100 million

Digitally Connected Healthy EU citizens

by 2027

A moonshot proposed by The Digital Health Society

the digital health society

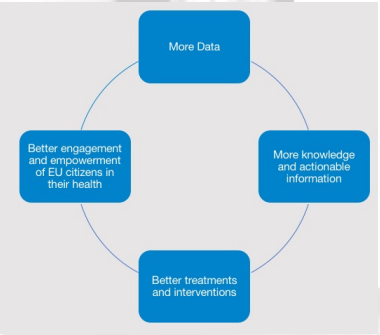
enabled by ECHAlliance

INTRODUCTION

In 2018, the European Commission (EC) will make comprehensive proposals for the next generation of financial programmes for the post-2020 Multiannual Financial Framework, which is the EU's long–term budget. The Commission's proposals will be designed to make it possible for the EU to deliver on the things that matter most, in areas where it can achieve more than Member States acting alone. This requires a careful assessment both of what has worked well in the past and what could be improved in the future. The EC launched a public consultation as an integral part of the process: Its objective is to collect the views of all interested parties on how to make the most of every euro of the EU budget.

As the **Mid-Term Review on the implementation of the Digital Single Market**[1] is stating, "*Digital technologies can help improve people's health and address systemic challenges for healthcare systems*". Digitising our European healthcare systems could bring benefits at several levels:

- Improve the health and wellbeing of European citizens with a better quality of care services in a more personalised approach;
- Ensure the sustainability of health and social care systems;
- Generate economic growth, new businesses and job creations and competitiveness of the European industry by innovation.



The report **Mission-Oriented Research & Innovation in the European Union**[2], produced by Mariana Mazzucato and recently published, describes a "problem-solving approach to fuel innovation-led growth". The document, delivered to Carlos Moedas, European Commissioner for Research, Science and Innovation, presents the strategic recommendations on mission-oriented research and innovation in the EU, to guide the future European Union Framework Programme for Research and Innovation.

It recommends to organise the next EU Framework programme around key missions bringing answers to broad challenges, such as the **Sustainable Development Goals**[3], but with a more wider scope and more ambitions than individual research and innovation projects: *"missions set clear and ambitious objectives that can only be achieved by a portfolio of research and innovation projects and supportive measures, such as policy interventions, deployment actions and involvement of end-users".*

Figure 1 below illustrates the movement from broad challenges to specific missions.

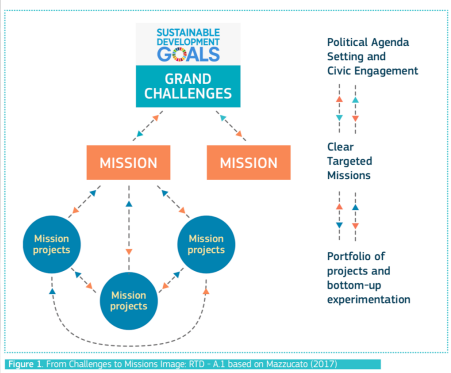


Figure 1 From Challenges to Missions Image: RTD – A L based on Mazzucato (2017)

[1] Mid-Term Review on the implementation of the Digital Single Market, A Connected Digital Single Market for All, COM(2017) 228 final

[2] Mission-Oriented Research & Innovation in the European Union, Mariana Mazzucato, 2018, https://publications.europa.eu/en/publication-detail/-/publication/5b2811d1-16be-11e8-9253-01aa75ed71a1/language-en

[3] Sustainable Development Goals, United Nations, http://www.un.org/sustainabledevelopment/sustainable-development-goals/

A moonshot mission proposed by the Digital Health Society (DHS)

Born during the Estonian EU Presidency in 2017, the DHS movement[4] is a community of organisations with Member States, Regional Governments, Health and Care Providers and Professionals, SMEs/start-ups and large companies, Research Organisations, Citizens' and Patients' groups, Insurers and Mutual Funds, NGOs, etc.

Over 200 organisations have joined the DHS movement in 2017. More are joining in 2018.

A Digital Health Society for European Citizen's benefit

The DHS movement is designed to be supportive of the **Digital Single Market strategy** of the **European Commission** and develop actions contributing to its main objectives which will be detailed in the upcoming communication on the future of the Digital health and care:

- *Citizen's secure access and sharing of health data across borders: a European Electronic Health Record and,*
- *European health data infrastructure to advance research, disease prevention, and personalised medicine, and;*
- *Accelerating deployment of new digitally-enabled care models.*

The DHS movement aims also to align its actions with the agenda defined by the **Member States** within the **eHealth Network**, in particular around the technical and semantic interoperability, patients' right for cross-border healthcare, data protection, eHealth guidelines, etc…

The **EU Council (EPSCO) Conclusions**[5], published in December 2017, include a chapter about "**Health in the Digital Society - making progress in data-driven innovation in the field of health**". The DHS movement is part of these conclusions adopted by the 28 Member States (art. 32): *"The engagement and commitment of the stakeholders underlined by the Digital Health Society Declaration adopted at the high-level "Health in the Digital Society. Digital Society for Health" conference, which took place on 16-18 October 2017 in Tallinn, launching multi-stakeholder task forces to work on actions addressing the main challenges of large-scale deployment of digital innovation in the field of health."*

The Digital Health Society, an open multi-stakeholder movement, is both:

- **A Digital Health thought leadership platform** to exchange knowledge, experiences, best practices, success stories;
- **A Lab, an Innovation Factory** able to incubate and accelerate research & innovation projects and experimentations, but also, with the "*Coalition of the Doers*", to deploy at large-scale innovative solutions for Digital Health. We will utilise the existing Networks of our members, in Regions, Countries and Communities to ensure practical implementations.

This document aims to share the Digital Health Society movement's vision of an **ambitious research and innovation programme for health and wellbeing in Europe, enabled by key support activities and involving the EU citizens and the whole society**. Its purpose is not to define each project or initiative but to define a moonshot target and to describe the components of the programme to reach this goal.

[4] Digital Health Society (DHS), https://echalliance.com/digitalhealthsociety
[5] Employment, Social Policy, Health and Consumer Affairs Council (EPSCO) conclusions on Digital health: http://data.consilium.europa.eu/doc/document/ST-14078-2017-INIT/en/pdf

MISSION:
100 million Digitally Connected Healthy EU citizens by 2027

This "Moonshot" Mission aims to develop a series of support activities and research & innovation projects, driving to **collect the data** (relevant for health purpose) **of 100 million European citizens, by 2027**, and **make them available** (under conditions) for the purposes of:

- **Research**
- **Improvement of health and care services enabling both personalised health and population health management**
- **Citizens' empowerment and self-management for a better health and wellbeing**
- **Innovation and development of innovative products and services**

Definitions

"**Digitally Connected**": the DHS moonshot mission aims to be able to collect all data (genome, clinical, behavioural and environmental data) around each citizen ensuring the compliance with data protection regulation and security. It also targets a free flow of these data across Europe (cross-border) and their availability for healthcare systems and research through platforms with legal and privacy principles respecting the citizens' rights. The EU citizens will be fully digitally connected if the communication is enabled in both senses: from the citizens to the system and the research, and from the system to the citizens in order to empower them as co-managers of their health and wellbeing.

"**Healthy EU citizens**": this term doesn't mean that the mission is only targeting healthy people, but the aim is to make healthier the citizens, e.g. preserving their health and wellbeing or managing in the best way possible their health condition or disease. In a nutshell, the mission should enable EU citizens to live better independently from their health status.

"**Population Health**": it refers to "*the health outcomes of a group of individuals, including the distribution of such outcomes within the group*"[6]. It includes 3 components: health outcomes, patterns of health determinants, and policies and interventions that link the two. The Population Health Management (PHM) is defined as "*the organisation of and accountability for the health and healthcare needs of defined groups of people utilising proactive strategies and interventions that are coordinated, engaging, clinically meaningful, cost effective and safe*"[7]. KLAS research and the ONC in the US (adopted also by NHS England) have developed the below 6 headers for the technical capacity and capability for population health: data aggregation, data analysis (including predictive models), care management, administrative/financial reporting, patient engagement and clinician engagement.

[6] Kindig D, Stoddart G (March 2003), What is the population Health? https://ajph.aphapublications.org/doi/full/10.2105/AJPH.93.3.380

[7] Implementing a successful population health management program, Philips white paper, 2016, https://www.usa.philips.com/c-dam/b2bhc/us/Specialties/community-hospitals/Population-Health-White-Paper-Philips-Format.pdf

"**Personalised health**": for the purpose of this document, this concept bring together the EU definition of "personalised medicine" referring to "*to a medical model using molecular profiling for tailoring the right therapeutic strategy for the right person at the right time, and/or to determine the predisposition to disease and/or to deliver timely and targeted prevention*"[8], and to the NHS England's definition of personal health and care which "*means empowering people to have greater choice and control over the way their health and care is delivered*"[9].

Technologies involved

The absence of such large cohorts of citizens' data sets is currently a challenge to develop high-level researches and ground-breaking innovations for health, taking advantages from the most advanced technologies such as:

- **5G** (5G for Europe Action Plan[10], 5G PPP[11])
- **Artificial intelligence**, **machine learning** and predictive analytics (European Artificial Intelligence-on-demand-platform[12], upcoming European approach on artificial intelligence and robotics[13])
- **High performance computing** (EuroHPC declaration[14], EuroHPC Joint Undertaking[15], cPPP[16])
- **Cloud computing** (European Data Infrastructure, European Open Science Cloud[17])
- **-omics technologies**[18]
- **Internet of Things**[19]
- **Cybersecurity**[20], **Blockchain**[21]**…**

The Council conclusions on "**Health in the digital society – making progress in data-driven innovation in the field of health**"[22] adopted by the Council on 8 December 2017, inviting the Member States to "*invest in and make active use of data-driven tools and methodologies which enable the provision of safe and high-quality healthcare services and support sustainable health systems*" and the Member States and the Commission to "*build on the European Cloud Initiative, the EuroHPC and the European Open Science Cloud, and work together with the aim of improving access to larger European datasets, longitudinal data and world-class high performance computing infrastructure for health research and innovation purposes, while ensuring a high level of data protection*".

The challenge for healthcare is how to take advantage of such a wide range of sometimes disparate technologies. This challenge is compounded by the national EU health markets with no pan European single market and the public health systems which negate the fast deployment of B2C products and services.

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[8] Use of -omics technologies in the development of personalised medicine, Commission Staff working document, SWD(2013) 436 final, 2013
[9] NHS England, https://www.england.nhs.uk/personalised-health-and-care/
[10] https://ec.europa.eu/digital-single-market/en/5g-europe-action-plan
[11] https://5g-ppp.eu/5g-ppp-phase-2-projects/
[12] https://ec.europa.eu/digital-single-market/en/news/european-artificial-intelligence-demand-platform-information-day-and-brokerage-event
[13] https://ec.europa.eu/digital-single-market/en/artificial-intelligence
[14] https://ec.europa.eu/digital-single-market/en/news/eu-ministers-commit-digitising-europe-high-performance-computing-power
[15] https://ec.europa.eu/digital-single-market/en/eurohpc-joint-undertaking
[16] https://ec.europa.eu/digital-single-market/en/high-performance-computing-contractual-public-private-partnership-hpc-cppp
[17] https://ec.europa.eu/digital-single-market/en/european-open-science-cloud
[18] SWD(2013) 436 final, https://ec.europa.eu/research/health/pdf/2013-10_personalised_medicine_en.pdf
[19] SWD(2016) 110 final, http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016SC0110&from=EN
[20] JOIN(2017) 450 final, http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52017JC0450&from=EN
[21] EU Blockchain Observatory, http://europa.eu/rapid/press-release_IP-18-521_en.htm
[22] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2017:440:0003:0009:EN:PDF

Main challenges

Following the 2017 EU Council conclusions, this mission proposed to tackle some of the main challenges we face in order to establish a real **digital society for health**:

- **Allow citizens to access their data** and associated tools and services to transform these data into actionable information and knowledge for (self-)managing their health and wellbeing;
- **Ensure trust (quality, security, safety, data protection, ethics)** for the European rights for citizens to access their data
- **Enable cross-border health data exchanges**;
- **Ensure availability of high-quality data** for research and innovation purpose, but also for care services quality improvement;
- Develop a **full data-driven approach** for more **personalised treatments and interventions**, using Digital technologies to reinforce the communication between the health professional and the patient;
- **Progress on efficiency** of EU health and care systems and **improve patient's safety**;
- **Overcome the barriers for scaling-up** Digital Health solutions across Europe, toward a **Digital Single Market for health**;

This Mission also have **the ambition to attract the citizens and trigger their interest and commitment** to reach this objective (100m), as one of the great objectives that Europe is collectively trying to reach. The Mission should be designed to **inspire** both **professionals and experts** of the health and social care sector, **but also inspire each EU citizen**. Giving the latest evolution of the European Union and the recent people's expression through democratic votes, **the aim is also to reconnect the EU society with its institutions, its values of openness, solidarity and innovation for the well-being of its citizens.**

To achieve this, **the Mission** aims to **bring together existing** initiatives related to health innovation and technologies excellence and **develop a series of activities (support actions and research & innovation projects)**:

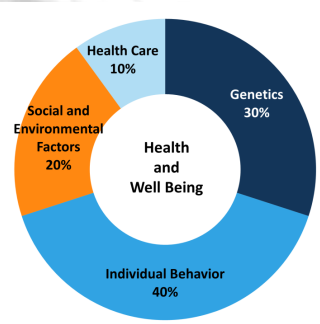
Research and Innovation

Human health and wellbeing components are multiple. Most of these parameters could be the target of interventions. The Mission proposes to develop research and innovation projects about more personalised and efficient interventions and treatments, using data from several categories (variety), with large datasets (Volume) enabled by fast (velocity), multi-channels and cross-border communications.

#AllHealthDeterminants

The main factors on risk of premature death are the following:

- **Genetics and biology**
- **Health and care access**
- **Social and Environmental factors**
- **Individual behaviours and Lifestyle**



Source: Schroeder, SA. (2007).
We can Do Better – Improving the Health of American People, NEJM, 357-1221-8

#AllData

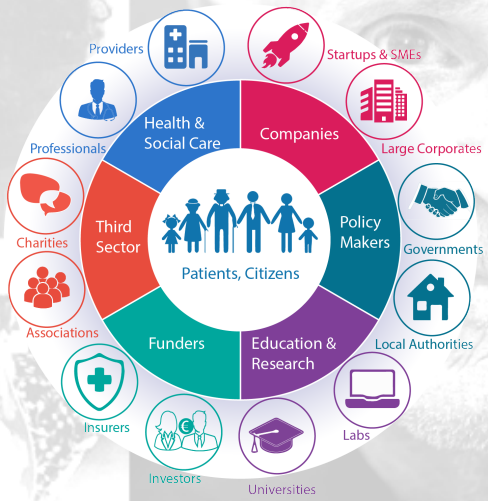
So, adopting holistic approach for more relevant data-driven innovations, **multiple data sets** should be targeted such as:

- **Genome data**
- **Clinical & healthcare system data (**EHR, PHR, PACS-RIS, public health, social care, payers/insurances…)
- **Behaviours and Lifestyle data (**Quantified self with wearables, personal devices… data from Telcos & mobile operators, internet providers…)
- **Environmental data** (Smart cities, Public health, social care, eGovernment / eAdministration, public transports, traffic, air quality, energy consumption, police…
- **Crowd sourcing** (tracking of information/data from Internet, social networks…)
- **Other sources** (Local community services, GIS/satellite maps, Banks…)

#AllStakeholders

Research and Innovation projects should embrace all health components and support projects which will involve **multi-disciplinary teams** (AI, IT/digital, medical/public health, biology, genetics, urban development, gaming/VR-AR, social sciences -behaviour change, sociology, communication, change management...-) able to tackle the **complex societal challenges** the EU is facing.

Innovation is coming from the collaboration within the **multi-stakeholders ecosystem**.



#AllHealthConditions

Research and innovation projects should target the whole spectrum of health conditions, **from healthy living to acute care**, developing **prevention around risk factors**, support to **chronic patients** and **ageing population** and enabling **soft and seamless transition between home, local health and care services and hospitals through digital tools**.

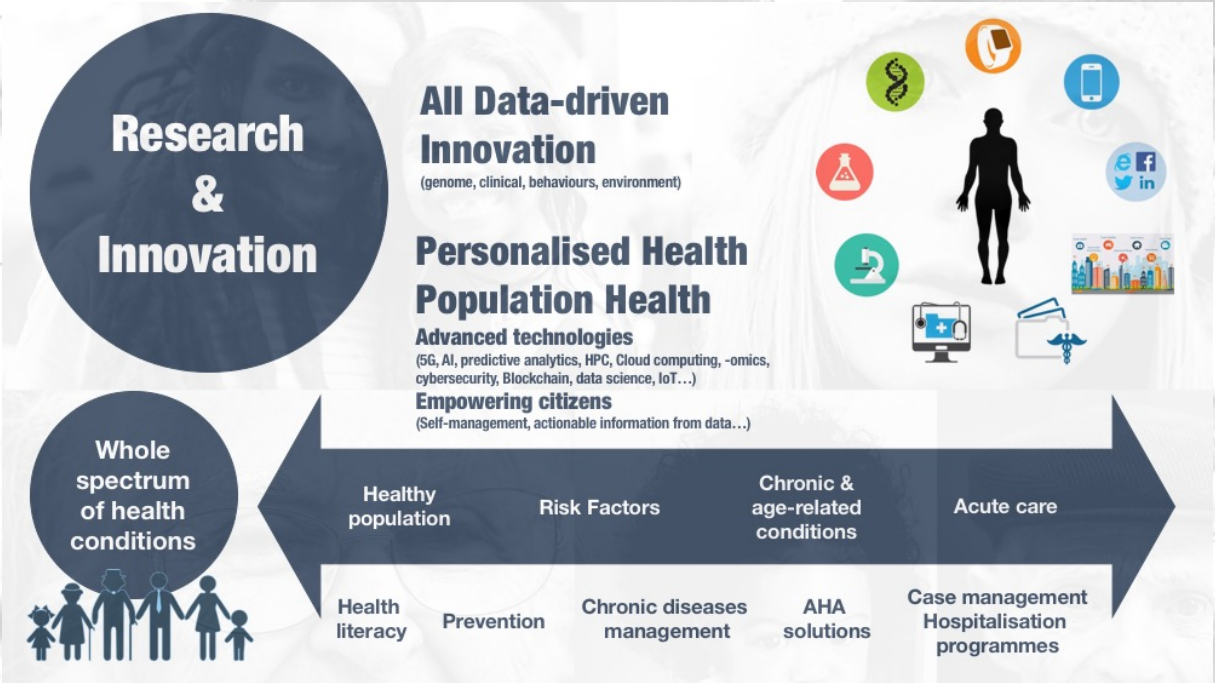
We should adopt a **holistic** and **dynamic vision for health and wellbeing**, because:

- **Citizens** are evolving dynamically from one condition to another during their **lives**;
- **Digital Technologies** (*see above p.5*) enable both a **Population management** approach with a **hyper-personalisation** of the content and services driven by personal data, so the same solutions could address the whole population and at the same time be specific to citizen's conditions and use-cases, generating efficiency and more integration of care.

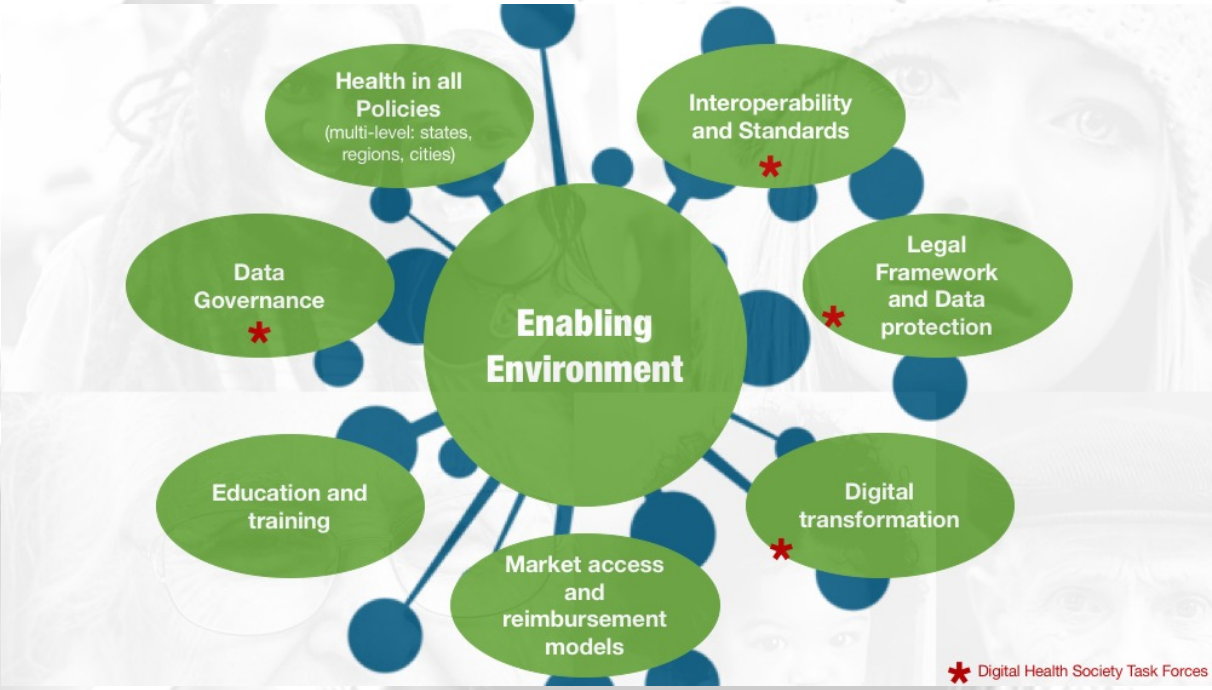
The main challenges our healthcare systems are facing are in large proportion, **lifestyle-related conditions**, requiring the creation of tools that **enable the citizen** to:

1) **access her/his data**
2) **understand what the data means for her/him**
3) **inspire people to take responsibility and (self-)manage their health**
4) **empower citizens, generate behaviour changes and hook each individual to new healthy habits.**

Research and Innovation projects should reflect the important shift in the healthcare approach **from a majority of curative interventions and acute care to more preventive and personalised approaches**, in order to tackle these lifestyle-related conditions which represent the major part of the financial burden of most of healthcare systems in the world.
With data science supporting life sciences, technologies can enable discoveries of new treatments and interventions and personalised approaches, predicting the response from each individual and optimise its chances (example of immunotherapy).
The Mission will **bring together current and upcoming initiatives** such as EOSC, IMI, ELIXIR, BBMRI, IC PerMed, 1M Genome project, etc…



Enabling Environment



In order to deploy, implement and scale up the innovative solutions developed through the Research and Innovation projects, the European stakeholders should also act to create an **Enabling Environment**. Several **supportive measures**, certainly for most of them, **centralised for the whole Mission and all innovative projects**, could be envisaged. The DHS has developed **Task Forces** to tackle some of these challenges, as described below.

Interoperability and standards

The main objective is to promote the alignment and the convergence of national and regional eHealth interoperability strategies. It covers both technical and semantic interoperability.

Number of initiatives have been developed around interoperability models and standards the last years in Europe and across the world. We believe that number of ways are possible to discuss this question depending on the context, the type of solution or the targeted use-case. "*One Size Doesn't Fit all*", but, building on previous works done, a **platform** is needed in order to share best practices between healthcare stakeholders (health and care providers, Member states, regions, industry, Standards organisations, users…).

We can anticipate that a large majority of the Research and Innovation projects will have to deal with this matter and it would make sense to create a **central group with interoperability experts/organisations** for the whole duration of the Mission in charge of organising best practices and information sharing, defining guidelines for each use-case and supporting each project consortium in defining the relevant interoperability frameworks and models.

Within the Digital Health Society movement, the Task Force[23] 1 has been formed around this topic. Several Member states, regions, standard organisations, healthcare providers, research

[23] Presentation DHS Task Force on Interoperability, Tallinn, October 2017, http://c.ymcdn.com/sites/echalliance.com/resource/dynamic/blogs/20180310_023340_16584.pdf

and industry representatives are part of this group. Based on previous work around interoperability (such as the ENSOM protocol initiative, the eStandards Roadmap or the interoperability work within the eHealth Network and the JAseHN), the DHS Task Force 1 is currently developing **a platform, a marketplace for sharing good practices and lessons learnt**, which describe the "*why*" (with a specific focus on the perspective of patients/clients/citizens), the "*what*" and the "*how*" the solution and the standard are implemented (and how it can be transferred/adapted/scaled). This taskforce focuses on bringing together what everyone has achieved and that has proven its worth in daily practice. The work plan is targeting the convergence of individual strategies on interoperability across Europe, facilitating the **free flow of data across the borders between MS and regions**, but also **providing the industry with clear guidance** for the development of solutions and reveal the **Digital Single Market**.

Legal Framework and data protection

The upcoming activation of the **General Regulation for Data Protection**[24] (**GDPR**) next May has already resulted in major changes in the practices of both public organisations and companies treating and using personal data across Europe. Even if GDPR is not health-specific, some of its elements have huge impact on the health and care sector.

The DHS has also created the Task Force 3 on this topic. Several lawyers, national or regional policy-makers and companies are discussing the legal barriers to overcome to enable the **Free flow of data with cross-border exchanges of health data and the secondary use of health data** for research or innovation purpose.

An example is for instance around the concept of consent, defined as follow: "*any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her*". The DHS Task Force is also working on the concept of "**Dynamic Consent**[25]", bringing an answer to the continuous evolution of solutions and purpose of the use of personal data, and enabled by Digital tools.

As the legal framework for health is a competence of Member states and/or regions, the Task Force will develop a **set of common and shared principles**[26] around the **use of all health and care data**. Then each country or region can write and adopt the new laws following same principles. These agreed principles could then be formalised into a **European Health and Care Data Convention**.

Digital Transformation

The health and social care stakeholders in Europe have to transform digitally their organisations. It doesn't only mean that they have to launch investments in IT equipment, but they have to define new processes, new relationship with the citizens (whether patients, carers or families), new way to work for health professionals, etc. It is a whole change management strategy they have to set up.

[24] https://ec.europa.eu/info/law/law-topic/data-protection_en

[25] See this presentation from Petra Wilson, member of the DHS Task Force on legal Framework http://www.cocirehealthsummit.org/files/Panel4/3.P.Wilson-Panel4.pdf

[26] See Bleddyn Rees presentation (Task Force leader) here: https://www.eiseverywhere.com/file_uploads/5ee26ee7fb133d70d93c4417ca0acbe8_Rees_Digital-Health-Society-Task-Force.pdf

The DHS Task Force 4 has published recently a report on methodology and best practices for change management in healthcare organisations[27]. Its objectives are:

- **Enable digital transformation and change management** in health and social care organisations across the EU by the definition of a **Blueprint**;
- **Create a platform** for **health and social care managers** for best-practices sharing share internationally best practices of Digital Transformation and identify champions and game-changers;
- **Digital Health Academy:** bring together existing EU initiatives for digital training of health/social care professionals (such as NHS Digital health academy) and define best content and change management programmes (online/offline);
- **Hospitals Data Sandbox**: bring together best-in-class and innovative healthcare providers willing to engage cooperation on data-driven innovation with research, SMEs/start-ups, and industry;
- **Design a vision of the "Future Health"**: design a futurist patient experience in a short format and disseminate it to specific audiences (politicians and policy-makers, hospital managers, healthcare administrations…)

Data Governance

New approaches should be developed to ensure the **EU citizens' control of their personal data and its safety and security**. Depending on Member states, healthcare systems and local laws, the governance of personal data is managed by different stakeholders and different organisations with different rules. The role of Member states and regions should not be to compete with the private initiative but define a framework and data governance principles. Nowadays, **citizens wish to be in control and decide where, when, who and what about the use of their data**. Several initiatives[28] have emerged recently in Europe, sometimes led by the public sector, sometimes private or citizens' initiatives in order to offer solutions for such a control, such as the **health data cooperatives**. It is now important to bring together these initiatives together in order to collect the proof of concept and define best practices and principles or guidelines.

Trust is a major stake. Governments and citizens groups can secure these new models but also technologies, such as Blockchain, could help to build trust bringing more (cyber-)security around personal data. The **right balance between regulation and innovation** should be defined. **Incentives for citizens to share their personal data** is also a challenge. A significant work has to be done on the **"monetisation" models**, not only around financial incentives but also around free services that could be provided to the citizen, bringing her/him actionable information based on her/his data, in order to (self-)manage her/his health and wellbeing. Data are not limited to healthcare systems data but refers also to Social Care and other Personal Data.

We should also **associate the EU citizens** to this data-driven innovation process**, raising awareness about the benefits of data sharing** for research purpose and healthcare services improvement, such as it has been done around blood or organs donation. Ensuring security of these personal data, the openness of such systems should be also ensured to make them available (with anonymization processes) for research and innovation. These initiatives should also integrate dynamic consent models, engaging a continuous dialog with citizens.

The DHS Task Force 2[29] is focused on these topics. Its aim is to develop **citizen-controlled data governance models** and drive a specific work around the **Data Donation**.

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[27] Report DHS TF4 on models, methodologies and best practices for change management in healthcare http://c.ymcdn.com/sites/echalliance.com/resource/dynamic/blogs/20180310_022148_23680.pdf

[28] See several initiatives: http://midata.coop, https://www.healthbank.coop, https://mydata.org

[29] See DHS Task Force on Citizen-controlled data Governance, Tallinn, oct2017, https://www.eiseverywhere.com/file_uploads/9f38cacef87cef33c9e77ae300c27b40_angela-brand_DATA-DONORS.pdf

Education and Training

The Digital Transformation of healthcare systems in Europe will be possible if it is enabled by **digitally-ready health and care leaders and digitally-ready citizens**. This means that we have to develop across Europe education and training programmes and materials both for professionals and citizens. The professionals need to be fully aware of the use and the potential of digital technologies to support their work. The programmes should target all health and care workforce including managers, decision-makers, clinicians, carers, support staffs, etc.

The DHS Task Force 4 about Digital Transformation brings together several initiatives across Europe, such as the NHS Digital Academy[30] in UK, or the programmes developed by Erasmus University in the Netherlands or the Hospital Clinic and the TicSalut Foundation in Spain. A collaborative work will be launched in order to share content, best practices, materials to define common standards and guidelines together. This will also be disseminate to other locations to set up new education and training programmes based on the same principles, facilitating the mobility across Europe of the health and care workers.

Also, the education and health literacy of EU citizens (including patients, carers and families) is an important challenge and the mission, in its relation with the European Society (see below section on Public engagement), will contribute to this objective linking the activities of DHS Task forces 2 and 4.

Health in All Policies

The mission aims to connect 100 million Europeans which are interacting with their healthcare systems and public services at different levels. Each level produces, manages and has access to different type of data. Regarding the transformation of health and care systems, decisions rely on national, regional and local policy-makers, who have to be supported in their choices by reliable information about innovative models, organisations and solutions.

That's why it is important that the Mission, in a holistic approach, aims to involve at the same time, member states, regions and cities, facilitating cooperation and consistency. The Mission will support bridges and coordination mechanisms between several on-going initiatives such as for instance the eHealth Network[31] (Members states), EIP on Active and Healthy Ageing[32] (mostly regions), EU Urban agenda[33] (cities, working group on Future of health), EIP on Smart Cities[34], etc.

Market access and reimbursement models

To meet the current main paradigm shifts in healthcare (such as preventive vs curative model, personalised health, data-driven collaborative care, population health management…), effort have to be focused on **innovation in market access processes, business cases and reimbursement models**. For instance, the way we evaluate digital health solutions could not be the same as for drugs or traditional medical devices. The connectivity dimension leads to a dynamic care relationship with the patient and a collaborative approach where several professionals will intervene around her/him. Additionally, the pace of innovation in technologies is not adapted to market access processes defined by health authorities. Collaboration between Member states around **Health Technologies Assessment (HTA)** is

[30] https://www.england.nhs.uk/digitaltechnology/info-revolution/nhs-digital-academy/
[31] https://ec.europa.eu/health/ehealth/policy/network_en
[32] https://ec.europa.eu/eip/ageing/home_en
[33] https://ec.europa.eu/futurium/en/urban-agenda
[34] Reference on EIP Smart cities, http://ec.europa.eu/eip/smartcities/

an on-going work, and despite number of achievements and progresses, some issues remain in Europe (*Impeded and distorted market access, duplication of work for national HTA bodies, unsustainability of HTA cooperation*[35]) and, as underlined in a recent communication[35], more efforts are still needed to reach a real single market in this domain.

Research activities and dialog between public authorities, demand side and suppliers should lead to the **definition of new assessment models**. This dialog could be inspired by international experiences such as the *Pre-Cert Pilot Program*[36], developed by the US Food and Drug Administration (FDA), which aims to assess the safety and effectiveness of software technologies without inhibiting patient access to these technologies.
In terms of reimbursement models, the Fee-for-Service (FFS) model, where services are unbundled and paid for separately, and which is the one mostly adopted in Europe, is creating negative incentives (increase prescriptions, consultations and treatments) and is not adapted to prevention or self-management approaches. Here also, new models have to be defined, focusing on outcomes instead of activity, e.g the **outcomes-based** or **value-based models**. The outcomes could be evaluated from a personal (patient) point of view, or related to clinical/health or social outcomes. Another promising way deployed in USA and currently analysed in several EU member states is related to **bundled-payment**[37], kind of intermediary model between FFS and capitation, which would reimburse the health and care providers "*on the basis of expected costs for clinically-defined episodes of care*"[38].
In some cases, when the impact and the results of an innovative interventions is difficult to forecast, **risk-sharing** models or **alliance contracting**[39] could then appear, where the risk could be shared between the healthcare providers, the public administration, the payer and the supplier of the technological solution (sometimes a 3rd party investor is involved like in the example of Social impact bonds).
The Mission aims to collect existing knowledge, disseminate/share recommendations and examples or case studies and organise the dialog between all stakeholders (decision-makers, demand and supply side) to **implement such innovative models across Europe**.

[35] Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU, COM(2018) 51 final
[36] FDA website, https://www.fda.gov/MedicalDevices/DigitalHealth/DigitalHealthPreCertProgram/default.htm
[37] Journal of American Medicine Association. (JAMA), The Next Generation of Episode-Based Payments, A.S. Navathe, https://jamanetwork.com/journals/jama/article-abstract/2629135?redirect=true
[38] Miller HD (2009). "From volume to value: better ways to pay for health care". *Health Aff (Millwood)*. **28** (5): 1418–28
[39] NHS England guidance document on Alliance contracting, https://councilfordisabledchildren.org.uk/sites/default/files/field/attachemnt/Alliance%20Agreement%20Guidance.pdf

Citizen Engagement / Empowerment

The Mission **100 Million Digitally Connected Healthy EU Citizen is about people, about the whole European Society, about each citizen**.

This moonshot should be an objective for policy-makers, scientists, the industry, etc. but also for **European citizens**, **positioning at the centre, the EU Society and the European values** such as human dignity, rights and freedom.

It targets both the **engagement and commitment of all EU citizens in this moonshot objective of 100 million people connected** for the benefit of the whole society, and also to **empower these citizens to become healthier**. That's why all the activities described above should be strongly linked with the public, **bringing information and seeking the society's responsibility**.

The Mission and each research and innovation project or support activities should look for the **involvement and participation of citizens**, and **continuously seek the Society's feedback** of its meaning, its impact and the further needs serving citizens' interests. Innovative mechanisms of consultation or **activation of collective intelligence**[40], such as design thinking and participative democracy approach (enabled by digital) will be developed to ensure this permanent link. A part of the review or evaluation of research and innovation project could be dedicated to citizens' representatives. In the same way, these representatives could be involved in the definition of work programmes and calls for projects.

Lifestyle-related health conditions are representing 80% of the financial burden on our healthcare systems. Medicine can still progress but to tackle this challenge, we collectively need that each individual adopts healthy lifestyle and habits. The 1st step for this is the **health literacy**. By creating communications channels in direct link with EU citizens, by using most recent technics of digital marketing, and coordinated with the supportive measures around

[40] See the example of Assembl project, http://assembl.bluenove.com/en/

Education and Training, the Mission will design and disseminate educational content about health and wellbeing via partnerships with public and private organisations.
As mentioned in the Research and Innovation section, this Mission should reflect the **EU society mind set shift** about **the need and the right** at the same time that **each citizen can control her/his data** and partially self-manage her/his condition.

Also, this **ambitious target of 100 million Europeans** will obviously build on the existing healthcare systems information systems and the existing research/innovation initiatives but will also need to communicate with the Society about the "why" and the "how" of this ambition. As it is done for health research purpose (supporting the research against cancer, HIV…) or for care services improvement (organs or blood donation), the Mission proposes to set up across Europe **Data Donors campaigns**. These campaigns will explain to citizens the benefits for the Society as a whole, and work on incentives models to motivate citizens to share their data through different way (see above on Data Governance). Europe needs this united and collective work to contribute

- the improvement of healthcare services,
- the research and the development of new and innovative treatments and interventions for healthier EU citizens.

Finally, the Society should be able to **monitor and assess the Mission**, its impact and potentially identify gaps with the citizens' needs. The Mission will set up a number of **Key Performance Indicators** (KPIs) and publish these regularly (open data), supported by projects descriptions and case studies. The indicators could be related to the countries/regions having Digital health strategy, the EHR coverage rate with or without citizens' access, the number of countries/regions with a legal framework for digital health and secondary use of data, with open data systems, the progress on EU interoperability framework, the map of past and upcoming investments by public organisations in Digital health, number of data donors campaigns, etc.

Digital Health Infrastructure

The Mission will build upon the existing infrastructures in Member states and region, but also at the European level, in particular around the **Connecting Europe Facility**, making available public open data but also developing several services such as eID, eSignature, Safer Internet and for eHealth, the ePrescription/eDispensation, the Patient Summary or supporting the European Reference Networks.

Within the Digital Health Society group, we have nevertheless identified several Member states and regions having detected needs for Digital health infrastructure. Some are planning to invest over the next years in this kind of infrastructure to modernize their healthcare system. These investments could cover:

1. Internet backbone
2. Fixed Broadband
3. Mobile Communications
4. Network infrastructure (wireless and spectrum)
5. Data Centres
6. Cloud Computing
7. Platforms
8. Software Applications
9. User Devices
10. IOT
11. Education and Training for workforce and citizens
12. Population Health management platform

Required to fully deploy and scale-up innovative solutions for health and fully digitise our European healthcare systems, the Mission and the stakeholders participating in it would benefit from the creation of a **European Fund** to support **these investments in Digital Health Infrastructure**.

the digital health society

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