- *The acceptance of mHealth as a reimbursable act in all European healthcare systems is of pivotal importance.* Being a possible driver for mHealth solutions this area cannot be neglected.
- *Stronger cooperation of Member States in the reimbursement of cross border mHealth services,* facilitated by the EU will be needed to lead the way to an increased deployment of mHealth solutions in 2025.

4.2.4 Inclusion and the application of ethical guidelines

mHealth is considered as an approach that has enormous inclusive potential. It has the ability to reach large parts of the population (not only in the EU but also in developing countries). It can promote increased access to medical care. In general access to information and to the Internet is integrated in order to guarantee inclusion in the information society. A non-discriminatory approach however is needed to ensure an inclusive future for mHealth services. Access to important services should not depend on socio-economic status. Marginalized and vulnerable groups deserve special attention. Patients are not a homogenous group which can be served with a 'one-fits-all-approach'.

Future challenges

- *The realization of inclusive, patient-centred approaches will create a general base for the acceleration of mHealth.* The current problem of a digital divide preventing parts of the population from having adequate access to new mobile technologies has to be overcome in the next decade. There will only be a general acceptance of the new developments in medicine if the accessibility of mHealth is guaranteed for the whole society.
- *Ethical guidelines concerning mHealth will help to increase the acceptance by safeguarding these issues but also by promoting patients' fundamental rights.* These not only include the right to privacy, data protection and access, but also a right to realize the best possible level of healthcare. The right to healthcare as established by the EU can be promoted by ethical guidelines and

realized by the widespread use of mHealth solutions. Guidelines can be promoted at a European level to aid dispersion throughout the EU.

4.2.5 Liability issues

The creation of trust strongly depends on the knowledge that liability of producers and caregivers exists as well as on an understanding of the system of liability. The current complex and not harmonized system of liability poses significant challenges on the mHealth market, particularly with regard to cross-border care.

The jurisdiction where the treatment occurred determines the setting and often the outcome of legal proceedings. The resulting uncertainties for the providers of mHealth solutions are obvious. Deploying technologies in a cross-border context is extremely difficult because such a deployment may be subject to different national jurisdictions. Legal scenarios in cross-border disputes can be very complex, possibly involving laws of different jurisdictions. mHealth complicates this by involving data which might be processed in another country than the one where the treatment takes place.

Future challenges

- Being a main jurisdictional hurdle, *liability needs to be, where possible, harmonized at the European level during the next years, in order to guarantee legal certainty for both providers and users of mHealth*. Here, the role of the European institutions harmonizing the current legislation (where possible) to create legal certainty and increase user trust is crucial to aiding the development of a pan European mHealth industry. Whilst once again the room for manoeuvre of the EU is limited by a need to respect national sovereignty, the EU does have the ability to act where needed to protect the European Single market. Action should ensure that both individuals and professionals are well aware of the liabilities they are exposed to when accessing or providing services in a member state.

4.2.6 Interoperable healthcare systems

Interoperability will be a key issue in the expected future increase of mHealth. This not only concerns technical standards, which have to be harmonized, but can also relate to the socio-economic sphere. Healthcare systems at the moment are often not interoperable. This applies to both the national and the European context. Even within countries healthcare standards are often not totally harmonized.

Future challenges

- *Coordination of therapies*. Different clinical guidelines prevent interoperability. In the cross-border context these problems increase. Furthermore, patients often experience a lack of integration within the healthcare system. Specialist therapies are not sufficiently coordinated and a continuity of care is consequently not guaranteed in the best way. The integration of different areas of medicine in order to ensure a better coordination of therapies can be facilitated by approaches using mHealth solutions.
- *Harmonisation of standards at national and European level*. During the next decade efforts will need to be made on the harmonization of standards in order to create interoperable healthcare systems. This must be in concert with efforts to address technical problems. An approach integrating other aspects of interoperability has to be foreseen.

4.3 Results of the consultation process

In accordance with the preliminary roadmap, the questions during the consultation process concentrated on the areas of data protection and privacy, new actors in healthcare, reimbursement schemes, inclusion and ethical guidelines, liability issues and interoperable healthcare systems. These issues have not been prioritized since they cover very different socio-economic aspects of mHealth and thus prioritising them would not respond to the differing value they have to different stakeholders in mHealth.

The most important conclusions that can be drawn after the consultation process are that the gaps, which had been identified in the preliminary roadmaps, have been confirmed. In particular, respondents highlighted the need for a higher amount of flexibility of data protection and privacy legislation in order to respond to changes in technology. There is also a strong agreement on the need of more harmonisation with regard to EU reimbursement schemes and liability in healthcare. Finally, it also emerges the great potential of mHealth as a new mean to create inclusion.

Following, the outcomes of the consultations will be summarised in the different thematic sections in order to provide further insights for the consolidated roadmap.

4.3.1 Data protection and privacy

During the consultation process it has been very obvious that there is neither a clear opinion on the sufficiency of the current data protection laws in the EU nor on the added value of the changes which the proposed regulation on data protection is going to bring. Legislation in this area must be able to respond in a timely manner to recent developments. Accordingly:

- *The lack of flexibility in current legislation is seen as one of the most important barriers in the area of privacy and data protection for the deployment of mHealth.* In fact, the lack of flexibility makes it impossible to sufficiently balance new developments in technology with data protection and privacy rights. In order to not limit further innovations, the EU should respond to this concern with a flexible framework.

Another challenge is the use of privacy by design, as already identified in the preliminary roadmap. This can be a chance to respond to the request of a high amount of privacy but is also seen as a challenge when demanded as a general measure.

4.3.2 New actors in healthcare

With the increasing importance of mHealth solutions in healthcare new actors are expected to enter the stage. Ideas and concerns with regard to the rise to new professions are very diverse and range from the expectation of tremendous changes to little or no changes, which imply that no new professions are actually emerging at present. However, the following issues have been highlighted with regard to changes of professions:

- *Increasing importance of computer scientists.* Nurses, physicians and other traditional caregivers might be (partly) replaced by new professions, particularly in the area of computer sciences. Some of these changes already started and the experts consulted agree on the growing importance of computer specialists in the provision of care.
- *Changing role of physicians and nurses.* Next to the rise of new professions in the intersection of healthcare and computer sciences, it is necessary to focus on the changing roles of physicians and nurses. Whereas, physicians are expected to give guidance enabling patients to find the right treatment amongst an increasing offer of new electronic means of healthcare, nurses become highly trained specialists, being able to make prescriptions and taking over some of the physicians' responsibilities.

Additionally, certain other issues should be taken into consideration:

- *The focus on profit might increase.* It can be highlighted that the changes due to a stronger employment of mHealth solutions are not only expected to impact the roles of health professionals directly but are also likely to increase the focus on profit (eventually, due to new less regulated professions and private companies).
- *Boundaries in healthcare are expected to become blurry due to a different perception of health and lifestyle.* The boundaries are unclear already and have been a long-disputed issue in the context of the MovingLife project. The growing influence of technologies that are (not yet) explicitly regulated, e.g. medical apps for smartphones will certainly demand a focus on this distinction.

4.3.3 Reimbursement schemes

Cross-border reimbursement schemes are one mean to realize the freedom of movement and services for EU citizens. Therefore, harmonisation on EU level is demanded even though it is often seen as too big a challenge. However:

- *It is equally important to reorganise healthcare at national level.* The need of more harmonisation is generally acknowledged. However, this is not always necessarily linked to EU level. It is of importance to have a well-functioning reimbursement system on national level before going to European level. Thus, there is a demand for reorganising the reimbursement schemes on national level first, and European cross-border healthcare is regarded as a bonus rather than a necessity. Furthermore, there is a demand for a focus on equity.

Furthermore, the question how physicians should be reimbursed is a disputed topic. In selecting the reimbursement schema, all agree that:

- *Focus on equity is necessary.* In fact, one possible way is a pay-for-performance system. But, when talking about pay for performance there has not been any clear proof for its effectiveness yet. In the MovingLife project this has been discussed as one of many different options. This is also reflected in the responses during the consultation process. Whilst some are voting in favour of using a pay-for-performance-system, others demand a better proof of its effectiveness. Additionally, the system is regarded as being against equity and equality.

4.3.4 Inclusion and ethical guidelines

The fact that mHealth can be a possibility to facilitate inclusion has been also acknowledged during the consultation process. By making the system more accessible, parts of the population which are normally difficult to reach can gain better access to healthcare. However:

- *Accessibility has to be guaranteed in financial terms as well as in educating care providers and patients in the use of new technologies.* The expected advantages can, in fact, be threatened by limited access to information technologies like the Internet. Particularly marginalized groups of patients often lack the competences to access new mHealth solutions.

4.3.5 Liability issues

In this topic, the consultation process confirmed that a better harmonisation on EU level is demanded. This will lead to a higher legal certainty and can facilitate business. No specific further insights are emerged.

4.3.6 Interoperable healthcare systems

During the consultation process the importance of mHealth in the process of building a more interoperable healthcare system has been questioned. In particular:

- *A discussion about the definition of interoperability and interoperable healthcare systems is still needed.* Is the interoperability of technology the golden standard or should there be a focus on a people-centred healthcare system which serves the patients instead of merely enabling an effective use of technologies? Technologies might even be inherent to a real patient-centred healthcare system.

In any case, it is evident that Technical standards as well as socio-economic standards need to be interoperable. mHealth puts interoperability on the agenda and emphasises its crucial importance for future healthcare systems. In this view, the consultation process allowed us to also highlight the main advantages of mHealth in creating interoperable healthcare systems. In particular:

- *Improving healthcare systems and reducing healthcare costs.* Interoperability is necessary to provide a good quality of care with low personal resources. This can be an advantage when personal resources will be limited in future. Additionally, increased interoperability can serve patients by freeing them from the need to repeatedly provide information to different providers. The same applies to researchers who can easier access a collection of data from different patients. On one hand, this can enable them to predict future developments in the healthcare systems and future health events of single patients. On the other hand, it entails certain risks with regard to data protection and privacy.
- *Increasing patient empowerment.* As a positive outcome more interoperability can lead to increased patient participation and strengthen the responsibility of patients. Patient empowerment is therefore one of the issues which highlights the importance of interoperability in healthcare.

4.4 The consolidated roadmap

The table below synthetically provide a snapshot of the proposed roadmap for the Medical Uptake area in terms of the preliminary research themes associated to the gaps and of the further insights emerging from the consultation process.

Table 12 – Socio-economic factors Consolidated Roadmap

GAP	Preliminary Research Themes	Further Insights
Data protection and privacy	<ul style="list-style-type: none"> • Development of a clear framework • Guidance on applicability of new developments in data protection to mHealth • Stronger emphasis on privacy by design 	<ul style="list-style-type: none"> ○ Higher amount of flexibility of data protection and privacy legislation is needed in order to respond to changes in technology
New actors in healthcare	<ul style="list-style-type: none"> • Improving guidelines • Harmonisation of regulation concerning new profession 	<ul style="list-style-type: none"> ○ Increasing importance of computer scientists. ○ Changing role of physicians and nurses. ○ The focus on profit might increase. ○ Boundaries in healthcare are expected to become blurry due to a different perception of health and lifestyle.
Reimbursement schemes	<ul style="list-style-type: none"> • Recognition of mHealth/eHealth as a reimbursable act • Stronger Cooperation of Member States 	<ul style="list-style-type: none"> ○ It is equally important to reorganise healthcare at national level. ○ Focus on equity is necessary, when selecting the reimbursement schema.
Inclusion and ethical guidelines	<ul style="list-style-type: none"> • Use mHealth to guarantee accessibility of healthcare • Establish and promote ethical guidelines 	<ul style="list-style-type: none"> ○ Accessibility has to be guaranteed in financial terms as well as in educating care providers and patients in the use of new technologies
Liability issues	<ul style="list-style-type: none"> • Harmonisation of liability at European level for both healthcare providers and users 	
Interoperable healthcare systems	<ul style="list-style-type: none"> • Harmonisation of standards at national and European level • Coordination of therapies 	<ul style="list-style-type: none"> ○ A discussion about the definition of interoperability and interoperable healthcare systems is still needed. ○ Main advantages of mHealth in creating interoperable healthcare systems are: (i) Improving healthcare systems and reducing healthcare costs and (ii) Increasing patient empowerment.

5 Conclusions

According to the collected results from the consultation survey, it can be safely stated that the elements already captured at the end of the gap analysis and the identified research themes have been confirmed and further refined. In particular, the qualitative approach in the survey lead to additional remarks which sometimes added new insights and also controversial statements triggering a further discussion and the necessity to assess the topics from another point of view.

The results collected so far have also shown that the future of mHealth depends on a large number of dimensions and variable, of which technology is one and probably not the most determining one. Therefore, there should be a strong effort in creating cross-synergies between the health sector, technology research, policy making and the business sector when developing mHealth solutions. For example, regulatory rules established with the participation of the business sector can unleash investment and more and better products. Similarly, if we do not consider EU-level harmonized reimbursement systems and involve national healthcare bodies in mHealth solutions, effective mHealth solutions will not be in place by 2020.

Starting from the consolidated roadmaps reported in Sections 2.4, 3.4 and 4.4, future work will focus on developing and publishing an action plan for how the roadmaps could actually be incorporated into medical guidelines, technology and policy design. This work will lead to the final roadmaps that will be presented and discussed at the MovingLife Stakeholder Conference (D4.4), which will be held on the 20th of February 2013 in Brussels.

ANNEX 1 – Questions for the consultation process

Medical Uptake area

Q1. In your opinion, how can the empowerment of patients across communities be ensured and that differences in language, culture, religious belief, age, level of education or technological know how are not barriers for using mHealth technologies? (you may select more than one option)

Subsidies (EU or national)
Do nothing (i.e. let market economics decide)
Public awareness campaigns
Training for patients
Training for healthcare professionals
Other (please specify in the box below)

Q2. In your opinion, should it be possible for patients to opt out of a prescribed mHealth treatment because of non-willingness to use mHealth solutions/apps?

No opinion
Disagree
Agree

Please provide comments on your answer

Q3. In your opinion, how can it be ensured that healthcare professionals have the right skills and understand their role when using mHealth technologies to treat patients across borders? (you may select more than one answer)

Strong legal framework (EU or national)
Public awareness campaigns
Training for patients
Training for healthcare professionals (post education)
Changes in curriculum at universities and other teaching institutions
Other (please specify in the box below)

Please provide comments on your answer

Q4. In your opinion, how can consensus and agreement be reached on medical guidelines that meet the existing standards and match the cultural contexts of countries across the EU? (you may select more than one option)

Engagement and decisions at national level
Through European level actions
Local actions, by doctors, health-care professionals and hospitals/clinics
No need for new medical guidelines for mHealth (existing guidelines sufficient)
Allow the market and consumers to find acceptable standards and guidelines
Other (please specify in the box below)

Please provide comments on your answer

Q5. In your experience, are several points of access to the right healthcare professionals crucial in establishing user acceptance (and trust) of mHealth solutions?

No opinion
Disagree
Agree

Please provide comments on your answer

Q6. How to agree upon the best case-examples of mHealth in order to communicate the benefits of mHealth?

Healthcare Technology Assessment (HTA)
Clinical trials
Other evidence based methods
Measurements of patient satisfaction
Measurements of patient empowerment
Adoption within health-care practice

Please provide comments on your answer

Technology and Applications area

Q7. In your opinion, are there any missing technological challenges in the roadmap which should be examined?

Yes
No
If yes please specify

Q8. Which of the reported research challenges are most important to maximise the impact of mHealth (i.e. prioritize the research challenges)?

Connectivity-interference
Interoperability-standards
Apps as medical devices
Security and safety

Please provide comments on your answer

Q9. In which of the reported research topics do you see the need for cross sector synergies to quickly achieve target objectives specified in the roadmap? (you can select more than one option)

Technology research
Policy making
Business sector
Other (please specify in the box below)

Please elaborate on your answer, you may also provide comments.

Q10. In your opinion, how should the reported research developments be measured? (please rank each option)

Benefits to EU health-care systems
Benefits to patients
Creating EU technological and industrial leadership
Creating sustainable economic growth and new employment

Q11. Are there other measurements not listed above which should be covered?

Q12. Do you see any differences between Member States (e.g. North vs South countries) in the broadband coverage take up (e.g. some technologies are ready or more suitable for specific countries)?

No sure/Don't know
No Differences
Minor Differences
Major Differences

Please provide comments on your answer.

Q13. In your opinion, are there any strong user acceptability/usability issues related to future implantable integrated devices?

Yes
No
Not sure

If yes please specify and provide comments on answer

Q14. In your opinion can regulatory frameworks solely be a sufficient solution to interference issues ? (if no you may select more than one option)

Yes
no, software solutions should be also adopted e.g. dynamically allocate spectrum
no, new frequency bands and wider spectral bandwidth per frequency channel are necessary
no, new dedicated connectivity protocols/standards should be developed
no, new class of communication (hardware) modules should be embedded in medical devices

Please provide comments on your answer

Q15. Are there any relevant energy-saving technologies, not identified in the roadmap, which in your opinion are suitable for mHealth devices?

Q16. Besides technology advancements to e.g. allowing for semantic interoperability, who in your opinion should take the lead for stimulating and/or harmonizing standardization efforts?

EU
Industrial standards associations
National healthcare systems
National governments
Trade bodies
Other (please specify in the box below)

Please elaborate on your answer, you may also provide comments.

Q17. In your opinion who has responsibility for ensuring the app complies with the Medical Device Directive?

App developer/designer
App store
Other (please specify in the box below)

Please elaborate on your answer, you may also provide comments.

Q18. In your opinion how can authorities perform market surveillance and, if needed, take preventive measures? (you can select more than one option)

Self-regulation and reporting by industry
EU actions (Directive or Regulation)
Consumer legislation, with trading standards monitoring compliance
International codes of conduct
Other (please specify in the box below)

Please elaborate on your answer, you may also provide comments.

Q19. Do you think the proposed centralised approach (cloud computing) for storing patient health record is more suitable/secure than decentralised solutions where the patient keeps her health records (e.g in its mobile or in other personal digital stores)?

Very unsuitable/insecure
Somewhat unsuitable/insecure
No difference
Somewhat suitable/secure
Very suitable/secure

Please provide comments on your answer

Socio-economic Factors area

Q20. In your opinion can the current data protection legislation and the proposed changes (new regulation) be regarded as sufficient safeguards for future developments in mHealth?

Q21. Which current (or future) issues in privacy and data protection do you consider to be the biggest challenges in the context of the deployment of mHealth?

The speed of the developments in mHealth technologies
The application of new rights in the context of mHealth
The uncertainties with regard to the implications of new rights in data protection for mHealth
The lack of flexibility of data protection legislation in order to adapt to rapid changes and new developments
The general use of privacy by design
Balancing data protection and privacy rights with technological innovation
Other (please specify in the box below)

Please elaborate on your answer, you may also provide comments.

Q22. The changes mHealth is expected to bring to the field of healthcare in the next decade might also include a number of new actors in healthcare. What do you expect from the rise of for example new professions? Are there particular challenges, chances and dangers which need to be regarded?

Q23. At the moment the power of the EU in terms of healthcare is relatively limited. Cross-border reimbursement is an important issue. Would you favour an increased power of the EU in healthcare in order to further harmonize reimbursement schemes?

Strongly disagree
Somewhat disagree
Neither agree or disagree
Somewhat agree
Strongly agree

Please provide comments on your answer

Q24. How important would you consider a pay for performance system as described in the scenario?

Very important
Somewhat important
Neither important or unimportant
Somewhat important
Very important

Please provide comments on your answer

Q25. Do you agree on the potential of mHealth for inclusion as described in the roadmap?

Strongly disagree
Somewhat disagree
Neither agree or disagree
Somewhat agree
Strongly agree

Please provide comments on your answer

Q26. In your opinion is a harmonization of legislation dealing with liability in health-care settings necessary in order to facilitate a widespread use of mHealth solutions?

Very unnecessary
Somewhat unnecessary
Neither necessary or unnecessary
Some necessary
Very necessary

Please provide comments on your answer

D 4.3 Consolidated roadmap for mobile healthcare (mHealth)

Q27. Where do you see the main advantages of mHealth in facilitating the creation of interoperable healthcare systems? (you can select more than one answer)

Reducing health-care costs
Increasing patient clinical outcomes (more effective treatment)
Increasing the effectiveness of health care professionals
Increasing patient empowerment
Improving health-care systems
Other (please specify in the box below)

Please elaborate on your answer, you may also provide comments.

Q28. How would you judge the role of mHealth in the creation of interoperable healthcare systems?

Very important
Somewhat important
Neither important or unimportant
Somewhat important
Very important

Please provide comments on your answer