European ethical principles for digital health

Supportive document V2

- Updated version -

An initiative of the French Presidency of the Council of the European Union
#PFUE2022
driven by the eHealth Network

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Editorial

Digital health improves the health life cycle, from prevention through diagnosis to treatment, monitoring, and management of health and lifestyle. The digitalisation of the healthcare sector allows for better care and empowers individuals through better control of their health data.

Yet digital health also comes with questions and concerns and building trust is key to enable its growth. For example, while the COVID pandemic has confirmed the important role of digital health, the experience of the digital Covid certificate (EU DCC) has also highlighted the need for an ethical basis. Hence, it is critical that the development of digital health, and the issues of strategic sovereignty that it carries, are included in a framework of humanist and civic values.

With the strong support of Sandra Gallina and her team at the DG Santé, we have collectively built and adopted in record time the European ethical principles for digital health. The Commission and Member states representatives launched the European ethical principles for digital health on February 2nd, 2022, during the ministerial conference "*Citizenship, ethics and health data*" organized in Paris, France.

A common will for clarity, legibility and understanding of the principles guided our work in order to promote the principle's adoption by the various actors and to establish compliance in an unequivocal manner.

We then needed to elaborate a companion document to build a common understanding of the principles. This supporting document offers detailed explanations of the ethical principles and use cases provided by member States. This first version of the document is the result of a novel collaborative exercise by all the representatives of the member States within the eHealth Network.

This document will be continuously improved through an iterative process and consulting with all stakeholders, in particular European citizens.

This approach will allow the ethical principles to become a living reality for digital health in Europe. The challenge is essential to support the deployment of digital health and a European health data space that is trusted by and acceptable to all Europeans. Without trust, citizens will not use digital health. The strong involvement of each and every one of the Member states representatives over the past few months has made all this possible. For this, we are deeply thankful. Thank you so much to all the Member states for their commitment!

Let's keep moving forward together and build an ethical and trustworthy digital health!

Paris June 2nd 2022

Laura LETOURNEAU
Digital Health ministerial Delegate
French Ministry of Health and Prevention

Executive Summary

During his inaugural speech of the French Presidency of the Council of the European Union (PFUE) on December 9, 2021, Emmanuel Macron, President of the French Republic, defined the strategic orientations for the upcoming French Presidency of the Council of the European Union with three main principles: strength, relaunch and sense of belonging. He called for Europe to build the next stages of a European ambition based on shared European values.

This approach is particularly relevant for digital health, as illustrated by the recent Covid-19 pandemic. With the acceleration in the use of digital health in all EU Member States and beyond, it has become essential to formalize a set of European values to condition its future development and deployment, while integrating the search for sovereignty in the European approach and method.

Preparatory legislative work on the European Health Data Space regulation commenced under the French EU Presidency. This new regulation addresses the main uses of health data, ranging from primary use (in the context of the provision of health care and patient healthcare trajectories), secondary use of data (re-use of health data for research, innovation and policy-making) to the re-use of health data from medical devices or wellness apps. This regulation aims to answer the expectations of citizens to track and control the use of their own data and meets the needs of European stakeholders to access and re-use health data for public policy, research and innovation. The regulation will have strong impacts on the functioning and operating of digital health and the health data ecosystem both at European, national and regional levels.

Due to its wide scope, the proposed regulation will have to be developed and implemented based on the trust of European citizens. The recent experience of the EU Digital Covid Certificate (EU DCC[1]) has demonstrated that a citizen-centred approach can work effectively in practice. The work of the EU DCC has indeed opened discussions on fundamental European values and ethics, with the EU DCC technical architecture following these requirements. This ethics-based approach is unique to the European Union and explains the success of the EU DCC, which has set a global standard for more than 70 countries and territories across five continents. This success story has set the bar high for policy-makers to choose a digital health model based on ethics, a sine qua non condition for moving forward.

Considering this experience and as part of its role and responsibility, the French Presidency of the Council of the European Union has decided to formalize a set of ethical values for the development and deployment of digital health. This approach, based on three pillars: ethics, interoperability and security, has been successfully implemented for more than three years in the national digital health roadmap in France. EU Member States and the European Commission recognized it as a prerequisite to pave the way for the new regulation on the European Health Data Space.

Building on the proposal from the French EU Presidency, eHealth network representatives developed and discussed in the very first weeks of the French EU Presidency, European ethical principles for digital health, then unanimously adopted them on January 26, 2022. Their aim was to express clear, simple, and self-explanatory principles in a direct and straightforward way, to be understood by all.

The European ethical principles for digital health were unveiled during the high-level PFUE Ministerial Conference "Citizenship, Ethics and Health Data" on February 2nd, 2022. Health Ministers from EU Member States and high-level representatives of the European Commission committed to being involved in the next steps to implement these principles in order to secure the acceleration of digital health uses based on a strong ethics framework.

Technical discussions in the eHealth network related to European ethical principles for digital health also stressed the importance of having a supportive document to explicitly explain each principle.

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021R0953

The purpose of the present supportive document is therefore to share all required definitions to ensure a common understanding of the principles. This document is mainly based on specific use cases and practical examples from EU Member States illustrating each of the principles.

This document is a 'living document'.
It will be reviewed and updated regularly, to mirror developments in digital health as well as the continuous improvement of digital health quality.

The document is organized in three parts:

1. For each principle, a **detailed explanation** is provided.
2. Each principle is then illustrated by **concrete examples** and use cases based on the experience from Member States.
3. An overview of the links between the principles with existing EU-level regulations and a glossary of terms to highlight already existing **regulations** pertaining to the European ethical principles for digital health.

Before unveiling the proposed regulation for the European Health Data Space, the European Commission reviewed the text in order to ensure its consistency with the European ethical principles for digital health. This provides a base for further implementation.

In line with the January, 26, 2022 adoption of the European ethical principles for digital health, the next steps in preparing for communication and governance around their implementation are also annexed to this document. This document includes macro-planning to ensure that concrete actions will be undertaken by all EU Member States and the European Commission, under the guidance of the EU Presidencies of the Czech Republic and Sweden, to ensure that all future digital health regulations, developments and deployments will be compliant with European ethical principles for digital health.

Implementing the European ethical principles will enable digital health ecosystems at both national and European levels to take ownership and engage in the implementation, while communicating all actions transparently. This will ultimately maintain and foster the trust of all EU citizens in digital health.

A consultation with the digital health ecosystem stakeholders (digital health industry, user associations, health professionals to cite a few) will allow us to compile a **collection of best practices** highlighting existing actions and bottlenecks in the implementation of each principle. **A large-scale consultation of EU citizens** will follow, in order to obtain feedbacks and insights from all citizens, thereby responding to the objectives set by the principles themselves.

This is not an exhaustive document and no EU country today can claim full compliance with all 16 ethical principles. We see this as an opportunity for continuous improvement. All digital health stakeholders from all countries are in a process of continuous learning, including developments in progress. Examples can be found in the field of artificial intelligence or several key regulations still under adoption such as the AI Act, the Data Act, and other European data spaces. This document seeks to harness the impact, opportunities and challenges that digital health services can provide to our health systems and citizens.

Therefore, a common and shared responsibility of all EU Member States and the European Commission to regularly monitor progress on each principle implementation is essential. A first tool to support the assessment of collective areas of improvement, initiate a virtuous improvement roadmap at all levels, and monitor progress has been launched. In later steps and modalities of monitoring these principles will improve based on lessons learned.

The ultimate rationale is the recognition that the development, deployment and use of digital health in the EU can be supported and sustained only if based on a clear and trusted framework reflecting European ethical principles.

<u>Reading Note</u>

In order to take into account the many different organizations which are part of EU Member State health systems, we have chosen to use the terms "national or local" to include the scope of national strategies and initiatives, as well as local initiatives, whether they are regional, departmental, municipal, federal, or community-based.

Introduction to the European ethical principles for digital health

Digital health shall be used to protect health and well-being for all mankind and the biosphere.

Progress towards these goals will benefit from guiding European ethical principles in line with our European humanistic tradition and values. The framework includes European Ethical Principles for digital health organized around 4 ethical dimensions.

It is the basis of European citizens' trust in digital health. It is not a full inventory but it focuses on the main challenges faced today, expressed in a direct and simple way. It goes beyond security and interoperability requirements. The principles also carry the same intention as digital principles proposed by the Commission, focusing on digital health. Some of these principles already form part of existing laws or already inspire future laws at both the Union and Member State levels. However, in some cases, more needs to be done e.g., in terms of their adaptation to the needs of the individuals benefitting from digital health services, or their technical implementation in practice.

The European Ethical Principles for digital health will be reviewed on a regular basis in the coming years. A supporting document, detailing the principles, linking them with existing and on-going regulations and providing examples from national experiences will be provided.

European Commission and Member States commit to further explore and discuss actions to respect these European Ethical Principles in their actions on digital health, monitor progress, and review them jointly in due time.

The European Ethical principles for digital health are an initiative of the French Presidency of the Council of the European Union, #PFUE2022, driven by the e-Health Network

[This introduction was unveiled together with the European ethical principles on 2 February 2022.]

European ethical principles for digital health

European ethical principles were presented on February 2nd, 2022 following their adoption by EU Member States representatives, Norway and Iceland and the European Commission as part of the eHealth Network on 26 January 2022.

European ethical principles are organized around 4 dimensions:

- Dimension 1 : **Base digital health on humanistic values**
- Dimension 2 : **Enable individuals to manage their digital health and data**
- Dimension 3 : **Make digital health inclusive**
- Dimension 4 : **Implement eco-responsible digital health**

These four dimensions allow to embrace the full scope of ethics for digital health. Each dimension is detailed into four principles.

Inscrire le numérique en santé dans un cadre de valeurs humanistes ***Base Digital Health on humanistic values***
1. Le numérique en santé complète et optimise les pratiques de santé effectuées en présentiel *Digital Health complements and optimizes face-to-face healthcare*
2. Les personnes sont informées des bénéfices et des limites du numérique en santé *Individuals are informed about the benefits and limits of Digital Health*
3. Les personnes sont informées des modalités de fonctionnement des services numériques en santé et peuvent facilement paramétrer leurs interactions avec ces outils *Individuals are informed about the functioning of Digital Health services and can easily customize interactions with them*
4. Lorsqu'une intelligence artificielle est mise en œuvre, le maximum a été fait pour qu'elle soit explicable et sans biais discriminatoire *When artificial intelligence is used, all reasonable efforts are made to make it explainable and without discriminatory bias*
Donner la main aux personnes sur le numérique et sur leurs données de santé ***Enable individuals to manage their Digital Health and data***
5. Les personnes ont un rôle actif dans l'élaboration des cadres européens et nationaux du numérique et des données de santé *Individuals are actively involved in shaping the European and national frameworks of Digital Health and data*
6. Les personnes peuvent récupérer facilement et de manière fiable leurs données de santé dans un format couramment utilisé *Individuals can easily and reliably retrieve their health data in a commonly used format*
7. Les personnes peuvent facilement obtenir des informations sur la manière dont leurs données de santé ont été ou peuvent être consultées et dans quel but *Individuals can easily get information on how their health data have been or may be accessed and for which purpose*
8. Les personnes peuvent facilement et de manière fiable donner l'accès à leurs données de santé et exercer leurs droits, y compris leur droit d'opposition quand il est applicable *Individuals can easily and reliably grant access to their health data and exercise their rights, including objection when applicable*
Développer un numérique en santé inclusif ***Make Digital Health inclusive***
9. Les services numériques en santé sont accessibles à tous, y compris aux personnes en situation de handicap ou avec un faible niveau de littéracie *Digital Health services are accessible by all, including by people with disabilities or low levels of literacy*
10. Les services du numérique en santé sont intuitifs et faciles à utiliser *Digital Health services are intuitive and easy to use*
11. Les personnes ont accès à des formations sur le numérique en santé *Individuals have access to Digital Health training*
12. Les services numériques en santé proposent une assistance humaine lorsqu'elle est nécessaire *Digital Health services include support through human communication when needed*
Mettre en œuvre un numérique en santé éco-responsable ***Implement eco-responsible Digital Health***
13. Les impacts environnementaux du numérique en santé sont identifiés et mesurés *Environmental impacts of Digital Health are identified and measured*
14. Les services numériques en santé sont développés dans le respect des bonnes pratiques d'éco-conception *Digital Health services are developed in compliance with eco-design best practices*
15. La réutilisation et le recyclage des équipements informatiques en santé sont prévus *Re-use and recycling of Digital Health equipment is ensured*
16. Les acteurs du numérique en santé s'engagent à réduire leur empreinte écologique *Digital Health stakeholders are committed to reducing their ecological footprint*

I. Dimension 1 - Base digital health on humanistic values

Dimension 1 extends the fundamental principles of healthcare to digital health, in particular the fact that each person's needs have to be taken into consideration and that each person needs to be kept informed. This dimension is about respecting the right for individuals to have their digital health managed based on humanistic values, such as choosing options corresponding to their preferences, values, or life projects.

1) Digital health complements and optimizes face-to-face healthcare

Detailed explanation and underlying philosophical concepts

Digital health services are a complement to, and not a replacement for, analogue (non-digital) health services. The use of digital health services should not be compulsory for patients if "face-to face" services exist (e.g., for certain digital health new services such as telemonitoring, there is no in-person equivalent). Digital health services ought to be considered as a complement to optimize healthcare, e.g., using digital health services can optimize face-to-face healthcare. Teleconsultation should never be mandatory. Neither should digital health services. Individuals should have access both to face-to-face consultations and teleconsultation services. Neither face-to-face consultations nor teleconsultations should be imposed. Individuals should be given the opportunity to choose between both options.

The scope of this principle is mainly telehealth and teleconsultation. In order for teleconsultation to be ethical, the choice between teleconsultation or face-to-face consultation should always be offered to patients, with no negative impact on patient care, no additional delay to get the appointment, an appointment with the same health professional, and at no extra cost for the patient.

The concepts of autonomy and freedom are the basis of this principle.

« Is it the same today with digital and AI? Are we facing the end of the physician? This is one of the questions we must answer. » [2]

Jean Gabriel Ganascia
Professor at Sorbonne University, former President of the ethics committee of the French National Centre for Scientific Research (CNRS), France

Member states use cases

In Norway, citizens can choose between teleconsultations and face-to-face consultations, if the general practitioner provides such a service. Not all general practitioners offer teleconsultations, but the pandemic helped speed up the process of giving citizens access to teleconsultations. The price of the consultation is the same. Citizens can only choose the option of teleconsultation if a face-to-face consultation is not required. Typically, physical consultation is required for the first visit, and teleconsultation for follow-up consultations. It is also possible to book and perform teleconsultations through the national health portal Helsenorge.no.

Spain is a decentralized state with regards to the organization and provision of healthcare. The deployment of healthcare services depends on the Regional Healthcare organizational levels. For example, there is a project to implement teleconsultations in the Madrid Community based on two tools. Today, telematics appointments through which healthcare professionals can perform consultations with citizens are via telephone. This approach, used during the COVID-19 pandemic has been maintained post-pandemic. Madrid's Health Services also provide an application called "*Mi*

[2] Ministerial conference on citizenship, ethics and health data - February 2nd 2022
https://presidence-francaise.consilium.europa.eu/en/news/ministerial-conference-citizenship-ethics-and-health-data/

carpeta de salud" where patients can contact their medical centre for online consultations. In those two examples, the use of teleconsultation is the choice of the patient.

In Finland, provisions on electronic transactions (i.e. tele-consultation) are, as a general rule, permissible and not mandatory. Various alternatives must be offered to individuals. Authorities must provide the opportunity for electronic transactions, but individuals cannot be forced to use exclusively electronic channels. Implementation of the electronic transaction services involve special administrative requirements, such as the customer's right to appeal against an administrative matter.

In Italy, the National Health Service includes the provision of healthcare services in telemedicine. National guidelines for the provision of telemedicine services adopted in December 2020 establish that televisits should be limited to follow-up visits for patients who have already been diagnosed during a face-to-face visit.
https://www.salute.gov.it/portale/ehealth/dettaglioContenutiEHealth.jsp?lingua=italiano&id=5525&area=eHealth&menu=telemedicina
https://www.salute.gov.it/portale/e-Health/dettaglioContenutiE-Health.jsp?lingua=italiano&id=5525&area=e-Health&menu=telemedicina

In France, national health insurance regulates the use of teleconsultation. Health professionals using teleconsultation must be located near the patient's home. This location aims to make it possible to ensure regular monitoring of patient's health and to organize face-to-face consultations when needed. Teleconsultations and face-to-face consultations should be carried out alternately in order to ensure best quality and safety of care.
In France the choice between teleconsultation and face-to-face consultation is made by the patient, except in specific cases (clinical examination is needed, too many teleconsultations in a row, etc.).
https://www.ameli.fr/assure/remboursements/rembourse/telemedecine/teleconsultation

In Germany, citizens are entitled to use digital health applications. This is not mandatory, so citizens can choose between teleconsultations and face-to-face consultations. Both options are possible.

In Luxembourg, the National Health Fund (Caisse nationale de santé or CNS) has introduced the teleconsultation solution "e-consult" during the COVID-19 pandemic for all potential COVID-19 patients, in order to avoid physically moving. In the future, this solution will be extended to other use cases and the legal basis for telemedicine, which does not exist now, must be determined.
https://econsult.esante.lu

In the Netherlands, digital health is reimbursed the same way as physical care to a certain extent, depending on the contracts between health care insurers and health care providers. There is a national programme on outcome-oriented health care: personalised healthcare takes into account both digital and regular care options to strive for the best care plan for a specific patient.
https://platformuitkomstgerichtezorg.nl/themas/ict+en+toegankelijkheid/default.aspx

In Sweden, regions are responsible for healthcare and decide the actual setting for how digital services are to be used or offered. Regions determine any difference in patient fees between a face-to-face and a digital care visit.
In addition, general principles developed by the National Board of Health and Welfare can help determine when it is appropriate or not to use a digital solution according to the particular situation:

1. Any constitutions or current knowledge management prohibit a digital meeting or require a physical meeting.
2. The digital service is adapted to the individual patient's needs and conditions for using the service.
3. The caregiver has access to sufficient information about the patient's health condition and medical history in order to be able to provide good and safe care.
4. Necessary follow-up and coordination with other actors is possible.

A motto is commonly used: "*digitally when possible, physically when needed*".

In Portugal, the SNS24 includes a teleconsultation system and services, integrated into the RSE system (electronic health records system) called "RSE live".

In addition, the National Tele-Health Centre has been developing a telemonitoring solution which includes the development of a web-based interface for the health professionals (Telemonitorização SNS) and a mobile app for patients (Telemonit SNS 24). Currently, this system is being applied to congestive heart failure, COPD (chronic obstructive pulmonary disease), and post-COVID recuperation. However, it is mandatory that doctors carrying out teleconsultations are located near the patient's home.

With the exception of the following medical specialties (dermatology, physiology, neurology, cardiology, paediatric cardiology and pulmonology), initial consultation must always be face-to-face and subsequently, follow-up consultations can be carried out remotely.

http://www.cnts.min-saude.pt/wp-content/uploads/2017/03/Despacho-3570-2013.pdf

In Cyprus, telemedicine and all related services to citizens are regulated by the National eHealth Authority (NeHA) according to articles 3 and 16 of the national eHealth Law. In particular, an alternative must be offered to the patient when using telemedicine. In addition, telemedicine consultations, when appropriate, will be reimbursed in the same way as face-to-face consultations but not necessarily with the same amount.

Greek version (official) http://www.cylaw.org/nomoi/arith/2019_1_059.pdf

English version (unofficial)

http://www.neha.gov.cy/MOH/neha/neha.nsf/All/89E06920562BC292C2258767002F0A48/$file/59(%CE%99)-2019%20English%20Version.pdf?OpenElement

In Poland, patients may choose to have a face-to-face or remote consultation. All relevant information on the available digital services in the health area is accessible via individual Patient's Internet Account (patient's portal).

2) Individuals are informed about the benefits and limits of digital health

Detailed explanation and underlying philosophical concepts

National or local policies should inform the public about the benefits but also the limitations of digital health. In addition, initiatives to evaluate people's understanding of this information should be encouraged at local and national levels. Any update of this information should be made available. Furthermore, all digital health services shall provide education and information on their benefits and limits. When choosing digital health solutions, individuals have access to adequate, complete and understandable information about the characteristics of a service. This complete information shall be made available by digital solution providers and accessible to end users at the time they consider to use the digital service or not. National and local policies should promote that digital health solutions provide clear and transparent information about the benefits and limits to users.

The philosophical basis of this principle includes the concepts of autonomy, transparency and freedom. It aims at allowing for self-determination.

« European inhabitants are being more and more exposed. We have to work on digital literacy, we have to explain the possibilities, but also the threats of data being misused » [3]

Annemieke Alenius
Deputy General Director, Swedish eHealth Agency

« We have the ethical imperative to use health data for citizens and not to divert it. Health data must be used anonymously with a very solid legal basis including heavy penalties against misuse. » [4]

Frank Niggemeier
Head of department "Ethics in Health, Health System Advisory Board", Federal Ministry of Health, Germany

Member states use cases

In Portugal, citizens can get information about existing digital health services/systems/tools on national digital health platforms and networks (e.g., National Health Service, NHS and SNS24 websites and social network campaigns).
https://www.sns24.gov.pt

In Luxembourg, an information campaign led by the Ministry of Health to promote the benefit of the national electronic health record (Dossier de soins partagé (DSP), as well as the eHealth platform, was launched in 2020, but interrupted due to the COVID-19 crisis. This information campaign should continue in future, once the COVID-19 pandemic is over.
https://www.esanté.lu

[3] Ministerial conference on citizenship, ethics and health data - February 2nd 2022
https://presidence-francaise.consilium.europa.eu/en/news/ministerial-conference-citizenship-ethics-and-health-data/

[4] Ministerial conference on citizenship, ethics and health data - February 2nd 2022
https://presidence-francaise.consilium.europa.eu/en/news/ministerial-conference-citizenship-ethics-and-health-data/

In Germany, the implementation of digital health tools and services implies an important cultural change for all users (e.g., health professionals, patients). Therefore, Germany has put into practice dedicated support and communication for patients and health professionals regarding Electronic Health Records (elektronische Patientenakte - ePA). The support focuses on highlighting advantages of using ePA, as well as providing support for the use of these new tools.

In France, to promote use of digital health in a monitored and secure approach, the Ministry of Health has launched a communication campaign: "*For my health, I say yes to digital health*". Four videos depict the use of digital health tools in different care pathways, to illustrate the help and ethical guarantees it provides.
https://www.sante.fr/actualites/pour-ma-sante-je-dis-oui-au-numerique

In Italy, a national platform for the dissemination and governance of telemedicine is currently under construction. This platform includes a section dedicated to training and information for all stakeholders. Contents are provided in multimedia formats to facilitate communication on how to use telemedicine services and the treatment opportunities it offers.
Digital health page: https://www.agid.gov.it/it/piattaforme/sanita-digitale
EHR page: https://www.fascicolosanitario.gov.it/it

In Norway, the government has published "Digital throughout Life" and "Strategy to increase the health competencies in the public 2019-2023". There are several initiatives to make sure people are informed and understand both the benefits and limits of digital health.

Individuals in Poland are informed about the rules, benefits and limits of digital health on pacjent.gov.pl., which has more than 20 million users. The portal publishes articles written in a simple language; links to these articles are posted on Patient Internet Account (IKP). Any users can easily find this information. There are also descriptions of the functionalities available in mojeIKP mobile app.

3) Individuals are informed about the functioning of digital health services and can easily customize interactions with them

Detailed explanation and underlying philosophical concepts

People have the ability to control their level of interaction with health applications within the limits of their purpose. This setting must be easily accessible and easy to perform. Individuals must be autonomous to do so.

Individuals may wish to make an extensive or limited use of digital health. For example, the individual may choose to limit or even definitely cancel notifications.

Transparency and autonomy are at the heart of this principle.

Member states use cases

In France, "Mon Espace Santé" (MES) is a service provided by the French administration; it mainly offers a customizable health data space for primary use. The user can choose to share health data in this space to bring all their data together in a single place. Moreover, in order to be integrated into MES, third-party services must meet selection criteria, including the possibility for users to personalize the intensity of their interactions with the solution (e.g. set up of the frequency of notifications).
https://www.monespacesante.fr/

In Sweden, “1177“ is the main and nationally available healthcare portal where people can access their health and medical information as well as a number of services connected to their health. People can choose how much they want to use it, or how much they want to take advantage of the services available there.
There are instructions on the website 1177.se on how to use the services. One local municipality, Uppsala, has produced a YouTube video on how to access and find information on 1177.se
https://www.youtube.com/watch?v=eqyNoMW_d6Y

In Portugal, the Citizen’s Area of the National Health Service portal integrates electronic health records, facilitating the sharing of information between citizens, health professionals and public health entities. With the aim of providing several digital public services in one place, the Citizen’s Area allows, among other services, to:

- Schedule consultations of primary care, including tele-Health;
- Access real-time teleconsultations via the RSE (Portuguese Electronic Health Records platform) Live Platform, implemented throughout the NHS for primary and hospital health care;
- Consult exams;
- Request a digital declaration of attendance at a consultation;
- Activate electronic notifications (via SMS) whenever an accredited health professional consults the patient’s registered clinical information;
- Request an exemption from user fees and Renew chronic medication.

The patient can enable the sharing of his/her patient summary with the health professional. This can be done through the SNS24 omnichannel solutions or during a conversation with the health professional.

In the Polish Patient's Internet Account users can both get the relevant information on the digital services offered and customise the way they use it.

4) When artificial intelligence is used, all reasonable efforts are made to make it explainable and without discriminatory bias

Detailed explanation and underlying philosophical concepts

Best practices and recommendations to develop Artificial Intelligence-based digital health solutions that are ethical by design should be available at national or local levels. Such best practices should be made available to providers and developers of AI-based digital health services, to ensure that a particular attention will be paid to building a system that avoids any discriminatory, ethnic, or geographical biases.

- Developers and providers must therefore ensure the representativeness of the learning sample and the quality of data. Artificial intelligence should only be used when its added value is proved and when it does not cause any harm.
- National or local strategies should provide labels or certifications to testify that all reasonable efforts have been made to make AI explainable. What is explainable and what is not explainable should be made transparent on the day the proposed digital solution is placed on the market.
- National or local policies should require that providers using AI based digital health services inform individuals that they are interacting with AI.
- Human oversight should be mandatory and health professionals should be able to maintain their decisional autonomy.

The concepts of transparency, no harm and non-discrimination guide this principle.

« If there is a conclusion to this tale it is not only to anticipate fictitious fears but to observe the functioning of moving machines while remaining vigilant. We must have the courage to dismantle them if they reveal themselves harmful. » [5]

Jean Gabriel Ganascia
Professor at Sorbonne University, former President of the ethics committee of the French National Centre for Scientific Research (CNRS), France

Member states use cases

In Norway, the Ministry of Health and Care services has initiated a national coordination project on AI. The project guides and helps the health service so that it can better succeed with the introduction of artificial intelligence. Issues regarding regulation, privacy, information security, sharing of data, ethics etc. are addressed in different parts of the project.
It is common practice to include ethical considerations in medical research via the seven regional ethics committees (RECs). RECs process applications for research ethics pre-approvals and dispensation from the duty of confidentiality in research projects. Questions regarding AI and digitalisation are becoming more frequent.

In Germany, in 2021 the 3-years project German Israeli Health Forum for Artificial Intelligence (GIHF-AI) has been established to discuss the latest developments, regulations, and application of AI solutions with relevant experts in the health sector from Israel and Germany. Necessary quality, variety, and interoperability of health data to prevent different types of biases will be discussed.

[5] Ministerial conference on citizenship, ethics and health data - February 2nd 2022
https://presidence-francaise.consilium.europa.eu/en/news/ministerial-conference-citizenship-ethics-and-health-data/

AI Sweden, the national centre for applied artificial intelligence is jointly funded by the Swedish government, the government agency for innovation and other public and private partners. AI Sweden mission is to accelerate the use of AI for the benefit of the society, their competitiveness, and for everyone living in Sweden. To achieve this, they run projects of national interest in areas such as information-driven healthcare. To address ethical aspects in healthcare a number of checklists and guidelines for trustworthy and ethical AI have been produced. To help implementing these guidelines and putting them into practice AI Sweden is launching the Swedish AI Ethics Lab with the aim to help move AI ethics in Sweden from abstract guidelines to practical application.

The Ministry of Health just finished a program called 'data for health', providing information for capacity building and tools for the ethical use of AI in healthcare.
https://www.datavoorgezondheid.nl/documenten/publicaties/2021/01/15/handleiding-aanpak-begeleidingsethiek-voor-ai--digitale-zorg

In Spain, the National Artificial Intelligence Strategy aims to provide a reference framework for the development of an AI that is inclusive, sustainable and focused on the citizens: 16062021-Componente16.pdf (lamoncloa.gob.es)

PL has developed a National Policy for AI Development which strives for a responsible and ethical deployment of artificial intelligence.
https://aipoland.org/public-policy/

In France, the digital health ethics unit from the ministerial e-Health delegation has provided guidelines for the ethical use of artificial intelligence in health. The dedicated working group has promoted an ethics-by-design-based approach. In particular, the working group has offered a self-assessment of the measures put in place to deal with the risks of discrimination. For example:
"*Have you assessed the limitations of the composition of the datasets used? Have you thought about the diversity and representativeness of users in the data? Have you tested specific populations or problematic use cases?*"

Portugal as an integral member of UNESCO, signed the World Agreement on the Ethics of Artificial Intelligence (AI) adopted by the 193 Member States of UNESCO at the 41st Session of the General Conference on the 25th of November 2021. One of the defined principles is based on non-discrimination "*AI actors should make all reasonable efforts to minimize and avoid reinforcing or perpetuating discriminatory or biased applications and outcomes throughout the life cycle of the AI system to ensure fairness of such systems.*"
https://unescoportugal.mne.gov.pt/pt/noticias/acordo-mundial-sobre-a-etica-da-inteligencia-artificial The National Strategy for the Health Information Ecosystem 2020-2022 (ENESIS 20-22) aims at providing guidance on how to deal with big data in health within the existing legal and regulatory framework, secondary use of health data and promote the innovative use of artificial intelligence data science and technology across the health and public health sector for the benefit of society, individuals and the performance of the NHS, thereby meeting the needs of multiple stakeholders and being citizen-centralized.

II. Dimension 2 – Enable individuals to manage their digital health and data

This second dimension underlines the key notions of the GDPR[6] for digital health, such as the control or portability of individual's digital health data. This allows for a patient-centric approach and means that people are in control of access to and processing of their data, both in real life and in digital health governance. This dimension aims to harmonize the application of GDPR in the MS and contributes to making it a daily concrete reality in the field.

5) Individuals are actively involved in shaping the European and national frameworks of digital health and data

Detailed explanation and underlying philosophical concepts

Individuals are considered as partners at all stages of regulation, design and development of digital health services. Individuals should be represented in digital health governance organizations at national or local levels. Individuals should also be active stakeholders in all decision-making bodies in charge of digital health strategy. Digitalization should always be designed for the benefit of individuals.

As end users, individuals are involved in service definition, data collected validation and choice of data collection methods. They also actively participate in design and assessment phases of digital health tools and services. Public debates are organized to collect ground needs as expressed by people. These debates need to be taken into account to shape the European and national frameworks for digital health services that meet all expectations.

The underlying ethical concepts of this principle are universality and solidarity.

« It is not enough to involve patients at the end of the process, when technologies are already developed and resources have already been allocated."[…] "Otherwise the risk is that technologies won't be adapted. (…) There are minimal requirements which include digital literacy, health literacy, real means to participate and feel heard in governance to achieve trust so that participants feel safe and that their input is listened to. » [7]

Milka Sokolovic
Director General, European Public Health Alliance (EPHA)

« It is necessary to have appropriate legislation to further develop international data sharing for primary and secondary uses but including trusted representatives in the decision-making process, especially not-for-profit stakeholders » [8]

Yann Le Cam
Director and CEO, EURORDIS

Member states use cases

In Spain, citizens can submit suggestions, recommendations or complaints through channels established for these purposes. For example, citizens are represented in the Spanish Advisory National Health System's Inter-territorial Council:

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[6] General Data Protection Regulation (EU) 2016/679
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=EN

[7] Ministerial conference on citizenship, ethics and health data - February 2nd 2022
https://presidence-francaise.consilium.europa.eu/en/news/ministerial-conference-citizenship-ethics-and-health-data/

[8] Ministerial conference on citizenship, ethics and health data - February 2nd 2022
https://presidence-francaise.consilium.europa.eu/en/news/ministerial-conference-citizenship-ethics-and-health-data/

https://www.sanidad.gob.es/organizacion/consejoInterterri/organos.htm
Also, citizens can directly participate in the drafting of regulations, through channels such as this one of Madrid's autonomous Region: https://www.comunidad.madrid/es/participacion/participacion-ciudadana?page=40 or this other one for the Ministry of Health:
https://www.mscbs.gob.es/normativa/consultas/consultasCerradasSan.htm
Finally, depending on the content of the regulation, Spain's public health authorities (and their political representatives) contact relevant stakeholders (such as patient's associations) to gather their opinion.

In Italy, citizens' associations are participating together with other stakeholders in defining the characteristics of the national platform for the dissemination and governance of telemedicine. In particular for information services about the use of telemedicine solutions.

In Germany, the Coalition Agreement of the German Federal Government (published in December 2021) foresees the development of a national digital health strategy putting in the centre the perspective of the users of digital health solutions.
There are several initiatives, through surveys or round tables, to question patients, family carers and health professionals about their needs and expectations related to care to identify required changes to be implemented (e.g., through AI, remote monitoring and, more broadly, all digital solutions).

In France, at the end of 2019, 5 citizen workshops were organized to give French people a voice on their vision of digital health. Workshops involving around fifty citizens with representative profiles of French society, were organized all around France in different areas to work on topics such as the protection of personal data or access to digital health, etc. This process was instrumental in defining the strategy as workshop after workshop, citizens collectively created the citizen health data space "Mon espace sante", the cornerstone of the digital health strategy now implemented at national level.
A citizen committee (comité citoyen) is part of the digital health governance and involves 30 citizens chosen to reflect French citizens diversity. This committee made recommendations to improve "Mon Espace Santé" and all recommendations were accepted.
Furthermore, a public event, citizens' meetings (Assises Citoyennes) were initiated in 2020, and are an unmissable health democracy event. They provide an opportunity for citizens, the Ministerial Delegation for Digital Health and its partners to review the state of play and work carried out throughout the year. They demonstrate the growing involvement of citizens in their digital health journey.
https://esante.gouv.fr/lagence/comite-citoyens

In Sweden, patient associations or patient interest groups are part of the democratic process. Indeed, they are consultative bodies for any laws or regulations that may affect them.
The Swedish e-Health Agency, as well as other agencies, has set up a reference group involving representatives from patient associations and from a pensioners' association. This reference group is being consulted about the interfaces and functionality of services that the agency provides to citizens.

The Norwegian Directorate of e-Health has established three different national advisory boards, one for governance, one for prioritization and one for different professional issues concerning e-health. Healthcare professionals and citizens are represented at all levels. The largest patient interest organization is representing citizens in these national boards.

Citizens are also invited through public hearings to comment on national e-health strategy, and it is common practice to involve users in workshops when developing new digital health services.

In the Netherlands, there is a formal consultation structure on health information and information exchange policy that includes all stakeholders, including patients.
https://www.informatieberaadzorg.nl/over-het-informatieberaad

In Finland, citizens or 'customer' boards are involved in the development of Kanta, national information system services (by Kela). Regional/local health care experts, national authorities and organizations are also involved in the collaboration in developing e-health services (by Kela, THL).
https://thl.fi/documents/920442/2816495/THL-Maarays_4-2021_Sote-tietojarj_Luokittelu-Sertifiointi.pdf/1d2fb82d-5bc1-e6b5-0bbc-803b220a138a?t=1638962140075

In Portugal, the national strategy for the development of digital health services ensures a focus on the citizen. PENTS is an example developed through a strong national stakeholder's engagement, in particular citizens and health professionals. PENTS National Strategic Tele-Health Plan - is a proposal from the Shared Services of the Ministry of Health, E.P.E. (SPMS) under the coordinating scope of the Portuguese National Centre of Tele-Health (CNTS) which has the objective to define a strategy to leverage the telehealth, taking advantage of Information and Communication Technologies (ICT), as valid means in the management of health and its services.

In Belgium, to ensure that all healthcare actors can trust and cooperate in the digitalization of healthcare, the eHealth platform is managed by representatives of these actors: healthcare providers, healthcare institutions, health insurance funds, patients, federal public institutions competent for aspects of healthcare and, since the cooperation protocol, also representatives of Communities and Regions competent for aspects of health policy.

All digital services in Poland are designed from the patient-centric perspective. Public authorities invite individuals to contribute to the digital transformation of healthcare (by submitting the innovative concepts or solutions). In addition, at national level, individuals can participate in the legislative process of the project through public consultation.

In Cyprus, the national strategy for the development of digital health services ensures to focus on the citizen following a citizen-centric philosophy as dictated by the National eHealth law N.59(I)/2019 which is currently implemented by the National eHealth Authority.
Their National eHealth Law provides the means for making the citizens actively involved in shaping the national framework and principles of digital health. The citizen-centric orientation of the law is helping in this direction.

In Luxembourg, all stakeholders have been involved in eHealth platform as well as all e-services development and implementation since the beginning in 2013. This is also valid for all other e-services contained, as for example the electronic health record (DSP). As a matter of fact, the main stakeholders are members of the board of the eHealth agency group of common interests too (G.I.E. Agence eSanté Luxembourg).

6) Individuals can easily and reliably retrieve their health data in a commonly used format

Detailed explanation and underlying philosophical concepts

This principle ensures the effectiveness of the right to data portability. In order to allow for data portability, the main requirement is technical and relies on the implementation of interoperable frameworks. The national or local digital health strategy should ensure the use of interoperable data models (Common data models, such as OMOP or HL7 CDA/FHIR) and of interoperable semantic coding frameworks (ICD, LOINC, SNOMED CT). People need to be able to extract any data from any digital health solution. The extraction should be possible in an actionable format (i.e. with the ability to print and read the data) and in a format that allows for data processing by a different digital health solution. For instance, individuals should be able to retrieve their data from a given digital health service and re-inject it in another digital health service as appropriate (in particular in the case of a change of health professional or to get a second opinion). Individuals should be able to extract their health data autonomously. This means they should be able to do it easily without any help from a third party.

Autonomy and freedom are the foundation of this principle. It aims at **self-determination**.

« It is the guarantee of the emancipation of individuals » [9]

Sandra Gallina
European Commission, DG SANTE, General Director

« This concretely means that access to health data is simple, reliable and fast and that the format is usable and reliable » [10]

Vincent Olivier
Digital health journalist - conference moderator

This is also consistent with the digital decade objectives of the European union. Indeed, the **2030 Digital Compass Communication,** followed by the proposal for the "Path to the Digital Decade" Policy Programme **sets the following targets in the Union by 2030:**

(4) Digitalisation of public services:

(a) 100% online accessible provision of key public services for Union citizens and businesses;

(b) **100% of Union citizens have access to their medical records (electronic health records (EHRs));**

(c) At least 80% of Union citizens use a digital identification (ID) solution.

Member states use cases

1/ Systems interoperability use cases	*2/ Use cases relating to the effective portability of health data for patients*
In Germany, since January 1, 2021, the statutory health insurance companies are obliged to offer their policyholders a cross-institutional standardized electronic	In the Netherlands, 'personal health environments' enable patients to access and share their data with health professionals. Related costs for

[9] Ministerial conference on citizenship, ethics and health data - February 2nd 2022
https://presidence-francaise.consilium.europa.eu/en/news/ministerial-conference-citizenship-ethics-and-health-data/

[10] Ministerial conference on citizenship, ethics and health data - February 2nd 2022
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health record (elektronische Patientenakte –ePA). Private health insurance companies can also offer them an electronic health record. The electronic health records must be developed according to the standardization and interoperability specifications of gematik and approved by Gematik.
https://www.gematik.de/anwendungen/e-patientenakte
The use of the electronic patient record is voluntary for the insured. Due to the technical standardization requirements (eg IHE, XML), the electronic health record can be used in all medical practices, pharmacies, hospitals, etc.

In France, applications must comply with a national technical policy including an interoperability framework to be included in the personal health space "Mon espace santé". Compliance with international standards is part of the technical doctrine.
https://esante.gouv.fr/sites/default/files/media_entity/documents/doctrine--technique-du-numerique-en-sante_version-2020_finale.pdf

In Italy, the electronic health record (EHR) is fed by local / regional systems with data and documents that comply with the international standards (e.g. HL7 CDA2) to ensure interoperability and portability between different systems.
Digital health page:
https://www.agid.gov.it/it/piattaforme/sanita-digitale
EHR page: https://www.fascicolosanitario.gov.it/it

In Luxembourg, a national e-health platform is being deployed since 2013 and involves a specific technical policy including an interoperability framework that all third-party applications must comply with. Luxemburgish specific technical framework is not public for security reasons.

In Belgium, in order to enable the electronic exchange of decentralised personal health data, standards and specifications have been defined according to which data are stored and communicated. In addition, mandatory standards exist for software packages; healthcare providers and institutions must comply with them. Existing norms, standards and specifications are based as much as possible on international references and relate, for developing such environments are currently partly reimbursed to the providers by the government as it is deemed very important for everyone to access their health data. General Practitioners are obliged since July 2020 to grant patients access to their data digitally either via a patient portal provided by the GP or via a 'Personal Health environment'.

In France, Mon Espace Santé allows patient to upload or download any document available within their personal health space.
https://www.monespacesante.fr/questions-frequentes/gerer-mes-documents-de-sante/3

In Portugal, most health data can be retrieved from the national health portal but not all data are available in the PT App (SNS24 App) for extraction - reinjection . Some features of personal health data are conceived to be downloaded in a common standard. Others are not meant to be extracted and/or reinjected.

In Finland, the Customer Information Act gives individuals the right to share their patient information with, for example, service providers in other sectors, authorities or welfare applications/ platforms of their choice.

All digital health services in Poland are GDPR compliant. Citizens have access to their health data and are entitled to receive a copy and information about processing.

The central patients' portal in Croatia named Health Portal is available to all Croatian citizens directly through the national e-Citizens System https://portal.zdravlje.hr
The system is accessible via authorized access using highly secure national e-Citizens authentication methods and credentials (National Identification and Authentication System - NIAS).
Patients are able to see all prescribed and dispensed medications from primary care, laboratory results from biochemistry labs within public primary care network, medical reports from the visits to GP practice and consultation notes from hospitals and outpatient facilities

instance, to quality, security, semantic and content interoperability.	(note however that the latter is not fully comprehensive documentation set, nor it includes historical records prior to system going live), and bookings done with specialized services in hospital care. COVID-19 section of the portal includes test results and vaccination data, as well as the option to place an order for COVID-19 vaccination by choosing the time and place. The system is almost fully read-only, with interactive functions like messaging of patients with their GPs and other chosen doctors of dental medicine and gynaecology, as well as requesting e-prescriptions for chronical condition. In Spain, the Ministry of Health cooperates with the regions (in charge of health) in the National Healthcare Records project (HCDSNS - Historia Clínica Digital del Sistema Nacional de Salud). All Spanish citizens have access to their electronic healthcare records through the regional nodes: https://www.sanidad.gob.es/profesionales/hcdsns/Accesos_HCD_SNS.htm In all public and private healthcare providers, citizens can exercise the right of portability by requesting their healthcare records and other portable information (such as clinical tests on a CD or DVD). Spanish regulations make it mandatory for organizations that collect health documents to keep health documentation for a period of time.

7) Individuals can easily get information on how their health data have been or may be accessed and for which purpose

Detailed explanation and underlying philosophical concepts

Access to any health data should always be tracked. Tracking allows to know who accessed which information and when. Such information should be made available to individuals through dedicated technical support.
Individuals should be informed about the primary and secondary uses, if any, of the processing of their health data. Digital health providers are required to guarantee individuals did actually understand the information provided regarding their health data processing.
For every data processing event, finality of primary and secondary use is made available to individuals. If there is no legal basis for data processing, informed consent is mandatory and must be recorded by digital health providers. Protection against data misuse must be ensured in any case.
In the case of secondary use, there should be a clear difference between secondary uses serving the public interest and secondary uses serving private interests including data trading. Individuals should be informed about this difference and data providers are required to guarantee individuals did actually understand the different types of re-uses.

This principle is based on the philosophical concepts of **autonomy** and **transparency**.

« To promote citizen's trust, it is essential to gather complete and transparent information on what is collected (what), how to proceed (how) and the reasons for the collection (why). It is also about showing what society, as a whole, gains through better knowledge of health issues. » [11]

Christian Léonard
General Manager, Sciensano, Belgium

« Regarding rare diseases studies in Europe: feedback on the use of health data and the outcome of health projects and research projects must be guaranteed for all participants. » [12]

Yann Le Cam
Director and CEO, EURORDIS

Member states use cases

In Germany, access by doctors, pharmacists, psychotherapists and other health care providers is only permitted with the consent of the insured person and technical data release via PIN. Every data-access is logged. The health professionals that, with the consent of the insured person, may access the data in the electronic patient file are defined by law. For access, health professionals have to authenticate themselves using an electronic health professional card or professional card.

In Norway, it is possible for the citizens to know who have consulted their data but also when, where and what institution the person works at. This information is accessible instantly.

In Italy, each digital health system that processes health data on an individual level must provide all the information required pursuant to articles 13 and 14 of the GDPR 2016/679. Electronic health records are automatically fed with data and documents produced during the healthcare life of all patients. However, each citizen can decide who can access her/his EHR and whether or not to receive notifications for access by authorized people.
https://www.fascicolosanitario.gov.it/it

In France, "Mon espace santé" allows users to see who has consulted their documents and profile data by simply checking online activity history.
https://www.monespacesante.fr/questions-frequentes/gerer-mes-documents-de-sante/6

In Sweden, when using the main nationally available health care portal, 1177, individuals can directly see who has had access to their information with date/time of access and work location of health professional.

In Portugal, when using the national SNS 24 healthcare portal, individuals have access to a section called "Who saw my information". This section allows individuals to consult information on which health professionals accessed their

[11] Ministerial conference on citizenship, ethics and health data - February 2nd 2022
https://presidence-francaise.consilium.europa.eu/en/news/ministerial-conference-citizenship-ethics-and-health-data/

[12] Ministerial conference on citizenship, ethics and health data - February 2nd 2022
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clinical information. Information provided is: institution, health professional and scope of access. This functionality was designed in conjunction with the National Data Protection Commission, which authorized the terms of data processing carried out through this platform in compliance with privacy and security conditions required by this entity.

In Spain, the Ministry of Health cooperates with the regions in the National Healthcare Records project (Historia Clínica Digital del Sistema Nacional de Salud / HCDSNS). All Spanish citizens have access to their electronic healthcare records through the regional nodes:
https://www.sanidad.gob.es/profesionales/hcdsns/Accesos_HCD_SNS.htm
In this system, patients can view who accessed their health data.
Patients can always request the list of access events to their clinical data by all healthcare providers for primary purposes. For most secondary uses the basis of personal data treatment is explicit consent. Some exceptions exist with an explicit legal basis, such as secondary uses for public policy definitions or the management of public healthcare institutions.

In Cyprus, a citizen will receive a notification when a healthcare provider accesses their health records kept in the central databank regulated by the National eHealth Authority. The procedure is fully explained in the National Law, Article 24.
Greek version (official) http://www.cylaw.org/nomoi/arith/2019_1_059.pdf ,
English version (unofficial)
http://www.neha.gov.cy/MOH/neha/neha.nsf/All/89E06920562BC292C2258767002F0A48/$file/59(%CE%99)-2019%20English%20Version.pdf?OpenElement

Finland has certain requirements for applications related to their national information system services (Kanta). The service provider ensures that confidential personal data are protected, for example by encrypting the communication, and that the receiving person has the right to see the information transmitted. Besides phone or post, a possibility is to use Suomi.fi/viesti –service for communication. In addition, the person consents to the disclosure of his or her data, if necessary and can access it.
https://thl.fi/documents/920442/2816495/THL-Maarays_4-2021_Sote-tietojarj_Luokittelu-Sertifiointi.pdf/1d2fb82d-5bc1-e6b5-0bbc-803b220a138a?t=1638962140075 https://www.suomi.fi/messages

In Luxembourg, the eHealth platform gives all required information regarding users of data. While deploying the national electronic health record (DSP) for the entire population in Luxemburg, citizens got a e-letter containing activation codes, all necessary information about the functioning of their electronic health records, about the national eHealth platform, and about rights and obligations regarding data treatments for data contained on the platform and electronical health records (https://www.esante.lu).

8) Individuals can easily and reliably grant access to their health data and exercise their rights, including objection when applicable

Detailed explanation and underlying philosophical concepts

The right to dispose health data remains ultimately with individuals who can decide who may access to their data. Thus, individuals may choose with whom they want to share which of their health data. In the same way, individuals may choose to block access to their data to all or certain persons.
When a given individual decides to stop using a digital health service, it is mandatory for the provider to erase all data related to the individual (except data which must be recorded by national health services for legal reasons) unless it is acknowledged by the individual that erasure is not necessary. This is true for both wellness and health applications.

When individuals decide to share some or all of their health data, they can do it autonomously and in a secure way.

The underlying concepts for this principle are mainly autonomy and freedom.

« Citizen 'consent to all' requests when quickly downloading an app should not be considered informed consent. Indeed, the Data is used for commercial purposes at least twice by the company to improve development devices, and by third parties for other products and services. The right to have opinions and to have data erased should also be offered » [13]

Ricardo Bellazzi
Professor, Department Chair in the Department of Electrical, Computer and Biomedical Engineering, University of Pavia, Italy

Member states use cases

In Sweden, individuals can choose to block access to their information in the national medication list about their prescribed and dispensed medication, either in whole or in part. Individuals can also block information in the medical records and have to leave a consent to the information being used in the first place when someone is treating them.

In Italy, electronic health records are automatically fed with data and documents produced over healthcare pathway of all patients. However, individuals can decide who can access their EHR and whether or not to receive notifications for access. It is also guaranteed that data obscuring is also obscured.

In Spain, the Ministry of Health cooperates with the regions (in charge of health) in the National Healthcare Records project (HCDSNS - Historia Clínica Digital del Sistema Nacional de Salud).
In this system, patients can prevent access to their clinical documents. A "broken glass" scenario is also implemented for health professionals for the national scenario. Spain's implementation of the Patient Summary service is based upon HCDSNS. For instance, if a Spanish patient prevents access to his patient summary document, this document will not be sent in the PS-A service of MyHealth@EU.
Patient data are considered to be the patient property; suppression requests must therefore be honoured accordingly. Specific procedures vary depending on the specific healthcare organization, with limitations to the exercise of this right

[13] Ministerial conference on citizenship, ethics and health data - February 2nd 2022
https://presidence-francaise.consilium.europa.eu/en/news/ministerial-conference-citizenship-ethics-and-health-data/

specified in the GDPR and Spain's Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos Personales y garantía de los derechos digitales
https://www.boe.es/buscar/pdf/2018/BOE-A-2018-16673-consolidado.pdf

In Norway, individuals can choose to have their information blocked. In Helsenorge.no patients can set the type of access provided. Individuals can also block information in their medications list and medical records.

In France, "Mon espace santé " (MES) is a service provided by the French administration to all citizens. Mon Espace Santé includes a medical agenda, a secured messaging system, an application store and a direct access to MES EHR which is a personally controlled EHR. This service is customizable by individuals.
Individuals can block access to their electronic health record for a legitimate reason, at the discretion of health professionals. They can object to the consultation of their electronic health record without having to invoke any reason.
Patients also have extended rights to manage the confidentiality of their health data. They may:

- Block one or more healthcare professionals without specific motivation. Professionals blocked by patients cannot supply or consult MES EHR.
- Hide some EHR documents (or all) to health professionals of their choice, including those that are authorized to access their MES HER.
- Close their MES at any time.

In Portugal, the SNS 24 Portal, individuals can access a section called "Authorizations".
In this section, citizens can indicate whether or not they authorize the sharing of their health information and can also verify who, when, and where their health information was accessed.

In Cyprus, citizen's and healthcare provider's rights and obligations are regulated by the National eHealth Authority. The procedure is fully explained in the National eHealth law, Articles 22-25.
Greek version (official) http://www.cylaw.org/nomoi/arith/2019_1_059.pdf ,
English version (unofficial)
http://www.neha.gov.cy/MOH/neha/neha.nsf/All/89E06920562BC292C2258767002F0A48/$file/59(%CE%99)-2019%20English%20Version.pdf?OpenElement

In Austria, the participation in the Austrian nationwide EHR-system may be objected to at any time (opt-out), as already suggested by the Article 29 Working Party (established under the former Directive 95/46/EC, now replaced by the European Data Protection Board under the GDPR) in their "Working Document on the processing of personal data relating to health in electronic health records (EHR)", adopted on 15 February 2007, under point III.1. ("Respecting self-determination") … Objecting EHR participants have to indicate whether their objection relates to all EHR data (general Opt-out) or just some kinds of EHR data (partial Opt-out). In addition, EHR participants may object the inclusion of EHR data for a concrete treatment or care case, and they have to be informed by healthcare providers about this right (situational Opt-out), particularly in case of EHR data related to HIV infections, mental illnesses, genetic data or abortions. Beyond the citizens' right to opt-out from the Austrian EHR-system, they are furthermore allowed to modify the general access authorizations (which otherwise apply by default) by means of individual access authorizations to (1) show or hide electronic references and EHR data for EHR healthcare providers, as well as delete them; if deletion is excluded due to other legal documentation obligations, the references shall be made inaccessible for the EHR-system; (2) shorten periods for existing access authorisations; and (3) designate an EHR healthcare provider of special trust (thus allowing access authorisations for up to 365 days), provided that the respective EHR healthcare provider agrees to this designation.

In Germany, all insured persons will in future be provided with an electronic patient record (ePA) to manage their health data. Insured persons can access their electronic health records via their smartphone, tablet or desktop

computer and easily read their data or download and upload data. Insured persons can manage their data via a user interface (ePA-App) which the health insurance company has to offer them. With the consent of the insured, the treating health professionals are granted access to the electronic patient record, where health information can be recorded as completely as possible. The access of the health professionals can be restricted by the insured person to specific data.

In Luxembourg, national electronic health records (DSP) implemented on the national eHealth platform (https://www.esante.lu) are a free service offered by the national eHealth Agency (Agence eSanté) to the entire population, as the agency is sponsored by the State (Ministry of Health) and the National Health Fund.
Individuals may adjust the access to their EHR as foreseen in article 6 and to consult the logs as foreseen in article 8 of the grand-ducal regulation on the national electronic health record (Règlement grand-ducal du 6 décembre 2019 précisant les modalités et conditions de mise en place du dossier de soins partagé).
Individuals may choose at any time to close their EHR and to retrieve the information contained within. He / she just needs to make a request to the agency, knowing that he/she cannot retrieve the information.

In Poland, medical data are protected by appropriate regulations and mechanisms. Access to patient's medical data is granted to the doctor who produced it, as well as to the GP (primary care physician), nurse and midwife whom the patient has independently and consciously selected.
Other medical professionals, such as specialist doctors or pharmacists, must obtain the patient's consent to access their data. Furthermore, consent can be withdrawn by the patient at any time.
The Patient Internet Account (IKP), including mojeIKP mobile app, allows patients to access the functionality of sharing their medical data with relatives and medical practitioners or pharmacists, as well as specifying the time and extent of this access. Patients who do not use these tools can also make their electronic medical records available to a specialist doctor via SMS with an access code.
All information on patient's rights regarding their medical data is available on pacjent.gov.pl portal, as well as on the Patient Internet Account (IKP) and mojeIKP mobile app.

III. Dimension 3 - Make digital health inclusive

This third dimension deals with the need to ensure all individuals can benefit from digital health by taking into account all specificities or issues they may face such as digital divide, low levels of health literacy and all forms of disabilities. It aims at leaving no one behind.

9) Digital health services are accessible by all, including by people with disabilities or low levels of literacy

Detailed explanation and underlying philosophical concepts

Accessibility in the digital space guarantees digital health services are usable by all, including people with low levels of literacy or disabilities of any kind. Accessibility means that digital health services can be used by all individuals without restriction (barrier-free), regardless of individual limitations or technical capabilities. Accessibility is considered effective when digital health services can be used by anyone without requiring any specific adaptation.

Digital health services must be accessible in an equivalent way to any individual, whether or not they have any kind of disabilities (visual, auditory, language, motor, dysfunctional disorder, etc.). To facilitate the implementation of digital accessibility, digital health services need to be based on common references and best practices ...

National or local policies should promote the implementation of such best practices. Labels or certifications can be awarded to distinguish digital health services that implement such accessibility guidelines. Likewise, financial incentives can support the implementation of these guidelines.

National and local initiatives aiming at improving accessibility of digital health services should be regularly evaluated. This evaluation should involve people with all kinds of disabilities and low literacy.

This principle relies mainly on concepts of universality and non-discrimination. It also implies solidarity, equity and accessibility.

« Lots of people come across challenges of not understanding things or not being able to access services on a daily basis, and solving this problem is not simple. In this regard, the Netherlands tried as much as it could to make its Corona Apps accessible to everyone, especially to blind and hard hearing people.»[14]

Ron Roozendaal

Co-Chair of EU eHealth Network and Director of Information Policy, Ministry of Health, Welfare and Sport, The Netherlands

Member states use cases

In Italy, all applications providing digital health services within the National Health Service must meet the accessibility requirements set out in the "Guidelines on the accessibility of the IT tools" of the Digital Italy Agency implementing EU Directive 2102/2016. Applications are monitored to verify their compliance with all requirements of technical standards on accessibility (example: presence of voice commands, voice reader, etc.).
https://www.agid.gov.it/it/design-servizi/accessibilita/linee-guida-accessibilita-strumenti-informati

In Germany, services of the statutory health insurance system are required to respect the needs of citizens with disabilities. The Social Code creates obligations for digital services to assure that services are accessible. Furthermore, a

[14] Ministerial conference on citizenship, ethics and health data - February 2nd 2022
https://presidence-francaise.consilium.europa.eu/en/news/ministerial-conference-citizenship-ethics-and-health-data/

German initiative is being launched in 2022 through a study on the use of digital technology and robotics (especially artificial intelligence), as levers to facilitate and personalize healthcare and empower elderly or disabled people.

In Portugal, the national healthcare portal, SNS24 makes a sign language video functionality available, to allow deaf citizens to communicate with NHS professionals. The communication is done at a distance through video call, and with the support of a sign language interpreter.
The service is provided by an interpreter recognized by the Portuguese Federation of Deaf Associations, 24 hours a day, and 7 days a week and there is no associated cost for the citizen.

In the Netherlands, Coronacheck, the Dutch app for covid certificates, is made to be accessible for all, using an inclusive testing team, including people who are visually impaired.
https://coronacheck.nl/en/

In France, the Ministry of Health has ensured to make "Mon espace santé", the French health data space for citizen accessible to everyone, including people with disabilities in accordance with article 47 of law no. 2005-102 of February 11th, 2005.
"Mon espace santé" offers all its users a catalogue of referenced digital apps that can accompany them on a daily basis in the field of health, well-being or maintenance of independence.

- To be listed, candidate digital services must meet a number of criteria, of which an ethical assessment of the service including accessibility.
- It includes for example the following criteria:
    - ACC.1.1 Inclusion of all audiences: The system MUST be developed with the intention of not excluding any audience (cultural diversity, disability, literacy, etc.)
    - ACC.1.2 Intuitive and understandable: The system MUST be intuitive, i.e. easy to use for all audiences, easily understandable and requiring no special training

https://convergence.esante.gouv.fr/pictures/publish/12

In Austria, the (general and partial) opt-out from the EHR-system may be given not only electronically by way of the eHealth access point (an online citizen portal) but also in writing to Opt-out Offices (as the analogue pendant) in order to address the digital divide and ensure full inclusiveness of all citizens in the Austrian EHR-system. Similarly, citizens who have not (generally) opted-out from the EHR-system are entitled either electronically by way of the eHealth access point or by written statement to the ELGA-Ombudsman to fully access all their EHR data including all logging protocols (displaying who has accessed which of their data, when and for how long), thus also ensuring full transparency of all access operations in the Austrian EHR-system in an inclusive way for all citizens regardless of their digital literacy and skills.

In Finland, Kanta produces digital services for the social welfare and healthcare sector. These services are made available for the benefit of citizens as well as social welfare and healthcare service providers. You can access the Kanta services wherever you live in Finland. Users of Kanta services include citizens, pharmacies, healthcare services and social welfare services from both public and private sectors.
The maintenance of the Kanta.fi online service has an accessibility statement that describes how accessible the online service is, the shortcomings in its accessibility, and how you can give feedback on accessibility issues. Accessibility of the online service has been assessed by an external accessibility expert and the statement was updated on January 24, 2022.
https://www.kanta.fi/en/accessibility-statement-for-the-kanta.fi-web-service

In Spain, public administrations have the mandate to reduce the digital divide, developing intuitive products, as described in Spain's digital health Strategy:
https://www.mscbs.gob.es/ciudadanos/pdf/Estrategia_de_Salud_Digital_del_SNS.pdf
This should be verified by subjecting each product to validation processes that check usability from the point of view of citizens, as well as alignment with international best practices (such as the Web Accessibility Initiative (WAI) and the Web Content Accessibility Guidelines (WCAG). All citizen-facing applications in Spain's Public Administrations have to comply with the "*Real Decreto 1112/2018, de 7 de septiembre, sobre accesibilidad de los sitios web y aplicaciones para dispositivos móviles del sector público",* which enforces compliance with international accessibility standards.

In Sweden, requirement for accessibility are expressed in the "Act on Accessibility to Digital Public Services". They apply to all public organisations regardless of what kind of service they provide. The act specifies expected requirements and when they must be met.

In Norway, the national health portal is accessible to all, and also contains information service for citizens with reading disabilities. Currently, central services are also set up and translated for Ukrainian refugees in their own language.
http://www.Helsenorge.no

In Cyprus, the integrated national electronic health record is being implemented by the National eHealth Authority (NeHA) in collaboration with the Pancyprian Medical Association (PIS) and with the contribution of the Federation of Patients Associatios (OSAK). A decree will be issued by the Minister of Health after the recommendation of NeHA. The direct opinions, wishes and needs of people with disabilities, are expected to be raised by OSAK and this procedure is legally covered by the national eHealth law. Greek version (official)
http://www.cylaw.org/nomoi/arith/2019_1_059.pdf
English version (unofficial)
http://www.neha.gov.cy/MOH/neha/neha.nsf/All/89E06920562BC292C2258767002F0A48/$file/59(%CE%99)-2019%20English%20Version.pdf?OpenElement

In Luxembourg, national electronic health records (DSP) have been implemented with the participation and contribution of the national "Patient representation" (Patiente Vertriedung). However, direct opinions, wishes and needs of people with disabilities, have not been directly considered and integrated.

10) Digital health services are intuitive and easy to use

Detailed explanation and underlying philosophical concepts

This principle aims at facilitating and simplifying the use of digital health services. Such end can be achieved by integrating design component into digital tool development projects in order to ensure a high level of quality. Interfaces and interactions between individuals and digital health services must be adapted to users' needs, requests, and characteristics.

National or local policies should provide best practices and incentives to digital health service manufacturers to design intuitive and easy to use digital health services. For example, users should be involved at all stages of the design and development of digital health services.

The intuitiveness of digital health services should be regularly evaluated for the sake of continuous improvement. In addition, users must be able to provide their feedback when appropriate.

This principle focuses on universality and autonomy.

« There is a need to design user-friendly, person-centred systems and services that can accommodate the needs of people at all literacy levels. It is important that governments make this a political choice, and that systems are found to facilitate a coherent approach that starts from the dignity, empowerment and rights of people. » [15]

Kristine Sorensen
Global Health Literacy Academy Founder, President of the International Health Literacy Association, Denmark

« For physicians and healthcare users alike, if we want enthusiasm for the options of technology, it must be easy to use. »

Christiaan Keijzer
President, Standing Committee of European Doctors (CPME)

Member states use cases

In Italy, usability is an essential requirement in every digital service (for example, limited number of clicks to join a specific information). Each public authority must release an accessibility statement and provide a feedback mechanism.
https://www.agid.gov.it/it/design-servizi/accessibilita/dichiarazione-accessibilita
https://www.agid.gov.it/it/design-servizi/accessibilita/meccanismo-feedback

In Norway, the national health portal, www.Helsenorge.no has developed the user interface according to General Accessibility Regulation for Administrations' recommendations.

In Germany, depending on the service (notably for digital health applications), government regulations create obligations to ensure digital health services are easy to use.

[15] Ministerial conference on citizenship, ethics and health data - February 2nd 2022
https://presidence-francaise.consilium.europa.eu/en/news/ministerial-conference-citizenship-ethics-and-health-data/

In France, in order to ensure "Mon espace santé" (MES) is accessible to everyone, including people with disabilities, the development of user interfaces has followed General Accessibility Regulation for Administrations' recommendations (RGAA). An audit is currently underway to attest the RGAA compliance of MES user interfaces.
https://www.monespacesante.fr/accessibilite

In Sweden, there are two legal texts in place: "Act on Accessibility to Digital Public Services" and "Web Accessibility Directive". They imply requirements to make the public service, which includes digital health services, more accessible. This means possible to perceive, manageable, understandable and robust.

In Luxembourg, the national eHealth platform was designed and developed in order to be used by the entire population, targeting citizens of all age. However, no specific attention was focused on people with disabilities This may be considered in future.

In Portugal, SNS 24 website follows recommendations of the Decree-Law no. 83/2018, of 19 October, which transposes Directive (EU) 2016/2102 of the European Parliament and of the Council, on the accessibility of websites and mobile applications.
https://www.sns24.gov.pt/acessibilidade/

11) Individuals have access to digital health training

Detailed explanation and underlying philosophical concepts

National or local digital health policies should ensure that digital health training is available for individuals. Such strategy ensures individuals can develop their skills independently through educational content. It should be avoided that digital health training is 100% digital.

National or local policy should also provide that specific digital health training for health professionals is mandatory and is certified.

Digital health training should include aspects of ethics.

Digital health providers should offer training materials such as video tutorials to help users getting started with a digital health service. Such training material should always be easily accessible to all audiences.

The conceptual design of educational and training content should support especially people in the digital health sector and raise awareness among health professionals about the digital divide and the challenges of dealing with new digital tools.

This principle ensures autonomy and freedom.

« This is a significant proportion of people, there are people from 50 to 95 years old who are the biggest users of health care and they are the biggest challenge in using the digital technologies. So how much are we focusing to find solutions for those people?

This is a main issue, and if we don't find solution, this is going to slow down the access to digital health for a significant proportion of the population. » [16]

Serge Bernasconi

CEO, MedTech Europe

« *We need to put the patient at the centre for personal health and this requires models and approaches to give them opportunities to accumulate high quality data in an ethic and compliant manner and employ this output as relevant information and knowledge building on their capacity to understand and make choices to cope with everyday living.* » [17]

Anne Moen

Professor in Health informatics and Nursing at the Faculty of Medicine, University of Oslo, Norway

Member states use cases

In Portugal, many initiatives support digital health capacity building among the citizens and health professionals, such as the INCoDe.2030, an inter-ministerial initiative that aims at responding to major challenges: ensuring digital literacy and inclusion for the exercise of citizenship, stimulating expertise in digital technologies and applications for job qualification and a higher added value economy as well as producing new knowledge in international cooperation.

The literacy library of the SNS24 is another example. The health literacy library aims at promoting access to health information, making people more autonomous in relation to their health and the health of those around them, including digital health.

https://biblioteca.sns.gov.pt/

[16] Ministerial conference on citizenship, ethics and health data - February 2nd 2022
https://presidence-francaise.consilium.europa.eu/en/news/ministerial-conference-citizenship-ethics-and-health-data/

[17] Ministerial conference on citizenship, ethics and health data - February 2nd 2022
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In Italy, there is a specific information section for all stakeholders and also a training section aimed at both health and medical staff, as well as caregivers in the national platform for the diffusion and governance of telemedicine. This section also includes short video tutorials.
According to Italian guidelines, it is necessary to prepare information programs to support patients using new telemedicine tools. These programs should involve several organizations in order to ensure a maximum representation of involved parties. Information and training in telemedicine services should not be limited to technological aspects, but rather cover the complexity of the doctor-patient relationship in this new dimension.

In Sweden, the parliament decided to drive a digital strategy where there is a strong focus on digital skills. Everyone should know how to use digital tools and services and have the ability to follow and participate in the digital transformation based on their own situation.
Several initiatives are carried out in the country; libraries and senior networks are working to increase digital competences in the population for instance. An example is SeniorNet Sweden, a non-profit organization supporting seniors teaching seniors about digital communication and internet. Another example is the various "DigidelCenters" run under the responsibility of the local municipalities, where citizens can receive support with digital equipment, free of charge. "Digital help", a service from the Swedish Post and Telecom Authority, provides guidance, good advice and step-by-step guides that explain how to use some digital services that can make everyday life a little easier.
https://pts.se/sv/digitalhjalpen/guider-for-digitala-tjanster/

Present throughout the territory, “Mon Espace Santé Ambassadors” support citizens in embarking on “Mon Espace Santé”.
https://esante.gouv.fr/ambassadeurs-mon-espace-sante#:~:text=Pour%20devenir%20ambassadeur%20Mon%20espace,de%20connaissance%20de%20l'outil
In France, the national health insurance fund also provides video tutorials about how to use "Mon espace santé". https://www.youtube.com/watch?v=Vl0sn3xNdqA
The digital health ethics unit of the Ministry of Health has produced several films to help understand the challenges of digital health: https://www.youtube.com/watch?v=JyZpW7YeBZQ
Furthermore, training is a key pillar of the Digital Health acceleration strategy, endowed with 650 M€. A call for projects addressing universities and training institutes has been launched, to develop a repository of fundamental and cross-cutting skills for all health professions for both initial and continued education curricula: https://gnius.esante.gouv.fr/fr/strategie-dacceleration-sante-numerique/strategie-structurante

In Norway, municipalities offer online video tutorials for citizens to demonstrate how to use most central digital health services.

Finland has published recommendations on digital support organisation for companies and organisations. These recommendations highlight current needs and solutions in developing digital support and skills; they provide information and support for local and national government authorities, as well as for companies and other organisations engaged in business activities involving digital services. They target to support, plan and finance them.
https://dvv.fi/-/digipalvelun-sekavuus-lisaa-digituen-tarvetta-uudet-suositukset-kannustavat-panostamaan-laatuun?languageId=en_US

Patient federation of the Netherlands has a website dedicated to capacity building on digital health for patients: https://vliegwielcoalitie.nl

In Cyprus, there is not much development regarding education and training of citizens in digital health. The National eHealth Authority (NeHA) however is currently updating its official website which will accommodate education and training modules with a self-assessment facility. In addition, NeHA will offer seminars to schools in collaboration with the Ministry of Education and to the public in collaboration with municipalities for educating people.

In Spain, regarding training for individuals about the functioning of digital health Services, the Ministry of Health offers training for digital health services provided as part of the "Escuelas de salud":
https://www.redescuelassalud.es/
Regional initiatives also exist. For example, the Comunidad de Madrid region has launched an initiative to reduce the digital divide, which includes training for different digital services provided by this public administration:
https://edicion.comunidad.madrid/notas-prensa/2021/12/09/comunidad-madrid-hara-frente-brecha-digital-plan-especifico-formacion-dotado-2-millones-euros

.In Germany, statutory health insurance funds offer information, tutorials and face-to-face courses in order to familiarize interested citizens with all aspects of digital health.

Numerous information and education activities are carried out through campaigns in national press, TV and radio, as well as through leaflets, posters, press articles, videos and presence of e-health products in popular tv series. It also involves GPs (primary care physicians) who support patients on request and on 24/7 helpline of eHealth Centre's. The needs of older people with lower digital competencies are also considered. Surveys are carried out to see how comprehensible, intuitive and easy to use the services offered are which is very useful.
Quick response to patients' needs and an acceleration of the adaptation of services to their users' needs, especially during COVID-19 pandemic, resulted in a significant increase in users of e-health services.

12) Digital health services include support through human communication when needed

Detailed explanation and underlying philosophical concepts

This principle aims at ensuring the possibility of qualified human support to assist individuals who have difficulties using digital health services. Such human support may be based on synchron interaction (telephone, chat) or asynchron interactions (emails, call back). However, human support should never be limited to emails or electronic communication as users who need help using digital health services may face difficulties using email or any kind of electronic communication.
All indications about how to access human support should be easily accessible: opening hours for the telephone, call back within the hour or within 24 hours, delay in mail answer, operating modalities during weekends, etc.
When a human support is available, it may be relevant to get individuals' feedback.
Digital mediation in all its forms for those who need it, is a necessity in the successful implementation of the digital transformation of the health system.

This principle is based on **autonomy**, **freedom** and **solidarity**.

« At the same time, it must be taken into account that not all people have the necessary digital skills. Therefore, digital solutions should never be replacing face-to-face interaction between the care giver and his or her patient but implement and improve in-person healthcare. » [18]

Ron Roozendaal
Co-Chair of EU eHealth Network and Director of Information Policy, Ministry of Health, Welfare and Sport, The Netherlands

Member states use cases

In Sweden, the national health care portal – 1177 - offers support by phone, for services provided through the portal, all days between 06:00 am to 10:00 pm. Communication via email also an option if preferred.

In Norway, Helsenorge.no national health portal provides chat service and assistance by phone between 08:00 and 15:30 from Monday to Friday. Citizens have access to their health and medical information, as well as to multiple services and to their GP/doctor. They choose how and if they want to use it. A support service as well as a webpage with instructions on how to use the service are available.

In Germany, digital health tools and services implementation implies an important cultural change for all users (e.g., health professionals, patients). Therefore, Germany has, for example, put into practice dedicated support and communication for patients and health professionals regarding Electronic Health Records (elektronische Patientenakte - ePA). Support focuses on highlighting the advantages of using ePA, as well as on providing support for the use of these new tools.
Statutory health insurance funds offer information, tutorials and face-to-face courses in order to familiarize interested citizens with all aspects of digital health.

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[18] Ministerial conference on citizenship, ethics and health data - February 2nd 2022
https://presidence-francaise.consilium.europa.eu/en/news/ministerial-conference-citizenship-ethics-and-health-data/

In France, "Mon espace santé" provides online as well as human support. Advisors are available by phone from 8:30 a.m. to 5:30 p.m., Monday to Friday.
https://www.monespacesante.fr/nous-contacter

In Portugal, SNS 24 national healthcare portal hotline is available 24 hours a day / 7 days a week. The SNS24 Counter (in-person store, partnership with local level government) is available from Monday to Friday, from 9:30 am to 1:00 pm and from 2:00 pm to 5:30 pm too. This service also provides digital mediation, support and a computer to carry out a teleconsultation if needed. Therefore, online and human support are provided to citizens.

In Italy, digital health services such as choosing a family doctor or booking a specialist medical visit also provide the possibility of receiving assistance via telephone or via a dedicated counter.
See the National Guidelines for Unified Online Booking Centres:
https://www.salute.gov.it/imgs/C_17_pubblicazioni_1577_allegato.pdf

In Spain, all citizens can contact public administrations offering certain digital health services by telephone directly. Generic information phone numbers also exist such as the ""060"" phone number for the central administration.
https://administracion.gob.es/pag_Home/contacto/buzon-atencion.htm

In Luxembourg, both the national eHealth platform (https://www.esante.lu), and the Luxemburgish electronic health record (DSP) used for the primary medical data exchange, provide online information in 3 different languages (En, Fr, Ge) for all users. Helpdesk service of Luxemburg's eHealth agency (Agence eSanté) provides human support too. Advisors are available by phone from 8:00 a.m. to 6:00 p.m. from Monday to Friday, and over the following contact address:
https://www.esante.lu/portal/fr/contact-8-9.html

IV. Dimension 4 - Implement eco-responsible digital health

This fourth dimension engage all actors to commit moving towards eco-friendly digital health and to carrying out concrete actions in this area. Indeed, disease prevention undoubtedly involves reducing our carbon footprint. Taking into account the challenges of climate change and sustainable development is key today in all sectors, and especially in the health sector. Indeed, as reported by the World Health Organization, climate change is responsible for at least 150,000 deaths per year, a figure that is expected to double by 2030.

« In sustainability terms, if the global health sector was the size of a country, that country would be the 5th largest greenhouse gas emitter on the planet. » [19]

Cecilia Bonefeld-Dahl
General Director, DIGITALEUROPE

13) Environmental impacts of digital health are identified and measured

Detailed explanation and underlying philosophical concepts

This principle applies to the full scope of digital health tools and services, including their manufacturing and use. Environmental impact should be measured with a scientific method based on lifecycle analysis principles (manufacturing, transport, use, and second life, recycling). Impacts must be reported according to comparable values or metric systems.
Environmental impacts of digital health solutions should be made public to foster emulation.

Sustainability, solidarity and no harm are the heart of this principle.

« Despite this awareness at HOPE level it must be said that is not the case in all hospitals and healthcare services. In any case, conflicting issues arise with the fast digitalisation of healthcare, not only because of covid. We can notice the impact of digitalisation on the environment (for example for the production of digital tools we use) and the impact of digitalisation on the climate (for example for the energy consumed by digitalisation). » [20]

Eva Weinreich-Jensen
Member of Presidents Committee and Former European Hospital and Health care Federation (HOPE) President, Denmark

Member states use cases

In France, a tool for calculating the environmental impact of hospital information systems is being developed. The score would then be used as a specific criterion for hospital information systems certification (MATURIN-H, supported by the French Ministry of Health).
Another tool has been developed for measuring the environmental impact of health and wellness apps, whether web or mobile as an eco-score based on energy consumption, performance and a quantitative evaluation of data flows. The score will be used as a criterion in the evaluation of mobile apps to be selected in the store of the French personal health dataspace "Mon espace santé".

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[19] Ministerial conference on citizenship, ethics and health data - February 2nd 2022
https://presidence-francaise.consilium.europa.eu/en/news/ministerial-conference-citizenship-ethics-and-health-data/

[20] Ministerial conference on citizenship, ethics and health data - February 2nd 2022
https://presidence-francaise.consilium.europa.eu/en/news/ministerial-conference-citizenship-ethics-and-health-data/

In Italy, equipment of all digital systems must be disposed of in accordance with the legislation (Legislative Decree no. 49 of 14 March 2014, which transposes Directive 2012/19 / EU on waste from electrical and electronic equipment). For digital health systems, in compliance with the legislation on the protection of personal data, specific security measures may be adopted by data holders both in the design phase and in the disposal phase.
https://www.garanteprivacy.it/home/docweb/-/docweb-display/docweb/1583482

In Sweden, a national ordinance (2009: 907) on environmental management in government agencies requires that any agency has an environmental management system that integrates environmental considerations into the agency's operations; this allows for direct and indirect environmental impacts of operations are systematically taken into account.
Environmental management systems should include: environmental analysis and identification of impacts, environmental policy and goals, action plan, division of responsibilities and routines, environmentally adapted procurement and annual follow-up.
The Swedish e-Health Agency has identified the environmental impact of France ehealth services and infrastructure, and ranked them in order of influence. We have made an analysis, according to the ordinance, and set up an action plan.

In Spain, public administrations already integrate the climate change perspective in all programs, including the allocation of specific funding for this purpose. Parties involved are politicians, companies, associations, and the media.

14) digital health services are developed in compliance with eco-design best practices

Detailed explanation and underlying philosophical concepts

This principle applies to all digital tools and services. The principle encourages the development of guidelines for eco-design, defined at national or local level. It is about recommendations for each step of the lifecycle of the tools:

- Sustainable purchasing (i.e., favour the purchase of reconditioned equipment, favour rental rather than the purchase of new products, ensure the origin of the equipment and the ethics of the producers, durability and reparability of these equipment),
- Eco-conception (use of low-level encoding languages, implementation of a meaningful digital health, answering only the question asked, for instance retrieving the first 20 returns to a request on a search engine instead of returning all returns that no one read, etc.),
- Eco-use (for relevant care),
- Second use to increase the lifespan of materials (for equipment that is still functional, encourage internal re-use or via associations or organizations),
- Recycling (proper management of electrical and electronic equipment through an approved eco-organization).

In particular fighting the forms of bloatware (i.e. unwanted pre-installed software on a computer or device) makes necessary to fight against planned obsolescence of products marketed in all their forms, and to promote the publication of indices of reparability.
Overall, the principle relates to the holistic approach to eco responsibility that needs to be pursued.

The underlying concepts for this principle are sustainability, solidarity and no harm.

« It is essential that we work together with digital stakeholders to successfully carry out both green and digital transition in health, from the sharing of eco-design practices to the development of digital health services. » [21]

Ponciano Oliveira
Administrator at the Shared Services for Ministry of Health (SPMS, EPE), Portugal

« The objective is to meet the just needs of individuals by producing useful services that consume less energy and for the inclusion of all, services that are more efficient and then fairer. » [22]

Jean-Christophe Chaussat
President of the Institute for Digital Responsibility, France

Member states use cases

In Norway, architecture is used in the development of new e-health solutions that divide solutions into smaller components that can be scaled up and down independently of each other. In combination with modern container technology, this means better use of hardware and reduces energy consumption.

[21] Ministerial conference on citizenship, ethics and health data - February 2nd 2022
https://presidence-francaise.consilium.europa.eu/en/news/ministerial-conference-citizenship-ethics-and-health-data/

[22] Ministerial conference on citizenship, ethics and health data - February 2nd 2022
https://presidence-francaise.consilium.europa.eu/en/news/ministerial-conference-citizenship-ethics-and-health-data/

In Sweden, to help companies or organisations develop digital health services the Swedish Institute of Standards provides ISO14006 standard supporting products and services development. It includes guidelines to establish, document, implement, maintain and continually improve their eco-design management as part of an environmental management system. Guidelines are applicable to any organization regardless of type, size or products provided.

In Germany, various projects at operational level exist to promote healthcare sector sustainability. One example is the handbook of green practices; it provides easy accessible information to help ambulant healthcare providers achieve more climate and carbon footprint reduction in their working environment (waste management, purchasing, trips, etc.).
https://healthforfuture-hamburg.org/wp-content/uploads/Handbuch-Gruene-Praxen-H4F-HH-final.pdf

Spain's core public procurement law (*Ley 9/2017, de 8 de noviembre, de Contratos del Sector Público, por la que se transponen al ordenamiento jurídico español las Directivas del Parlamento Europeo y del Consejo 2014/23/UE y 2014/24/UE, de 26 de febrero de 2014*) fosters the implementation of "green" public procurements clauses, such as the acquisition of power-efficient computing platforms.

In France, a report of the digital health ethics unit from the French ministerial e-Health delegation aims to raising awareness of the environmental impacts of digital health. It includes recommendations to promote good practice in digital tools eco conception.
https://esante.gouv.fr/sites/default/files/media_entity/documents/rapport_gt6_210517-2.pdf
https://collectif.greenit.fr/ecoconception-web/115-bonnes-pratiques-eco-conception_web.html

In Portugal, PNGR - Horizon 2030 is promotes awareness of the prevention of waste production aimed at all value chain actors.
This goal aims to promote training campaigns, dissemination of good practices, and awareness of importance of informed and environmentally conscious choice in the acquisition of goods and services. It is based on criteria that promote prevention like choices that prolong the lifecycle of the products and subsequently, generate a lower environmental impact.
https://www.industriaeambiente.pt/userfiles/files/blog/PNGR%202030.pdf

15) Re-use and recycling of digital health equipment is ensured

Detailed explanation and underlying philosophical concepts

Digital health services providers should be aware of their individual responsibility.

This principle aims at reducing manufacturing environmental impact by increasing the lifespan of digital health tools. This means to favour re-use (internally or via associations or organizations), as well as repair. The third dimension is to recycle digital services and materials, to save and re-use what can be saved and re-used.

(Digital) health policies should create an effective framework regarding development, production and institutional use, in order to ensure re-use and recycling. Digital health product manufacturers receive incentives to increase their product lifespan and prioritize the use of recycled components. When materials are built from recycled components, they receive an eco-responsible label or certification. Information about recycling and re-use processes of digital health solutions is published.
This principle is based on solidarity and do no harm concepts.

« Within its digital health priorities, Portugal has been developing and implementing digital health based on the target of re-using infrastructures and data whenever possible. Portugal is placing emphasis on centralization of infrastructures, which allows for resources to be allocated in more efficient ways. With this approach, Portugal aims to reduce the energy consumption of the Ministry of Health entities, optimize the storage, and increase the efficacy of the management of the sovereign capacity. » [23]

Ponciano Oliveira
Administrator at the Shared Services for Ministry of Health (SPMS, EPE), Portugal

Member states use cases

In Italy, re-use of software developed for public services is envisioned in application of the Italian law (Digital Administration Code),. Developed applications are made available for re-use through a catalogue dedicated to public administrations (see guidelines for software reuse by public administrations).
https://www.agid.gov.it/it/design-servizi/riuso-open-source/linee-guida-acquisizione-riuso-software-pa

In France, the advisory circular of February 25th, 2020 related to State commitments for eco-responsible public services, includes measures for digital technology: in particular, measure 20 indicates that the State shall develop by July 2020 a footprint reduction strategy which will especially include a process of raising awareness among agents of digital eco-gestures and the purchase of refurbished equipment or consumables.

Spain's core ad intra administrative law (*Ley 40/2015, de 1 de octubre, de Régimen Jurídico del Sector Público*.) establishes to re-use existing applications developed in public administrations.
Many are available for reuse through a publicly accessible portal:
https://administracionelectronica.gob.es/ctt/CTTprincipalEs.htm?urlMagnolia=%2Fpae_Home%2Fpae_SolucionesCTT.html
Reusing software tools allows for sharing best practices, lack of duplication and is generally more resource-efficient.

[23] Ministerial conference on citizenship, ethics and health data - February 2nd 2022
https://presidence-francaise.consilium.europa.eu/en/news/ministerial-conference-citizenship-ethics-and-health-data/

In Austria, a relatively new chapter of the Austrian Health Telematics Act regulates “eHealth applications” which are defined as the use of the technical central/core components (patient register, healthcare provider register, access control centre, protocol system and online access portal) that were initially established only for the Austrian EHR-System “ELGA” by citizens and healthcare providers for specific purposes other than for ELGA and with different legal rules. The first application benefitting from this new chapter is the e-vaccination certificate based on a central vaccination register, which uses the above mentioned technical central/core components but follow other legal rules than ELGA (e.g. no citizens’ right to opt-out from the central vaccination register as a public health application). This allows to take advantage of not only the economic but also environmental added value of the investments already made by preventing the building of new software and hardware, thus avoiding the creation of costly as well as environmentally harmful parallel systems.

16) Digital health stakeholders are committed to reducing their ecological footprint

Detailed explanation and underlying philosophical concepts

This principle aims at reducing the ecological footprint. It covers a broad scope, including society itself in the context of digital health, and all stakeholders. This includes engaging in a corporate social responsibility (CSR) approach. It also requires raising awareness on the part of individuals on issues of eco responsibility. Digital health providers should also raise awareness and educate their employees.

The concepts of sustainability, no harm and solidarity are the basis of this principle.

« Some hospitals developed a strategy where they reduce their ecological footprint very much. For example, they work on sustainable public procurement, establish eco-friendly criteria, pay attention to working conditions and to human rights in the supply chain. » [24]

Eva Weinreich-Jensen
Member of Presidents Committee and Former European Hospital and Health care Federation (HOPE) President, Denmark

« The French digital ecosystem has been working on the subject for ten years, but is also a very fragmented ecosystem. The Planet Tech'Care initiative aims at gathering all actors and having them work together on the subject to accelerate approach and dynamics around environmental issues linked to digital. » [25]

Véronique Torner
Board member of NUMEUM, Planet Tech' Care co-founder,General Manager of Alter Way, France

Member states use cases

In Norway, hospitals have agreed to reduce the carbon footprint by 40% by 2030, and to have a climate neutral operation by 2045. Therefore, a minimum of 20% of outpatient consultations must be made digitally, via video and telephone.

In Spain, all public-sector buildings must go through audited environmental impact, including hospitals. This generally results in a reduction in emissions and increase in power-efficient practices.

In France and since 2009, the Ministry of Health has committed to reducing its greenhouse gas emissions by signing an agreement in the context of "Grenelle de l'Environnement" with hospital federations to integrate environmental progress in their actions.

In Germany, Health System Advisory Council advices government on key issues relating to health system. In the last report, 2021 Health System Advisory Council, seven scientists address the issue of balance and equal responsibilities.

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[24] Ministerial conference on citizenship, ethics and health data - February 2nd 2022
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[25] Ministerial conference on citizenship, ethics and health data - February 2nd 2022
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They which be observed in the development of digital health, mainly due to the energy and resource use of digital health applications. The German government takes these issues very seriously and is in close contact with leading scientists.

In Portugal, ECO@SAÚDE is an environmental sustainability programme from the Ministry of Health.

ACSS (Central Administration of the Health System) has the responsibility for coordinating the Low Carbon Strategic Plan and the Energy Efficiency Program in Public Administration (Eco. AP) at the Ministry of Health, thus developing action plans that aim to promote energy and water efficiency, and mitigation of the amount of waste generated by the building activity of the Ministry of Health (MS), covering not only the primary healthcare entities of the National Health Service (SNS) but also, the entities of the central administration.

At the same time, the National Waste Management Plan (PNGR) - Horizon 2030 is a macro-planning instrument for waste policy, which establishes strategic guidelines, at the national level, for the prevention and management of waste, through the implementation of guiding principles that aim to protect the environment and develop the country.

In Sweden, the (2009: 907) national ordinance on environmental management in government agencies includes a paragraph on environmentally adapted procurement that states that "the environmental management system shall mean that the authority environmentally adapts its procurements to the extent that such an adaptation is possible".

European ethical principles for digital health are not legally binding. However, upon their adoption in January 2022, Member States committed to their concrete implementation.

The compliance of digital health services with these ethical principles should not remain an unreached target. We should provide visible achievements in order to raise awareness and enhance trust among individuals. It must be central to all future digital health developments.

Member States are keenly aware that they are not yet fully compliant with the 16 principles.

While moving forward to implement all principles, Member States were concerned with their ability to evaluate their state of play and the way they were addressing the objectives. Therefore, they collectively worked on an initial self-assessment grid (Self-assessment Grid Version 0), and based on lessons learned by doing the exercise, they proposed amendments to this initial version. An upgraded version of the self-assessment grid (Self-assessment Grid Version 1) is now available and the next step will therefore be for all Member States to complete it. This first-of-a-kind exercise will allow them to get an aggregated view of the European Union state of play concerning the European ethical principles for digital health.

Next steps and way forward

European ethical values are a pillar of the European construction of digital health, and the key for trust and support of European citizens in developing the use of digital health.

The unanimous adoption of the European ethical principles for digital health by Member States representatives from eHealth network on January 26th, 2022, was a major milestone for digital health in Europe.

As stated, there is no government, institution or industry that fully implements these principles and which is able to demonstrate a 100% compliance to them.

This is not an issue. On the contrary.

It demonstrates the willingness and commitment of all Member States to move forward and progress. The aim is to develop trust and increase the quality and strength of the European third way for digital health as part of the European sovereignty ambition.

The next steps must allow for the adoption of the principles by the greatest number of people and the implementation of the right governance and communication plans linked to it. Member States have validated the following macro-planning:

1. **Translation of the European ethical Principles for digital health in all languages of the Member States**
   In terms of communication, **the principles should be translated and made available to the public in all the languages of the Member States** represented in the eHealth Network.

2. **A supportive document for the European ethical Principles for digital health**
   The publication of the present **supportive document** marks another milestone. It includes a detailed explanation for each of the principles as well as providing examples of their implementation at member-state level.

3. **The evaluation of the global state of play in Europe**
   It will be followed by a **global evaluation**.
   This evaluation will complete the study carried out during the French presidency on the state of play of digital health in Europe[26]. The two new steps will be the subject of a press communication.

4. **The ecosystem consultation**
   In order to make the exchanges surrounding the ethical principles more inclusive, a broad **consultation of the ecosystem will be organised** by the eHealth network at the earliest. In particular, digital health and medical devices providers, industrials, but also service user associations and health professionals will be consulted. This will secure the consideration and appropriation of all stakeholders in the development of the regulation for a European health data space
   This consultation will make it possible to collect concrete and daily use cases towards the creation of a **best practice compendium.**

5. **The consultation of European citizens**
   At the same time, a **consultation of European citizens** will be initiated to open the discussion at the individual level and to share the principles broadly.
   Multiple dialogues constitute a fundamental pillar for building the trust and support of Europeans for digital health. This conversation will also allow all stakeholders both from the public and private sector to become aware of the situation, share experiences and identify the best possible way forward.

[26] Study on Digital Health implementation in the EU – French e-Health Delegation, French Ministry of Health with EY.

This Action plan will therefore ensure that a sustainable and ethics-guided, virtuous circle drives upcoming decisions in digital health.

The European Commission will ensure the publication of all materials adopted by eHealth network on the EU platform.

Glossary

Accessibility	Products must be designed and produced to maximise their foreseeable use by persons with disabilities and shall be accompanied where possible in or on the product by accessible information on their functioning and on their accessibility features.[27]
Artificial intelligence system	Software that is developed with one or more of the techniques and approaches among : (a) Machine learning approaches, including supervised, unsupervised and reinforcement learning, using a wide variety of methods including deep learning; (b) Logic- and knowledge-based approaches, including knowledge representation, inductive (logic) programming, knowledge bases, inference and deductive engines, (symbolic) reasoning and expert systems; (c) Statistical approaches, Bayesian estimation, search and optimization methods. And can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with.[28]
Autonomy	All persons have intrinsic and unconditional worth, and therefore, should have the power to make rational decisions and moral choices, and each should be allowed to exercise his or her capacity for self-determination.
Beneficence	The obligation of physician to act for the benefit of the patient and supports a number of moral rules to protect and defend the right of others, prevent harm, remove conditions that will cause harm, help persons with disabilities, and rescue persons in danger
Bias	An inclination of prejudice towards or against a person, object, or position. Bias can arise in many ways in AI systems.[29]
Collaborative	When all stakeholders bring together the structures, processes and skills necessary to achieve multiple levels of integration and achieve benefits.
Consent	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[30]
Consistency	The quality of always behaving or performing in a similar way, or of always happening in a similar way
Corporate social responsibility	A concept whereby companies integrate social and environmental concerns in their business operations and in their interaction with their stakeholders on a voluntary basis. Corporate social responsibility concerns actions by companies over and above their legal obligations towards society and the environment. Certain regulatory measures create an environment more conducive to enterprises voluntarily meeting their social responsibility.[31]
Data altruism	The consent by data subjects to process personal data pertaining to them, or permissions of other data holders to allow the use of their non-personal data without seeking a reward, for purposes of general interest, such as scientific research purposes or improving public services.[32]
Data provider	Any natural or legal person who has the right or obligation, in accordance with applicable Union or national law, and in the case of non-personal data, the ability, to make available certain data
Data user	Any natural or legal person who, in relation to contracts and practices covered by this Regulation, uses health data for purposes as research, innovation, statistics, regularity activities, policy making or healthcare

[27] Directive 2019/882 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019L0882&from=FR

[28] 2021/0106 (COD) AI Act proposal https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021PC0206&from=EN

[29] HLEG Guidelines for trustworthy AI https://ec.europa.eu/newsroom/dae/document.cfm?doc_id=60419

[30] REGULATION (EU) 2016/679 GPDRhttps://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=EN

[31] COM/2011/681 final – CSR https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52011DC0681&from=EN

[32] COM/2020/767 final DGA https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020PC0767&from=EN

Digital divide	The gap between individuals, households, businesses and geographic areas at different socio-economic levels with regard both to their opportunities to access information and communication technologies (ICT) and to their use of the internet for a wide variety of activities.[33]
Digital health product	Any item such as an apparatus, appliance or software, intended by the manufacturer to be used for processing electronic health data;
Digital health service	Digital health product or a combination of several digital health products that are offered for online use by healthcare providers or individuals in a form of an operational system, including EHR systems, tele-health and remote monitoring solutions, personal health data access services
Digital health service provider	An entity responsible for the provision and operation of a digital health service
Eco-design	Integration of environmental aspects into product design with the aim of improving the environmental performance of the product throughout its whole life cycle;[34]
Environmental impact	Means any change to the environment wholly or partially resulting from a product during its life cycle[35]
Eco-responsibility	The duty or obligation of a business or a business executive to promote environmental sustainability
Electronic health data	Personal or non-personal data related to physical or mental health, including data about the provision of healthcare, processed in an electronic form.
Electronic health records	Collection of personal electronic health data processed for healthcare purposes and controlled by one or more controllers
Equality	Ensuring that every individual has an equal opportunity to make the most of their lives and talents
Health data	Personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status
Individuality	Quality or character of a particular person or thing that distinguishes them from others of the same kind, especially when strongly marked.
Interoperability	Means the ability of two or more data spaces or communication networks, systems, products, applications or components to exchange and use data in order to perform their function[36]
Justice	fair, equitable, and appropriate treatment of persons
Liberty / freedom	ability to do as one pleases
Digital literacy	The skills required to achieve digital competence, the confident and critical use of information and communication technology (ICT) for work, leisure, learning and communication. Digital literacy is underpinned by basic technical use of computers and the Internet[37]
Meliorism	The belief that the world can be made better by human effort.
Non discrimination	Requires the equal treatment of an individual or group irrespective of their particular characteristics, and is used to assess apparently neutral criteria that may produce effects which systematically disadvantage persons possessing those characteristics
Non maleficence	The obligation of a physician not to harm the patient. This simply stated principle supports several moral rules – do not kill, do not cause pain or suffering, do not incapacitate, do not cause offense, and do not deprive others of the goods of life.
Post-market surveillance	'Post-market surveillance' means all activities carried out by manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from devices they place on the market, make available on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions[38]

[33] PAR/Briefing bridging the digital divide https://www.europarl.europa.eu/RegData/etudes/BRIE/2015/573884/EPRS_BRI(2015)573884_EN.pdf

[34] Directive 2009/125/EC https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009L0125&from=EN

[35] Directive 2009/125/EC https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009L0125&from=EN

[36] 2022/0047 (COD) Data act https://ec.europa.eu/newsroom/dae/redirection/document/83521

[37] Eurostat glossary https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Glossary:Digital_literacy#:~:text=Digital%20literacy%20refers%20to%20the,of%20computers%20and%20the%20Internet

[38] Regulation (EU) 2017/745 MDR https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02017R0745-20200424&from=EN

Primary use of health data	Use of health data for the provision of health services to individuals to assess, maintain or restore their state of health, including the prescription, dispensation and provision of medicinal products and medical devices;
Product information	A standard document containing information relating to a product, in printed or electronic form
Provider	Natural or legal person, public authority, agency or other body that develops a digital health system or service or that has a digital health system or service developed with a view to placing it on the market or putting it into service, whether for payment or free of charge.
Recycling	Reprocessing in a production process of waste materials for the original purpose or for other purposes but excluding energy recovery[39]
Reuse	Any operation by which a product or its components, having reached the end of their first use, are used for the same purpose for which they were conceived, including the continued use of a product which is returned to a collection point, distributor, recycler or manufacturer, as well as reuse of a product following refurbishment;[40]
Right to data portability	Data subject shall have the right to receive the personal data concerning him or her, which he or she has provided to a controller, in a structured, commonly used and machine-readable format and have the right to transmit those data to another controller without hindrance from the controller to which the personal data have been provided.[41]
Right to object	Data subject shall have the right to object, on grounds relating to his or her particular situation, at any time to processing of personal data concerning him or her, including profiling based on those provisions. [42]
Secondary use of health data	Use of health data for research, innovation, policy, making, statistics, regulatory purposes, protecting against serious cross border threats to health, ensuring high standards of quality and safety of healthcare and of medicinal products or medical devices, or for provision of health services individuals taking into account the information of other individuals. Data falling under the secondary use may include data initially collected under the primary use, in the process of healthcare, but also data collected in the first place for secondary use, such as registries, statistics etc.
Security / safety	Practice of protecting digital information from unauthorized access, corruption, or theft throughout its entire lifecycle.
Solidarity	A socio-ethical and political concept which states that it is fair and just that benefits and obligations are justly shared between members of the society
Sustainability	Processes and actions through which humankind avoids the depletion of natural resources, in order to keep an ecological balance that doesn't allow the quality of life of modern societies to decrease.
Tele-Health	Use of telecommunication techniques for the purpose of providing telemedicine, medical education, and health education over a distance
Tele surveillance	Involves capturing information on vital signs or clinical indicators to monitor a patient's condition.
Transparency	Need for any information addressed to the public or to the data subject be concise, easily accessible and easy to understand, and that clear and plain language and, additionally, where appropriate, visualisation be used
Universality	Which is true for "all similarly situated individuals"
User	Any natural or legal person, public authority, agency or other body using a digital health service or system
Wellness application	A digital health product or service intended by the manufacturer to be used for processing wellness data;
Wellness data	Electronic health data produced or collected by an individual, possibly using mobile applications, that is not part of an electronic health record, as the data is not collected in the health system

[39] Directive 2009/125/EChttps://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009L0125&from=EN
[40] Directive 2009/125/EChttps://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009L0125&from=EN
[41] REGULATION (EU) 2016/679 GPDR https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=EN
[42] REGULATION (EU) 2016/679 GPDR https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=EN

Person with disabilities	Persons who have long-term physical, mental, intellectual or sensory impairments which in interaction with various barriers may hinder their full and effective participation in society on an equal basis with others[43]

[43] Directive 2019/882 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019L0882&from=FR

References to European Regulation

Dimension 1	Proposal for a regulation of the European parliament and of the council laying down harmonised rules on artificial intelligence (artificial intelligence act) and amending certain union legislative acts[44] **Article 5 : The following artificial intelligence practices shall be prohibited :** the placing on the market, putting into service or use of an AI system that exploits any of the vulnerabilities of a specific group of persons due to their age, physical or mental disability, in order to materially distort the behaviour of a person pertaining to that group in a manner that causes or is likely to cause that person or another person physical or psychological harm **Article 7 : Identify high risk AI systems :** c) the extent to which the use of an AI system has already caused harm to the health and safety or adverse impact on the fundamental rights or has given rise to significant concerns in relation to the materialisation of such harm or adverse impact, as demonstrated by reports or documented allegations submitted to national competent authorities g) the extent to which the outcome produced with an AI system is easily reversible, whereby outcomes having an impact on the health or safety of persons shall not be considered as easily reversible; **Article 10 : High risk AI systems which make use of techniques** involving the training of models with data shall be developed on the basis of training, validation and testing data sets that meet the quality criteria such as an examination in view of possible biases **Article 14 : Human oversight** Design and development of a high-risk AI system should have an effective control by human being thanks to human-machine interface tools. This control prevents or minimises the risks to health. These controls allow to be aware of automation bias **Article 52 : Transparency obligation** Providers shall ensure that AI systems intended to interact with natural persons are designed and developed in such a way that natural persons are informed that they are interacting with an AI system, unless this is obvious from the circumstances and the context of use. **Article 53 :** **The AI regulatory sandboxes** shall not affect the supervisory and corrective powers of the competent authorities. Any significant risks to health and safety and fundamental rights identified during the development and testing of such systems shall result in immediate mitigation and, failing that, in the suspension of the development and testing process until such mitigation takes place. **Article 69 : Codes of conduct** The AI regulatory sandboxes shall not affect the supervisory and corrective powers of the competent authorities. Any significant risks to health and safety and fundamental rights identified during the development and testing of such systems shall result in immediate mitigation and, failing that, in the suspension of the development and testing process until such mitigation takes place.
Dimension 2	Regulation (eu) 2018/1725 of the European parliament and of the council on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC[45] **Article 10** (c) the processing is necessary to protect the vital interests of the data subject or of another person where the data subject is physically or legally incapable of giving consent; (h) the processing is necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems and services on the basis of Union law or pursuant to contract with a health professional and subject to the conditions and safeguards referred to in paragraph 3 (i) the processing is necessary for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of healthcare and of medicinal products or medical devices, on the basis of Union law which provides for suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy

[44] 2021/0106 (COD) AI Act proposal https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021PC0206&from=EN

[45] Regulation (EU) 2018/1725 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R1725&from=FR

	Article 5 **Collection of health data should respect a minimal legal framework :** - purpose of data collection should be identify - data treatment should be limited in regard of the purpose Regulation (eu) 2016/679 of the European parliament and of the council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) [46] **Article 9 : processing data concerning health or data concerning a natural person's sex life or sexual orientation shall be prohibited. Excepted :** - an explicit consent - processing necessary for the purposes and it respects fundamental rights and the interests of the data subject - to protect vital interests - processing is carried out in the course of its legitimate activities with appropriate safeguards by a foundation, association or any other not-for-profit body with a political, philosophical, religious or trade union aim and on condition that the processing relates solely to the members or to former members of the body or to persons who have regular contact with it in connection with its purposes and that the personal data are not disclosed outside that body without the consent of the data subjects - data are available thanks to a positive action to the person - processing is necessary for reasons of substantial public interest - processing is necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity - processing is necessary for reasons of public interest in the area of public health - processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes **Art 13 :** **Information compulsory :** the existence of the right to request from the controller access to and rectification or erasure of personal data or restriction of processing concerning the data subject or to object to processing as well as the right to data portability **Art 15 :** Data subject shall have the right to obtain from the controller confirmation as to whether or not personal data concerning him or her are being processed, and, where that is the case, access to the personal data and the following information : the existence of the right to request from the controller rectification or erasure of personal data or restriction of processing of personal data concerning the data subject or to object to such processing Art 16 : rectification data subject shall have the right to obtain from the controller without undue delay the rectification of inaccurate personal data concerning him or her **Art 17 : Erasure** The data subject shall have the right to obtain from the controller the erasure of personal data concerning him or her without undue delay and the controller shall have the obligation to erase personal data without undue delay. This is not apply to the extent that processing is necessary: for reasons of public interest in the area of public health. **Art 20 :** The data subject shall have the right to receive the personal data concerning him or her, which he or she has provided to a controller, in a structured, commonly used and machine-readable format and have the right to transmit those data to another controller without hindrance from the controller to which the personal data have been provided **Art 21 : Right to object** The data subject shall have the right to object at any time to processing of personal data concerning him or her. The controller shall no longer process the personal data unless the controller demonstrates compelling legitimate grounds for the processing which override the interests, rights and freedoms of the data subject or for the establishment, exercise or defence of legal claims. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC[47]

[46] Regulation (EU) 2016/679 GPDR https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=EN

[47] Regulation (EU) 2017/745 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745&from=EN

	Article 14 and following General obligations of distributors 1. When making a device available on the market, distributors shall, in the context of their activities, act with due care in relation to the requirements applicable. 2. Before making a device available on the market, distributors shall verify that all of the following requirements are met: (a) the device has been CE marked and that the EU declaration of conformity of the device has been drawn up; (b) the device is accompanied by the information to be supplied by the manufacturer in accordance with Article 10(11); (c) for imported devices, the importer has complied with the requirements set out in Article 13(3); (d) that, where applicable, a UDI has been assigned by the manufacturer. In order to meet the requirements referred to in points (a), (b) and (d) of the first subparagraph the distributor may apply a sampling method that is representative of the devices supplied by that distributor
Dimension 3	Directive (EU) 2016/2102 of the European Parliament and of the Council of 26 October 2016 on the accessibility of the websites and mobile applications of public sector bodies [48] Member States shall ensure that public sector bodies take the necessary measures to make their websites and mobile applications more accessible by making them perceivable, operable, understandable and robust. Directive (eu) 2019/882 of the European parliament and of the council of 17 April 2019 on the accessibility requirements for products and services [49] **Article 7 and following** When placing their products on the market, manufacturers shall ensure that the products have been designed and manufactured in accordance with the applicable accessibility requirements of this Directive.
Dimension 4	Directive 2009/125/ec of the European parliament and of the council of 21 October 2009 establishing a framework for the setting of eco-design requirements for energy-related products[50] Article 11 Requirements for components and sub-assemblies Implementing measures may require a manufacturer or its authorised representative placing components and sub-assemblies on the market and/or putting them into service to provide the manufacturer of a product covered by implementing measures with relevant information on the material composition and the consumption of energy, materials and/or resources of the components or sub-assemblies. Article 14 Consumer information In accordance with the applicable implementing measure, manufacturers shall ensure, in the form they deem appropriate, that consumers of products are provided with: (a) the requisite information on the role that they can play in the sustainable use of the product; and (b) when required by the implementing measures, the ecological profile of the product and the benefits of eco-design.

[48] Directive (EU) 2016/2102 https://eur-lex.europa.eu/eli/dir/2016/2102/oj?locale=en
[49] Directive 2019/882 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019L0882&from=FR
[50] Directive 2009/125/EC https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009L0125&from=EN