Appendix

Developing the roadmap for human-machine networks in eHealth

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This document is an appendix to the whitepaper on roadmap for human-machine networks in eHealth, presenting the background on which the roadmap was developed.

The roadmap has been developed in line with the HUMANE roadmapping process. Specifically, the development process covers:

- **Current technological situation, emerging and future trends:** which sets out the technical context in which the HMN operates;
- **Policy background and regulatory context:** describes the legal background of those HMNs;
- **Key challenges and goals:** the issues which face HMN stakeholders;
- **Suggested strategies and actions:** how to resolve those issues;
- **Overview of the roadmap:** what the resulting roadmap looks like;
- **Timeframe and prioritisation:** when and how the roadmap 'destination' may be reached; and
- **Roadmap dissemination:** how the roadmap is shared with the wider community.

HMNs in eHealth include networks for the management and dissemination of Electronic Health Records (EHRs), telemedicine networks and applications (including telesurgery) and networks for physiological monitoring of patients with smart mobile or wearable devices (Smart Wearable Health Systems and Applications - SWHS). ***The HUMANE roadmap focuses on the latter, which we call more generally as "personalized eHealth systems, devices and applications" or simply "eHealth HMNs"***, as the most typical example of HMNs in the eHealth domain and one of the most innovative and rapidly evolving technologies worldwide. The advancements in micro/nano, bio-technology and telecommunications have significantly extended the capabilities of eHealth HMNs, beyond the simple monitoring of vital signs. Today, there are devices and applications for the management of biochemical indices, heart problems, back pains, and many other medical conditions. Such devices are intended for a large public, but are adapted to the specific needs of individual patients, and store or communicate personal information, so that they become "personalized".

The need to address the high economic burden of the healthcare sector and to provide for an ageing population, and the high interest of both consumers and professionals make eHealth HMNs a promising and challenging sector. However, policies to efficiently integrate such technology in medical care and everyday life seem inadequate to match the pace at which such devices enter the market. As the analysis in D4.1 revealed, there are significant challenges regarding privacy and security, efficient information processing, and quality of service. The roadmap for eHealth HMNs aims to map the problems and propose efficient design strategies, as well as steps for their solution.

1 eHealth HMNs: Current technological situation, emerging and future trends

The use of HMNs in eHealth coincides with the trends observed in developed countries towards early detection of diseases, health status monitoring, healthy lifestyle, and improvement of the overall quality of life. This is also related to the higher life expectancy, population ageing, and the need for older people to be valuable economic and social resources.

According to evidence from the World Health Organization (WHO), life expectancy has increased globally in the last years, although great inequalities persist within and among countries. According to this year's "World Health Statistics: Monitoring Health for the SDGs" report, life expectancy increased by 5 years between 2000 and 2015, the fastest increase since the 1960s (World Health Organization, 2016). In a press release by the WHO in 2015 for the International Day of Older Persons[1], it was noted that the number of people over the age of 60 is expected to double by 2050, which will require radical change in order to ensure that these extra years are healthy, meaningful and dignified. However, as was noted in the WHO's "World report on ageing and health 2015"[2], there is very little evidence that the added years of life are being experienced in better health than was the case for previous generations at the same age. In other words, although more people live longer lives, their quality of life is generally not better than the one of people in previous decades that reached the same age. To

[1] http://www.who.int/mediacentre/news/releases/2015/older-persons-day/en/
[2] WHO, "World report on ageing and health 2015", 2015. http://apps.who.int/iris/bitstream/10665/186463/1/9789240694811_eng.pdf?ua=1

achieve a good life quality, a radical society change will be needed, in the way society deals with health and ageing as a whole. Cited research suggests that the benefits to society would far outweigh any investments that might be needed to provide the health services, long-term care and social security that older populations require.

Technological advances can greatly help in this direction, by facilitating treatments and monitoring the physiological condition of a person not only in older age, but throughout a person's lifetime, so that more people are able to reach higher ages in good health.

eHealth HMNs can be seen as a subfield of telemedicine, which generally refers to the application of electronic communication for the provision of medical information. However, the field of eHealth HMNs has grown so much that it can be seen as a separate sub-category of HMNs. They include stand-alone devices for the measurement of vital signs like ECG (Electrocardiography), blood pressure, heart rate, respiratory rate and oxygen saturation, skin temperature, and posture (e.g. monitoring the body positions and movements for determining relationships to sleep apnea). New developments include sweat sensors, i.e. strips that analyze the metabolic substances in sweat and help consumers track their internal biochemistry (information on electrolyte balance, hydration level and muscle exertion), devices for asthma management, management of lower back problems and quell relief, glucose sensors for the management of diabetes, and detection of cardiac problems like atrial fibrillation.[3,4] This also includes smartphones (where the relevant domain is often referred to as 'mHealth'), as they can also be turned into medical devices (e.g. with apps that allow the user to rest their finger on the case, which will then measure heart rate or alert the user if atrial fibrillation is detected). Furthermore, current research is moving towards monitoring of multiple vital signals, as well as towards their use in a networked online environment, where sensor results can be collected and transmitted to medical establishments in real time. There is an increasing number of eHealth software applications, both on mobile and desktop computers, that help people monitor and improve their health condition, with or without the use of specific devices (e.g. dietary advisors, fitness applications, applications for diagnosis of health status and diseases). Such solutions enable patients to live a more normal life, whilst facilitating efficient management of diseases and early diagnosis of symptoms from a distance. They also reduce the need for medical visits and save related expenses and time for both doctors and patients.

Personalized eHealth systems, devices and applications are also closely related to other HMNs in eHealth; obvious with other telemedicine applications (e.g. a doctor can interact remotely with a patient and read the measurements of an eHealth device), but also with EHRs. For example, telemedicine applications can benefit from having access to information in EHRs, while measurement results from remote monitoring devices can be aggregated and produce statistics which enrich a patient's EHR.

Personalized eHealth monitoring systems, devices and applications are also a cornerstone of the EU eHealth policy and research.[5] But, while such devices and applications are being used extensively by

[3] https://www.wearable-technologies.com/2015/04/wearables-in-healthcare/
[4] http://www.beckershospitalreview.com/healthcare-information-technology/5-digital-health-trends-for-the-new-year.html
[5] http://ec.europa.eu/information_society/doc/factsheets/009-ehealth-en.pdf

individuals, there is very small integration of such devices in every day clinical practice (Wicks, Stamford, Grootenhuis, Haverman, & Ahmed, 2014). This is complicated by the lack of legal clarity and certification of eHealth applications that are available for user devices. Relevant challenges were discussed in D4.1, and will be elaborated on here in order to help build the roadmap for the successful integration of such systems.

2 Policy background and regulatory context

The European Commission (EC) adopts its Digital Single Market strategy for Europe, which aims to make the EU's single market freedoms "go digital" and boost growth and jobs in the EU. The strategy is designed to prompt eHealth interoperability and standards in the EU, for the benefit of patients, health professionals, and health systems and industry.

The EC has adopted an action plan on eHealth for the period 2012-2020 (European Commission, 2012). According to this plan, one of the barriers to the development of eHealth is the lack of clarity on legal and other issues around mobile health ("mHealth") and "health & wellbeing applications" and about the role that network operators, equipment suppliers, software developers and healthcare professionals could play in the value chain for mHealth. In addition, following the adoption of the Directive on the application of patients' rights in cross-border healthcare, the EC established the eHealth network[6], a network of national responsible authorities on eHealth, in order to ensure the alignment of eHealth with health strategies and needs at the Union and national levels through the direct involvement of national health authorities.

In April 2014, the European Commission published a Green Paper on mHealth[7], which explored the potential of mHealth, and issues such as privacy, patient safety, legal frameworks and cost-effectiveness. Immediately after, a public consultation was launched, open until 10 July 2014, in which it invited stakeholders to provide their views on 11 identified barriers to the uptake of mHealth in the EU. It was targeted at several stakeholders, which are also considered by HUMANE: regional and national authorities, health professionals and practitioners, consumers, application developers, mobile manufacturers, but also insurance agencies and associations such as sports centres and health clubs. Based on the responses, it was concluded that privacy and security, patient safety, a clear legal framework and better evidence on cost-effectiveness are all required to help mobile Health care flourish in Europe.

Together with the Green Paper, the Commission also published a Staff Working Document on the existing EU legal framework applicable to lifestyle and wellbeing apps, providing legal guidance on EU legislation in the field to app developers, medical device manufacturers, digital distribution platforms, etc.[8] Following these works, the EC planned to establish an industry-led Code of Conduct for mobile

[6] http://ec.europa.eu/health/ehealth/policy/network/index_en.htm
[7] European Commission, "GREEN PAPER on mobile Health ("mHealth")". Brussels, 10.4.2014. Available online at: http://ec.europa.eu/newsroom/dae/document.cfm?doc_id=5147
[8] European Commission, "COMMISSION STAFF WORKING DOCUMENT on the existing EU legal framework applicable to lifestyle and well-being apps". Brussel, 10.4.2014. Available online at: http://ec.europa.eu/newsroom/dae/document.cfm?doc_id=5146

health apps, which was recently released[12]. The objective of this code is to foster citizens' trust in mHealth apps, raise awareness and facilitate compliance with EU data protection rules for app developers. [9] Furthermore, in February 2016 the EC appointed a working group with the mission to draft mHealth assessment guidelines. The group includes representatives of patients, health professionals and providers, industry, academia and public authorities. The group will seek to provide common quality criteria and assessment methodologies that could help different stakeholders, in particular end-users, in assessing the validity and reliability of mobile health applications. The guidelines are expected to build on existing initiatives and best practices in Europe.

Finally, under the Horizon2020 programme, the EU plans to invest more than €2 Billion on projects related to Health, Demographic Change and Wellbeing. Amongst the goals of the programme are to improve our ability to monitor health and to prevent, detect, treat and manage disease, as well as test and demonstrate new models and tools for health and care delivery. The 2014-2015 period included calls for ICT solutions for assisted living environments, self-management of health and disease and patient-empowerment through ICT, decision support systems for self-management, innovation in organizational and business models for service delivery, as well as standardization and interoperability of ICT platforms, methods and services for eHealth. For the 2015-2016 period, the above topics were also included; in addition there were specific calls for scaling up of ICT solutions for active and healthy ageing, as well as on Big Data methods supporting public health policies. Related calls should also address topics about ownership of data, data protection/privacy, liability and consumer protection.

3 Key challenges and goals

Here we provide an overview of the challenges and goals, focusing on personalized eHealth systems, devices and applications. The main implications brought by eHealth HMNs are the increased control and intervention by users and patients for the detection, treatment and management of diseases, the higher machine agency, which creates a need for security, for the protection of privacy and confidentiality of medical information, and the establishment of trust, and the increased size and geographical expansion of eHealth systems, which calls for the efficient management of large volumes of data, high availability and QoS guarantees in service provisioning, standardization and interoperability, as well as the provision of economically sustainable eHealth services and of coherent rules throughout the EU.

More specifically, technical challenges and goals are to:

- **Ensure the efficient management of very large volumes of data** from monitoring devices. Besides efficient storage, categorization and search of eHealth data, the focus should be on real-time event detection for early avoidance of severe health episodes and provision of hospital-level care remotely. Efficient data management also includes mechanisms for **protecting personal data**. In D4.1 we noted that wearable devices that can transmit data continuously can exacerbate the uncertainty regarding the access to and sharing of medical data that occurs without knowledge of the patient. We highlighted the need for transparency regarding access to and use of such data, as well as for accountability in case of misuse. From the processing viewpoint, we highlighted the

[9] https://ec.europa.eu/digital-single-market/en/news/mhealth-green-paper-next-steps

need for different levels of detail in data records, from the detailed history of treatment and results required by doctors, to anonymized statistics used to inform public policies.

- **Ensure the availability of systems and services**, especially those for critical diseases, such as remote heart monitors. Availability is required on the user side as long as the devices are used (a patient could decide to switch off the devices), and necessarily at the back end, where data from devices are processed. **Availability is related to QoS-enabled medical services and avoidance of congestion episodes, as well as security and protection from attacks** (DoS attacks, power drain attacks, etc.). In D4.1, we noted the need to provide QoS-enabled services for real-time monitoring operations, especially when large amounts of data have to be transferred. This is not always possible with best-effort Internet services that are vulnerable to congestion. We highlighted the difficult problem of providing QoS-enabled services, as envisaged by the Open Internet Regulation (EU) 2015/2120, while at the same time not undermining the general quality of the Internet access.
- **Provide for medical data security**. In D4.1, we highlighted the fact that many of the sensor networks applications in healthcare are heavily relied on technologies that can pose security threats like eavesdropping and denial of service. The EC, in its 2014 Green paper on mHealth,[7] noted the risks for accidental exposure of medical data to unauthorized parties, and the risks from loss or theft of devices storing sensitive information. They concluded that mHealth solutions should contain specific and suitable security safeguards such as the encryption of patient data and appropriate patient authentication mechanisms to mitigate security risks.
- **Achieve interoperation between eHealth devices of different manufacturers**. This is related to global efforts for **standardization** of M2M communications. Currently, eHealth standardization is under active consideration in different standards fora such as ETSI TC M2M, ETSI TC e-Health, ITU-T Focus Group (FG) on M2M etc. Interoperability and standardization are also expected to create economies of scale that can provide more **cost-efficient systems and services**. There is a need for harmonizing the spectrum in which these devices operate across the whole of Europe and ideally, worldwide, as the Industrial Scientific and Medical (ISM) band seems to be overcrowded. Barriers to standardization include the existence of proprietary systems, the massive amounts of data being collected from these systems, the lack of standard content format and the lack of open freely available standards (Fan, Haines, & Kulkarni, 2014).

Non-technical or policy goals are to:

- **Educate** people for the handling of more complex health conditions, and to **motivate** otherwise healthy individuals to monitor their health conditions. Personalized eHealth systems, devices and applications imply increased control and intervention by patients for the detection, treatment and management of diseases. While knowledge and activation on the part of patients used to be necessary for the management of chronic diseases such as diabetes and hypertension, patient activation and knowledgeability, and generally **user engagement**, is now required for more sophisticated conditions, like heart problems, but predominantly for the monitoring of vital signs and the uptake of a healthier lifestyle, in order to prevent diseases.
- **Provide eHealth HMNs at reasonable cost**, so that they are widely adopted. This is related to the need to provide **business models to ensure the sustainability of the offered services**. In a 2010 report on business models for eHealth (Rand, 2010), the authors attested the need to evaluate different business models and share best practices for funding and financing individual eHealth

systems, such as tax breaks, different reimbursement procedures or co-funding mechanisms. It is also known that the legal and social environment where eHealth services are provided plays a major role in the choice of business models (Kimble, 2015).

- **Provide a clear legal framework about the status of eHealth applications**, the norms that they should adhere to, and the responsibilities of manufacturers and developers towards the end-users. Such a framework can also help to **facilitate clinical trials**, as well as **increase consumer trust in such products**. In 2014, the EC published a report on the existing EU legal framework applicable to lifestyle and wellbeing apps.[10] Therein it was noted that there is still several room for interpretation regarding the applicability of existing legislation on the newly developed eHealth applications. The current legal framework is intertwining between the *Data Protection Directive*, the *e-Privacy Directive*, the *Consumer's Rights Directive*, the *eCommerce Directive*, and the *Unfair Commercial Practices Directive*.
- **Perform clinical validations of eHealth HMN**, which will attest the safety and efficacy of such systems. Clinical validation may include the combination of data from eHealth monitoring devices and data from traditional clinical procedures (Wicks et al., 2014). Validation of all systems of eHealth HMN is an impossible task, because of the sheer number and pace at which such systems enter the market, therefore this task should rather relate to **standardization**, and the need for these systems to **follow certain norms and procedures**. The appropriateness and efficacy of the latter should be verified by clinical trials. Currently, the knowledge about the results of clinical trials on mHealth applications is fragmented within individual research projects, which included clinical trials for mHealth services.[11]
- **Protect the privacy of individuals and confidentiality of medical information**: this has to be ensured through **efficient data management** and **security mechanisms**, i.e. encryption and authentication mechanisms on all communicated data (sensor-to-sensor communication in a body area network or home network, or data communication from the home network to a hospital backend). Additionally, it is necessary to apply **consistent rules in the EU for the management of medical information**, including patient data. Data protection rules are expected to tackle another challenge, that of **increasing trust and mitigating resistance from the patients and healthcare providers in using such products**. As previously mentioned, the European Commission has facilitated the creation of a Privacy Code of Conduct on mobile health (mHealth) apps, which is expected to be applied into practice soon.[12]

An interesting observation in the analysis of these challenges is that they are to a high degree interrelated. Above we have highlighted these challenges, and how they relate to each other. For example, medical data security is closely related to privacy and confidentiality, which is in turn related to increasing consumer trust in such products. Or, standardization can facilitate clinical trials, which

[10] European Commission. "COMMISSION STAFF WORKING DOCUMENT on the existing EU legal framework applicable to lifestyle and wellbeing apps", Brussels, 10.4.2014. Available online at: http://ec.europa.eu/newsroom/dae/document.cfm?doc_id=5146

[11] European Commission, "eHealth projects Research and Innovation in the field of ICT for Health and Wellbeing: an overview", June 2016. Available online at: http://ec.europa.eu/information_society/newsroom/cf/dae/document.cfm?doc_id=2852

[12] https://ec.europa.eu/digital-single-market/en/privacy-code-conduct-mobile-health-apps

would ensure the appropriateness and efficacy of the products and again increase consumer trust. The following table (Table 1) shows the interrelation of challenges.

	Efficient data management	Availability	QoS-enabled medical services	Security	Interoperability	Standardization	User engagement	Cost-efficiency	Clear legal framework	Trust	Clinical validation	Privacy & confidentiality
Efficient data management												X
Availability			X	X								
QoS-enabled medical services		X										
Security		X					X			X		X
Interoperability						X		X				
Standardization					X			X				
User engagement				X				X		X		X
Cost-efficiency					X	X	X					
Clear legal framework										X	X	X
Trust				X			X		X		X	X
Clinical validation									X	X		
Privacy & confidentiality	X			X			X		X	X		

Table 1: Interrelations of eHealth HMNs challenges (x signifies an interrelation)

The HUMANE approach can provide solutions that tackle these challenges from the initial design of such systems, and thus help promote eHealth HMN.

4 Suggested strategies and actions

In this section we suggest design strategies, as well as detailed actions for achieving the goals set in the previous section.

Patient information is a key component of self-management and **user engagement**. Therefore, initiatives need to be undertaken by authoritative entities, such as ministries, health organizations and hospitals. These should not only be temporary information campaigns; we believe that a permanent information structure is required, which provides continuous support to patients and individuals for the use of eHealth HMNS, so that people feel and understand that is an essential part of prevention and treatment. Usually, providing information on health advancements is a two-stage process: health professionals are first informed, which then communicate the information to their patients. However, the rate of advancements in eHealth and the use of web information channels often results in a horizontal process, where patients may even know first about new methods, devices, and uses. Therefore a mechanism for information dissemination needs to be setup that keeps abreast with the latest developments and coordinates the services that can be provided by healthcare professionals, with the provided information.

Moreover, for increasing **user engagement**, we need to design eHealth HMN systems that are simple and user-friendly, by employing relevant design strategies. Additionally, user engagement depends

largely on establishing trust, which in turn depends on guaranteeing user privacy, confidentiality, as well as the integrity and security of medical devices and data, which are separate goals themselves.

In order **to ensure the security of systems and data, the protection of privacy, as well as the efficient management of medical data** stored and communicated by eHealth monitoring devices, we consider that realistic large scale studies are required, which will systematically examine the application of advanced data management by eHealth HMNs. Besides efficient storage, categorization and search of eHealth data, the focus should be on real-time event detection, for early avoidance of severe health episodes. Different levels of detail should be provided depending on the intended use (e.g. raw data for use by medical researchers or aggregated data for statistical reports) and the level of authorization of the persons accessing the data. In addition, techniques should be demonstrated that empower the users to take control of their personal data, and provide transparency with regard to their exploitation by the data collectors and any third parties. The demonstrated systems should also be robust to attacks and eavesdropping, and have advanced encryption and authentication mechanisms.

To ensure the availability of critical eHealth services offered by monitoring devices in the public Internet, it is necessary to develop eHealth services with guaranteed QoS. Providing QoS guarantees in the public Internet is a longstanding problem existing for about 35 years, and failures to do so are attributed to a mixture of technical, business, and political reasons (kc claffy & Clark, 2015). Currently, the penetration of Internet services in everyday life, including critical human and societal functions, has refurbished the interest in this topic. There is increasing talk about 'specialized' or 'managed' services, or services 'other than Internet access services', as is the terminology in the recent European Open Internet Regulation (EU) 2015/2120. We believe that a concerted effort of the involved parties (ISPs, content providers, and consumers) is required to provide such services in practice without undermining the general quality of the Internet, and jeopardizing the benefits that Internet freedom and equality has brought to the public.

To ensure the interoperability of eHealth devices and data from such devices, it is necessary to harmonize the frequency band for the operation of such devices, and to encourage the development of standard content formats for the exchange of generated medical information. Other functions for which standards should be developed are the networking architecture, as well as the configuration of devices and reading of measurement data (kc claffy & Clark, 2015).

Regarding the need **to provide such systems at reasonable cost**, it is necessary to harvest the experience by offering products with eHealth monitoring capabilities in recent years. A study of existing business models is required that compare different models and forms of state subsidies, and also examines regulatory differences in each country, as well as differentiations based on the social conditions and mean income.

Regarding the **legal framework**, it is necessary to review and merge the provisions of the different regulatory documents that relate to eHealth HMN: the Data Protection Directive, the e-Privacy Directive, the Consumer's Rights Directive, the eCommerce Directive, and the Unfair Commercial Practices Directive. It should aim at removing redundancies and resolving ambiguities in the marketing and use of eHealth HMN.

Clinical validations should aim at deriving best practices and discovering the safest and most efficient monitoring systems, and at demonstrating the integration of eHealth HMN with current clinical practice procedures. Such practices could then become norms that such products should follow. To this end, there is also a need to collect the experience from clinical tests that have already been performed with eHealth monitoring devices.

Finally, there is a need **to apply privacy-by-design mechanisms** in commercial eHealth HMN. This is related to the empowerment of users to manage their personal information, and to control the level of confidentiality. Similarly to data management, we consider that large-scale pilot studies of such systems would be extremely helpful. In addition, we should examine the application of the forthcoming mHealth code of practice and assess its efficacy.

4.1 Design strategies and technology solutions

There are several dimensions of interest in eHealth HMNs. Because of the immediate concern for human life, more emphasis is placed on human-centred dimensions such as human agency, the social tie strength of human-to-human (H2H) interaction (usually between doctors and patients) and the human-machine relationship strength of human-to-machine (H2M) interaction (between a patient and the monitoring application). Nevertheless, dimensions such as the size and geographical expansion are also important for the design of such systems.

We may have different degrees of human agency and human-machine relationship strength, depending on the type of medical condition the systems are supposed to manage and the degree of human intervention. For example, a device that only performs monitoring of vital signs and sends the measurements to a remote medical centre has high machine agency, but the corresponding human agency is usually low. Whereas a system with glucose sensors that notifies the human user of required insulin doses, prompts for a higher level of human agency, as it requires user intervention — which in its turn impacts the measurement results.

On the other side, human-to-machine interaction strength is always high, because of the high dependency on machines to complete the tasks; even machines used for mere monitoring tasks mediate the results to patients, and potentially to medical establishments, and thus impact both the patients and doctors. Some of the devices are also used for therapeutic purposes (also known as "wearapeutics")[13], in which case their importance and agency greatly increases. For example, devices which deliver drug doses (such as insulin patches), or devices for quell relief. Services need to be accurate with limited or no errors (especially if they are also used for therapy). They need to analyse health data quickly, and need to be secured and transparent, and available anytime and anywhere.

The degree of H2H interactions usually varies based on the purpose for which they are used, and the severity of the medical condition. In eHealth systems such as fitness applications or dietary advisors there is usually no or very little interaction between patients and doctors. However, in systems used for severe health conditions such as heart monitors day to day communication may be required. Other H2H interactions include interactions between the users and IT experts, or technology providers, to

[13] https://www.flextronics.com/live-smarter/wearable-technology-wearables/wearable-medical-devices-wearapeutics

ensure the proper functioning of equipment, as well as mutual exchanges of experiences between users or between doctors; the latter often provide significant feedback for the system functionality.

The size of eHealth HMNs usually varies proportionally to the number of their users, and the number of vital signs they are supposed to monitor: from simple systems that monitor single vital signs, to more complex ones, such as body area networks, that monitor multiple vital signs. These systems may be enriched with location sensors, or sensors that measure environmental parameters (temperature, humidity, light, pollution), which can be combined for assessment by doctors or researchers (Milenković, Otto, & Jovanov, 2006). In view of the intended uptake of eHealth HMNs by large parts of the population, a single eHealth HMN could consist of thousands of users and should definitely be designed to manage very large volumes of data.

Finally, the geographical reach of an eHealth HMN is more likely to be limited by the number and density of users, and the limitations in scalability. So if there is a dense set of users in a small area, an eHealth HMN connected to a medical establishment could be setup to serve the users in this area. In a rural area where there is lower system load, a large area could be covered. The geographical reach also depends on movement limitations imposed by the monitoring system itself: in e-monitoring applications with non-wearable devices, the patient may only be free to move within a closed area where continuous connectivity can be provided easily. Wearable technologies, on the other hand, are designed to allow more movement, and combine different access technologies (Wi-Fi inside the home or cellular networks outside) along with data transmission techniques and synchronization methods that allow continuous monitoring even in cases of intermittent connectivity.

According to the above dimensions, we describe the design strategies from (Følstad et al., 2016, 2017) which are considered more relevant, and explain their suitability for eHealth HMNs.

Behavioural change through social motivation[14]

Even though people are intrinsically motivated to look after their personal health and the health of other people in their environment, the widespread adoption of eHealth HMNs requires a break in a pattern of behaviour that exists for many decades. People are used to visit their physician even for simple incidents, and to think that disease monitoring and – much more – therapy can only be provided at medical establishments. The design strategy for *Behavioural change through social motivation* aims to attract a critical mass of first adopters, which can subsequently motivate other users to participate in the eHealth HMN. As described in (Følstad et al., 2016, 2017), this can be facilitated by the creation and support of groups of users with common attributes.

Making behavioural change a basic premise of the HMN[15]

HMNs that depend on behavioural change in their human actors should consider explicating benefits of HMNs, not just for the user himself, but for society as a whole. For example, devices and apps for training such as Fitbit[16] engage their users in a HMN where the aim is to get help to change behaviour, be nudged to reflect on own behaviour change, and get feedback on own progress.

[14] Code of design strategy from (Følstad et al., 2016, 2017): 14.2.1.2
[15] Code of design strategy from (Følstad et al., 2016, 2017): 14.2.1.1
[16] https://www.fitbit.com/

Collaboration through gamified engagement[17]

Gamified engagement is an approach typically seen in online games, but also in social networks. Gamification is the use of game design elements in non-game contexts and offers great potential regarding the engagement and motivation of the elderly (Gerling & Masuch, 2011). Gamification in eHealth should not aim at merely adding visual components of games, such as points and rewards, but to achieve long-term motivation and adherence (de Vette, Tabak, & Vollenbroek-Hutten, 2015).

Supporting trust across HMN interactions[18]

This design strategy addresses the lack of user trust in relation to their data or their contribution(s), and is mostly related to the H2M interaction. In eHealth HMNs there is a need to increase the trust of patients in using eHealth HMNs. A user of an eHealth device or application may wonder what happens to the data that are recorded and communicated. In addition, a user should be able to authorise the parties which are using the data, and the ways in which they are used. Possible solutions, as described in (Følstad et al., 2016, 2017), are to turn one-way interactions into multi-directional, so that the user receives feedback on the actions performed, and to track usage traces for the provided data. Additionally, a data management service could be offered that tracks data access attempts, as well as refuses data release without explicit consent and/or generic agreement.

Maximising the benefits of affordances[19]

This strategy addresses the problem of confused or inappropriate user response to signals and alerts. In eHealth HMNs it is important to increase the probability of correct response to signals or of appropriate input. It is important when the machine agency in these systems is high, such as in eHealth HMNs for monitoring critical diseases. It is important to accurately guide the users, and prevent panicking or leading the users to perform actions that would cause the eHealth HMN to malfunction. For implementing this design strategy, solutions should relieve user pressure, extend contextual awareness and shift to a mode of engagement with human agency that promotes either automatic responses (schema-based) or refocuses attention to re-evaluate a situation (Følstad et al., 2016, 2017).

Enhancing security in HMNs concerning data aggregation and content curation services[20]

This design strategy is meant to address the problem of unauthorized access to user information, or improper user of such information and also contributes to *supporting trust across HMN interactions*. It is particularly important in eHealth HMNs, because of the personal nature and sensitivity of health information. It is much more important when there is high H2M interaction and high machine agency, where a user does not control the information that is collected and possibly communicated. The solution is to apply enhanced security mechanisms in order to prevent attacks on the HMN. Apart from authentication mechanisms, there should be strict control on how aggregated data can be provided for third-party services, control for fake profiles and strict privacy and confidentiality agreements.

Securing HMNs[21]

[17] Code of design strategy from (Følstad et al., 2016, 2017): 14.2.2.1
[18] Code of design strategy from D2.2: 14.4.3.3
[19] Code of design strategy from D2.2: 14.1.1.2
[20] Code of design strategy from D2.2: 14.4.1.1
[21] Code of design strategy from D2.2: 14.4.2.1

This design strategy aims to address the burden incurred from separate authentication and authorization mechanisms in a network, when a large number of nodes exists. For example, it cannot be expected by a member of the medical staff to manage different authentication and authorization processes for each different individual of an eHealth HMN. At the same time, there is a need to protect individual user privacy. Therefore there is a need for a single 'authority' who would vouch for individual agents, humans or machines, to mediate their access to other services.

Managing privacy[22]

Having provided content, data or information to an eHealth HMN, the original user (data subject or source), in this case the patient, may lose control over who can access such data and what they do with it. It is important when machine agency is intermediate/high. This design strategy shares common features to the design strategies for supporting trust and enhancing security in HMNs. A solution proposed in (Følstad et al., 2016, 2017) calls for a repository controlled by a trusted third party. Data subjects, content providers, and information sources would be able to specify who and under what circumstances the data or content can be released, even responding to ad hoc requests from unknown parties. In this way, first the data or content would be managed on behalf of the source; secondly, there would be an audit trail to the last authorised party should the data subject or owner suspect that it has been compromised.

Increasing trust of users through strict, clear privacy policies[23]

A common problem in HMNs is the increasing trust requirements for the handling of personal data and the confidentiality of information. Complex, obscure or insufficient rules for the protection of personal data are likely to deter users from submitting data or providing comments and opinions, or even from registering and participating in the HMN. Thus it is important to increase trust of patients with strict privacy policies for the use of their data. The user should know beforehand how his/her personal data are being used and who has the right to access them, if such data are shared with third parties and under what conditions, and how this data can be deleted. Additionally, accountability mechanisms could be installed so that the user knows when personal information is accessed and by whom, and methods to detect and remove fake profiles.

Moreover, potential new design strategies for eHealth HMNs are presented in Annex I.

4.2 Breakdown of the roles of stakeholders

In this section we list the actions described above and outline the roles of stakeholders in implementing these actions.

- ***Establishment of a permanent structure for providing continuous support and information about the use of eHealth HMNs***
    - ***Role of stakeholders:*** The permanent structure should be part of the national healthcare system, and should be an authoritative entity for public health information programs. National healthcare administrators should lead the effort, supported by eHealth

[22] Code of design strategy from D2.2: 14.4.1.2
[23] Code of design strategy from D2.2: 14.4.3.5

manufacturers and experts. The information program should include both healthcare professionals and the general public.

- ***Conducting realistic large scale studies to examine the application of advanced data management by eHealth monitoring devices and systems, and the application of user-engaging and privacy-by-design mechanisms in commercial eHealth HMNs***:
    - ***Role of stakeholders:*** EU and national authorities can direct research funds to encourage the conduction of such pilot studies. They should encourage all other stakeholders to participate, including health professionals so that pilot studies are integrated in clinical trials.
- ***Developing eHealth services with guaranteed QoS***:
    - ***Role of stakeholders:*** This is a complex task that primarily involves researchers, ISPs and providers of eHealth monitoring devices and applications. Researchers and IT experts involved in standardization groups can provide recommendations on feasible and efficient systems on end-to-end service delivery with guaranteed QoS, something that has not been possible until today. Regulatory authorities and EU bodies can assist by laying rules and supervising the provision of so-called 'specialized' or 'managed' services. A valuable output of the roadmap would be a regulatory document elaborating on the provision of such services mentioned in Regulation (EU) 2015/2120, possibly (but not necessarily) focusing on eHealth services and applications.
- ***Providing interoperable eHealth devices and common data formats***:
    - ***Role of stakeholders:*** Standardization groups and organizations should continue the work to harmonize frequency bands, and provide recommendations for networking architecture, device configuration and data formats. A problem with standards is that they are often published without being adequately applied in practice over long periods of time. This requires the cooperation of national authorities and health professionals and is more time-demanding.
- ***Study of business models for eHealth monitoring in European countries***:
    - ***Role of stakeholders:*** The study should cover all applications of eHealth monitoring devices, from simple mHealth apps to more complex remote monitoring networks and cover different countries, with diverse economic levels and social environments. The study should be conducted by research experts and be facilitated by EU and national authorities.
- ***Review and merge the provisions of the different regulatory documents that relate to eHealth HMN***:
    - ***Role of stakeholders:*** This task is recommended to be undertaken by EU authorities, with the cooperation of the national authorities.
- ***Perform clinical validations for assessing the safety and efficiency of eHealth monitoring devices***:
    - ***Role of stakeholders:*** This task should be performed by medical research experts and health professionals, and be facilitated by EU/national authorities and eHealth device manufacturers.

5 Overview of the roadmap

In this section, we provide an overview of the eHealth roadmap, consisting of the implications brought by eHealth HMNs, the objectives and actions we have set in the eHealth roadmap in an effort to address these implications and challenges, and the HUMANE design strategies that can assist in the realization of the actions.

eHealth HMN implications	**Roadmap objectives**	**Actions to implement the objectives**	**Related HUMANE design strategies**
Increased human agency (increased user control and intervention for the detection, treatment and management of diseases)	Educate and motivate people to use eHealth HMNs	- Establishment of a permanent information structure - Improvement of application design, with emphasis on user engagement and behavioural change	- Behavioural change through social motivation - Making behavioural change a basic premise of the HMN - Collaboration through gamified engagement - Maximising the benefits of affordances
Increased machine agency and H2M interaction (increased machine role in disease management, collection and communication of large volumes of sensitive information)	Protection of privacy and confidentiality of medical information	Application of privacy-by-design mechanisms in commercial eHealth HMN	- Supporting trust across HMN interactions - Managing privacy - Increasing trust of users through strict, clear privacy policies - Efficient management and protection of sensitive data through different levels of detail and authorization
	Increased human trust	- Developing reliable eHealth services with guaranteed QoS - Application of privacy-by-design mechanisms in commercial eHealth HMN - Clinical validations for assessing the safety and efficiency of eHealth monitoring devices	- Supporting trust across HMN interactions - Increasing trust of users through strict, clear privacy policies

eHealth HMN implications	Roadmap objectives	Actions to implement the objectives	Related HUMANE design strategies
	Increased security	- Efficient management and protection of medical data - Developing reliable eHealth services with guaranteed QoS	- Enhancing security in HMNs concerning data aggregation and content curation services - Securing HMNs
Increased size and geographical expansion	- Provide scalable eHealth systems - Provide eHealth HMN at reasonable cost - Availability of critical health services - Standardization and Interoperability of eHealth devices and data	- Efficient large-scale data management mechanisms - Harmonize frequency bands, provision of standards for networking architecture, device configuration and data formats - Review and merge the provisions of the different regulatory documents that relate to eHealth HMN - Study of business models for eHealth monitoring in European countries	- Efficient management and protection of sensitive data through different levels of detail and authorization - QoS guarantees in critical eHealth services offered by monitoring devices in the public Internet - Interoperability of eHealth devices and data from such devices

6 Timeframe and prioritization

In this section we provide a timeframe for implementation, based on the required implementation effort.

The establishment of an eHealth information structure is an administrative procedure, which consists of setting up the rules and procedures, establishing links with eHealth industry and communication channels, finding offices and recruiting personnel. A timeframe of 1 year is envisaged for setting up a basic structure.

We consider the standardization and interoperability of eHealth devices and systems as a basis for conducting large scale pilots studies and clinical trials, as well as for providing QoS-enabled services. An initial assessment of the timeline and effort can be made by reviewing the status of standardization activities in two large organizations, ETSI and ITU:

- The standardization activities of ETSI on personal wearable and portable communicable systems include those for medical implants, health portals, and many other ICT-based tools assisting disease prevention, diagnosis, treatment, health monitoring and lifestyle management. Vital aspects considered by the ETSI project (EP) eHealth are: Security of systems and data, Quality of services, Interoperability and validation by testing, Usability.[24] So far EP eHealth has developed an initial report in developing eHealth user service models, and examined the applicability of existing ETSI and ETSI/3GPP deliverables to eHealth. The models which have been developed address interoperable solutions for healthcare data collection, transmission, storage and interchange with the required security, privacy and reliability. According to their website, the next step of this work will be to develop requirements and service architecture to provide improved eHealth services involving the relevant stakeholders, including users, medical professionals, etc. At the end of 2016, ETSI had also early drafts on recommendations for short-range medical devices, while in 2017, they are expected to release recommendations on paging services and use cases for eHealth.[25]
- The ITU-T study group 16 is the lead ITU-T Study Group on e-health. It originally focused on the standardization of Multimedia Systems to support telemedicine applications, but has also recently produced recommendations for the interoperability design guidelines for personal health systems, and a suite of conformance testing specifications of personal health devices.[26] There are currently no other work items under development.

Therefore, we see that the currently the standardization effort has focused on general design guidelines and not at complete system specifications. It is likely that such specifications will emerge as de facto standards from large manufacturers who are able to dominate the market.

The design requirements of such systems are well known, both from the aforementioned recommendations and the eHealth literature. Hence we consider that large scale pilot studies that examine the application of advanced data management by eHealth monitoring devices and systems, and the application of user-engaging and privacy-by-design mechanisms in commercial eHealth HMN are a mature work-package that could be conducted by a coordinated stakeholder effort through EU-funded projects, typically for a 3-year duration.

On the other hand, a preparatory work may be required to study the aspects of eHealth HMNs that must be systematically studied in clinical trials, in order to have a concerted effort at EU level and avoid fragmentation. This preparatory phase should also collect the knowledge and experience from previous eHealth projects that included clinical trials.[27] We envisage 1-2 years for this preparatory phase, followed by clinical trials that last for 3-4 years.

The study and development of efficient business models is a stand-alone task that could be undertaken in 1-2 years. On the other hand, reviewing and merging the provisions of the different regulatory documents that relate to eHealth HMNs (the Data Protection Directive, the e-Privacy Directive, the Consumer's Rights Directive, the eCommerce Directive, and the Unfair Commercial Practices Directive)

[24] http://www.etsi.org/technologies-clusters/technologies/ehealth
[25] ETSI Work Programme (accessed 2-1-2017)
[26] http://www.itu.int/en/ITU-T/studygroups/2013-2016/16/Pages/ehealth.aspx
[27] European Commission, "eHealth projects Research and Innovation in the field of ICT for Health and Wellbeing: an overview", June 2016. Available online at: http://ec.europa.eu/information_society/newsroom/cf/dae/document.cfm?doc_id=2852

is a significant task, which may require 2-3 years, in view of the need to study the design requirements, conduct discussions in EU institutions and member states, as well as public consultations. This review can benefit from input of standardization efforts, as well as business model requirements.

Finally, we consider the development of eHealth services with guaranteed QoS as the most difficult task, which requires the concerted effort of the involved parties (ISPs, content providers, and consumers) because it disrupts the current best-effort nature of the Internet. It may also require the improvement of communications infrastructures, as well as the development of new QoS standards. We see this as a challenging task for the next decade, which may also be impacted by the evolutions for providing QoS for multimedia entertainment services such as IPTV, or for emergency preparedness services.

The eHealth HMN timeframe is shown in Figure 1. We show the timeline for a 10-year period. The standardization and interoperability of eHealth devices, as well as the provision of eHealth services with guaranteed QoS are considered as continuous tasks during the whole period. The periods for the remaining tasks have been estimated based on experience and the degree of difficulty of the tasks, as discussed here.

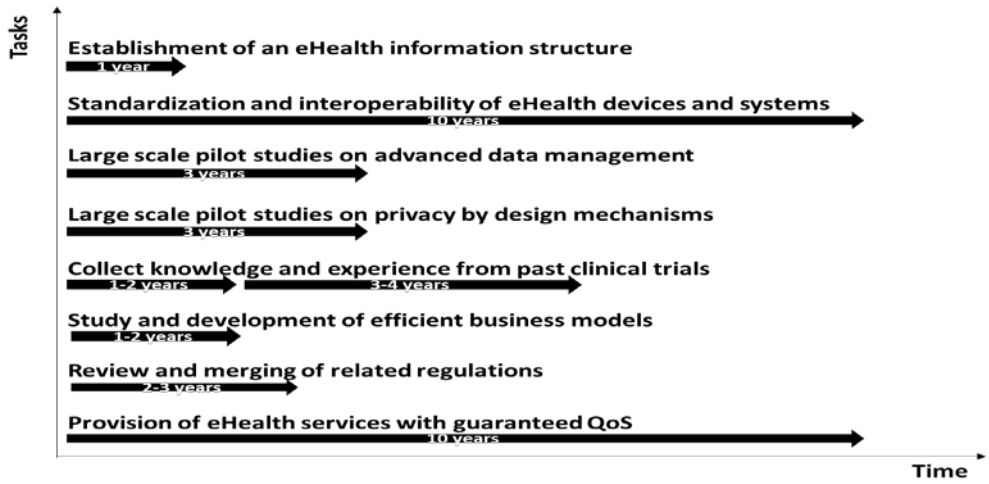

Figure 1: eHealth HMN timeframe

Among these actions, setting up a basic information structure and creating a modern and coherent regulatory framework can be considered as a priority, as they will help to exploit the eHealth HMNs that are already in operation, so they can bring their benefits to society. Overall however, a concerted effort on all aspects and all stakeholders in necessary to achieve the full potential.

7 Roadmap dissemination

We have prepared a short white paper (https://humane2020.eu/2017/05/15/a-roadmap-for-future-human-machine-networks-in-ehealth/) on the eHealth HMN roadmap, which is intended to provide a quick overview of the roadmap that is easy to read and understand, and will help to increase awareness among the target stakeholders. The paper starts with a brief introduction to eHealth HMNs, followed by a description of the policy background and regulatory context. We then proceed by explaining the implications of HMNs, such as the requirement for more engagement on the part of patients for self-management and prevention of diseases, the need to protect privacy and establish trust, and the large

size and geographical expansion of such networks. Finally, we describe the actions in the roadmap which help to address these implications.

The eHealth roadmap white paper is published on the project website, together with the roadmaps on other domains. In addition, it will be published on the project's Mendeley page (group: Humane), as well as on social media channels (Twitter).

In addition to the eHealth white paper, we have created a summary of eHealth HMN implications, objectives, actions and related Humane design strategies in table format, as well as a graphical illustration of the roadmap. These will help to create promotional and dissemination material (leaflets, fact sheets, posters) to be distributed to eHealth stakeholders.

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