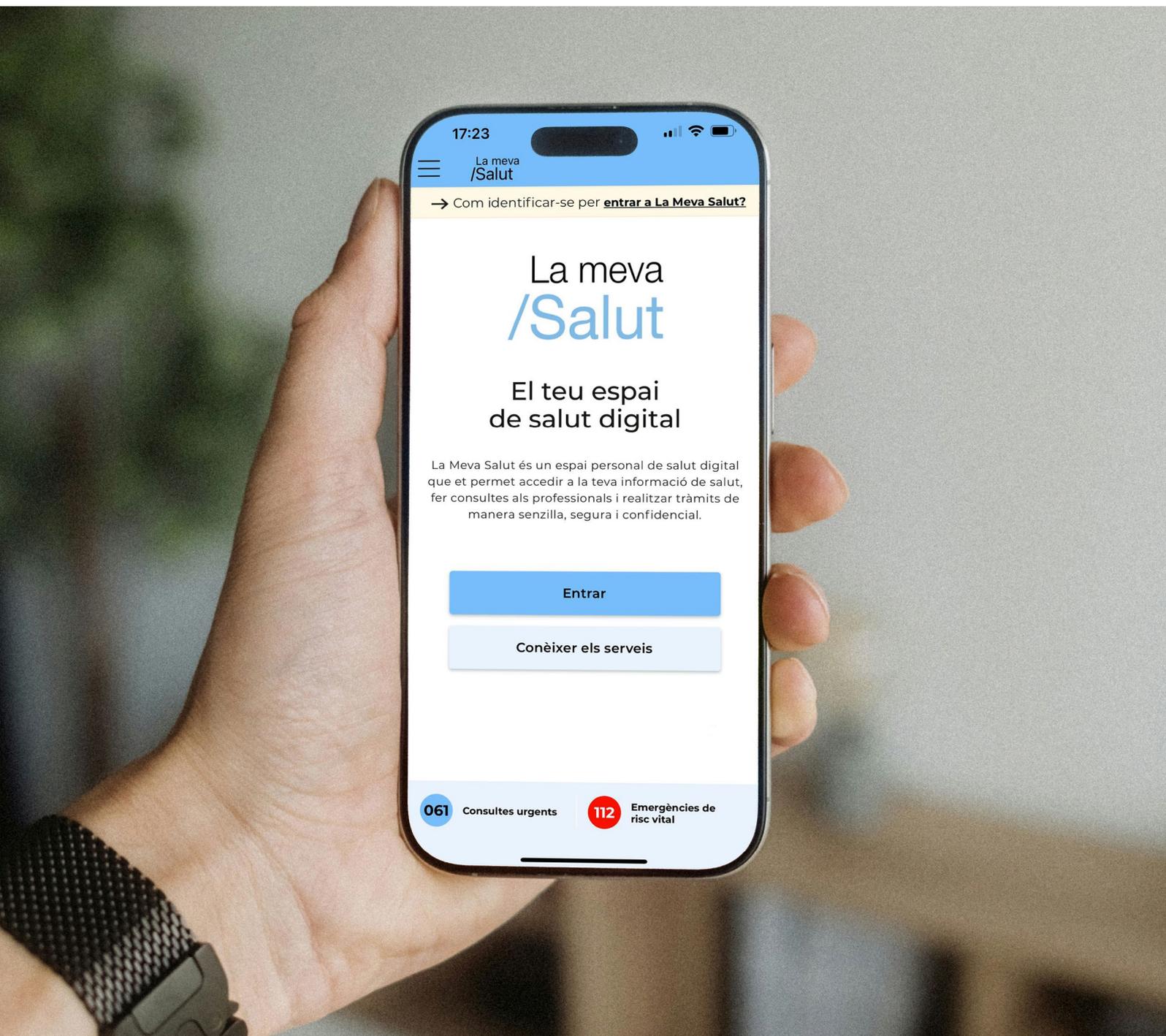


# GOOD PRACTICE GUIDE FOR DEVELOPING DIGITAL ASSETS FOR CITIZENS

June 2025

\*Applies to all digital health and **well-being products and services aimed** at providers of the Comprehensive Public Health System of Catalonia (SISCAT)



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## PRESENTATION

Due to the increasing availability and use of digital assets in the Comprehensive Public Health System of Catalonia (SISCAT), by mid 2023 **Digital Assets for Citizens Department**<sup>1</sup> of the TIC Salut Social Foundation, together **with the Citizens, Innovation and Users Department**<sup>2</sup> of the Catalan Health Service (CatSalut), establish a commitment to promote its good use and promote equity for citizens in their access through three lines of work.

First, a dynamic **digital asset radaris** consolidated, whose main aim is to identify all those digital solutions and services offered by the sector, developed both in SISCAT supplier centres and in other institutions and research and innovation centres.

Secondly, a **Directory of Digital Assets**<sup>3</sup> is made available within the scope of provider centres and citizens in order to promote access to health services through digital assets and facilitate their implementation throughout the territory.

And finally, through this **Good practice guide for developing digital assets for citizens**, it is intended to disseminate what are the relevant aspects that a digital asset or service needs to achieve in order for it to be accessible from **La Meva Salut**<sup>4</sup>, applicable for all digital health and well-being products and services intended for the Comprehensive Public Health System of Catalonia (SISCAT).

<sup>1</sup> Digital Assets Department for Citizens of the FTSS. More information: <https://ticsalutsocial.cat/que-fem/actiusdigitals/>

<sup>2</sup> Citizens, Innovation and User Department of Catsalut. More information: <https://web.gencat.cat/ca/adreces-i-telefonos/detall/index.html?codInf=21406>

<sup>3</sup> Directory of Health and Social Digital Assets. Access: <https://ticsalutsocial.cat/que-fem/actiusdigitals/actius/>

<sup>4</sup> *La Meva Salut* (My Health). More information: <https://catsalut.gencat.cat/ca/serveis-sanitaris/la-meva-salut/index.html>

**This guide aims to empower the developers of digital assets aimed at SISCAT so that they can align with La Meva Salut and, thus, facilitate a more consistent mSalut experience for all the citizens of Catalonia\*, with safe, effective, reliable, usable digital assets, and that guarantee the rights of the people who will use them. In this way, all developers can contribute so that the public have quality digital assets, which allow them to manage their health and improve their well-being.**

**The document details the specific requirements of the digital solutions so that they adapt to the needs of CatSalut and SISCAT. It includes information to ensure that the assets have appropriate clinical content and functionality, are easy to use by the entire population, guarantee data security and privacy, and are technologically robust.**

\*In cases where the digital asset has potential for integration or authenticated access from La Meva Salut, it will be necessary to carry out a unique assessment of the digital asset and a project to monitor the service over time.

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# GLOSSARY

**Accessibility.** The degree to which the products, systems and services can be used by the maximum number of people regardless of the needs, characteristics or capabilities of the users.

**Digital asset in health and social.** Digital element (product, process or service) that facilitates the practice of health and social welfare activities centred on the person, and that is accessible through a web page, a mobile application or other user interfaces.

**User subscription or registration.** Process whereby a user person creates a new account in a digital asset. In general, the user's identity needs to be validated before allowing access to the personal services of the digital asset in use. Mobile application. Software application designed to be used on touch tablets, smartphones and other mobile devices.

**Web application.** Software application designed to be used as a client through a web browser, either internet or intranet.

**Authentication.** Post-registration process, which consists of the verification of the access credentials associated with a user account and which, if they are correct, allows access to the personal services of the digital asset in use.

**Health benefit.** Positive impact or desirable result of an action in terms of health.

**Health condition.** Illness or health problem; or characteristic related to the physical, mental and social well-being, not necessarily pathological, of a person or population group.

**Effectiveness.** Ability to produce the intended result.

**Evidence.** Directly measurable characteristic of a process or product that represents an object, demonstrable proof that a specific activity satisfies a specific requirement.

**Personally Identifiable Information (PII).** Any information that makes it possible to establish a link between the information and the natural person to whom it refers.

**Health intervention.** Act carried out to ensure, improve, maintain or promote the health conditions of a person or population.

**Health.** A state of physical, mental and social well-being, and not just the absence of disease.

**Digital service.** Digital element or benefit designed to fully or partially cover an assistance and/or social need or a health intervention, developed through the functionalities of a digital solution.

**Digital solution.** Web or mobile application with universal access that facilitates the practice of health and social welfare activities centred on the person, and which is intended to provide a set of services.

**Intended use.** Functionality for which the manufacturer has designed and manufactured a product. It is essential to ensure that the product is useful safely and effectively for the intended purpose, thereby avoiding health risks and maximizing the expected benefits.

**Digital product.** Article that is created and distributed in digital format, usually through online platforms or electronic devices. Digital products may include software, mobile applications, multimedia content, online courses, online games, among others. These products are characterized by being intangible and can be distributed and replicated easily without the need for a physical support. Therefore, this term can be used in this guide as a synonym for digital solution.

1.

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# Introduction

## 1.1 What is a digital asset?

**In the TIC Social Health Foundation and the Citizenship, Innovation and User Department of the Catalan Health Service (CatSalut), we use the term digital assets in the health and social sphere to refer to any digital solution that facilitates the practice of person-centred health and social welfare activities, and is accessible through a website, mobile application or other user interfaces.**

When we talk about a **digital solution** we refer to a web or mobile application with universal access that facilitates person-centred health and social welfare activities and that is intended to provide a set of services.

When we talk about a **digital service** we refer to a digital element or provision designed to fully or partially address a care and/or social need or a health intervention, carried out through the functionalities of a digital solution.

Therefore, digital assets can be considered a **digital solution** in its entirety, or part of the solution with a specific digital service.

## 1.2 What drives the creation of digital assets?

It is a reality that technologies have become a key element in the digital transformation in many areas of people's lives and in the field of health is a great example. From simple aspects, such as searching for health information, video calls, sharing reports and other content; such as more complex aspects such as telemedicine, applications for health monitoring and management, therapies through games, etc. All these elements represent a clear example of the growing proliferation of tools and resources aimed at making life easier and meeting the needs of the sector.

The motivation for which a developer decides to create a digital health and/or social product for the population can be very diverse, although it must always respond to a detected need and must provide value. One of the fundamental reasons that drives the creation of these solutions is to

offer relevant content for a group of people; in the form of recommendations, procedures or assisted registration, among others, all adapted to web browsers or mobile devices that support users at all times and that enable the use of sensors, the sending of notifications, etc.

## 1.3 Context and starting point

The availability and popularity of digital assets is constantly growing. These solutions have become indispensable elements within the system, both for the management of health and personal well-being, and for the support they offer in clinical practice.

Within SISCAT, a large volume of highly useful health and well-being applications are already being used by patients and healthcare professionals, which makes it possible to redefine the relationship between professionals and patients in terms of efficiency and effectiveness. Even so, the high number of apps available — the digital markets have hundreds of thousands of mobile health and wellness apps — makes it difficult to make an optimal choice of the best apps. In addition, the need to download them — in the case of mobile applications — and access each of them from a different platform can hold patients and professionals back when it comes to using them.

With regard to access to personal health information - and the services that facilitate its management -, the citizens of Catalonia have **La Meva Salut (My Health - LMS)**. This is the personal digital health space, accessible via web and app, which allows citizens to interact with the Catalan Health System in a non-face-to-face manner. It makes it easier for users to consult clinical reports, diagnoses and results of clinical analyses and tests that are part of their clinical history, consult appointments for visits and diagnostic tests and download the current medication plan, among others services.

Additionally, a large part of the SISCAT health centres have their own digital assets that allow citizens to communicate more specifically with their hospital of reference, which we call **specific relational assets**. Visit management services, emergency waiting times, admission

to the centre, among many others, are offered, which provide users with greater autonomy. However, in order to manage their health digitally, citizens must consult both La Meva Salut and the assets of the centre or hospital they are assigned to.

These facts have encouraged CatSalut's Citizenship, Innovation and User Area together with the TIC Salut Social Health Foundation to join efforts to define a set of requirements aimed at digital products and services used within SISCAT and which will allow:

- **Guarantee a framework of trust that allows the promotion of quality solutions and in this way ensure better care to the person.**
- **Having these assets in a single space, La Meva Salut, which will facilitate the access of users to these platforms and allow a more generalized and harmonized use, enhancing public care and facilitating the work of healthcare professionals.**

## **1.4 Objectives and content of the document**

The main objective of this guide is to accompany SISCAT suppliers in the development of quality health and well-being digital products and services, as well as other developers of digital solutions for use within SISCAT.

The guide is a collection of good practices adapted to the requirements defined for La Meva Salut. In this respect, it aims to identify the aspects that affect the creation of **effective, reliable, usable, safe applications that guarantee the rights of the people who will use them.** For this reason, technical specifications with international validity are presented that allow the developers of these solutions to optimize the development of their products and services. The document addresses both the functional aspects, as well as the technical and security aspects that any digital application must incorporate to meet the requirements established for LMS.

First, the document focuses on identifying what is the relevant information about the asset that needs to be known in order to analyse it, addressing aspects such as **the use of sensitive data, the intended use and the impact on the population**, essential parameters to determine the risks and benefits of its use among the population.

Next, the guide explains four blocks that define the quality of the asset. First of all, it focuses on **healthy and functional** content, which includes aspects such as the reliability of the clinical or well-being content of the solution – the guarantee that its use does not harm the health of the user, and provides a benefit for health or well-being while taking into account the basic principles of ethics in order to ensure that the asset is healthy and safe. Secondly, it addresses all those aspects related to the accessible design and usability, dealing with aspects such as accessibility, usability, user experience, language and communication that make the asset easy to use for everyone. The third point points out the specific regulations applicable to the digital solution in health, focused on **secure data** in order to preserve people's privacy. The fourth part focuses on topics such as **robust technology and performance** in order that it will be a solid and reliable asset.



### **Healthy content and functionality**

The asset must have reliable clinical and social welfare content and useful functionalities. It is necessary to take into account the health benefits and risks derived from its use, as well as the ethical aspects, so that the asset is healthy and safe.



### **Robust technology and performance**

The asset must work efficiently and reliably from a technological point of view. It must conform to minimum functionality acceptable to the end user, guaranteeing robustness and consistency.



### **Accessible design and usability**

It is necessary that the asset presents an intuitive use and a design suitable to the required function, and that it guarantees accessibility. It is also necessary to ensure the use of understandable language for the intended audience. In short, make it easy to use.



### **Secure data and privacy**

It is necessary to ensure the existence of mechanisms to preserve the security and privacy of user data and the confidentiality of its transmission, in accordance with current regulations.

## **1.5 Considerations for Developers**

Before developing a digital asset is recommended that you **verify that there are no similar assets with the same functionalities** that what you want to create. In this way you will avoid duplicating efforts and having very similar or practically identical elements.

For this reason, it can be very useful to consult reference application directories such as the **Directory of Digital Health and Social Assets of the TIC Salut Social Health Foundation**,

available to all provider centres and the general public. The Directory aims to publicise all relevant digital health and social assets in the Catalan territory, as well as their functionalities, with the aim of promoting access and facilitating their implementation in the system. In this way, the Directory collects digital assets recommended by health or social centres, or identified in reference frameworks that evaluate their quality. **The health and wellness mobile apps that have been successful in the Foundation's certification process are also included.**

It is important to highlight the capacity we have as a Health System to create synergies between SISCAT providers and, whenever possible, deploy or adapt existing resources from a provider for other organisations in the System, in order to make the most of the efforts already made. This is also applicable to already developed digital assets.

**On the other hand, before creating a relational asset supplier entities are also urged to review the services that are already offered in La Meva Salut<sup>5</sup> so as to avoid duplicating services already offered to citizens.**

## 1.6 Other matters

In this guide there are linguistic formulas that define the degree of involvement of the agents and the proposals, based on part 2 of the ISO/IEC<sup>6</sup> directives :

- “**must**” and “**have to**”, and the relevant conjugated forms, denote a requirement.
- “**advise**” and “**recommend**”, and the relevant conjugated forms, indicate recommendations.
- “**urge**”, and the relevant conjugated forms, indicate particularly desirable recommendations.
- “**can/may**”, and the relevant conjugated forms, indicate permission, possibility or ability.

<sup>5</sup> La Meva Salut. Services. Access: <https://lamevasalut.gencat.cat/web/cps/ajuda/serveis>

<sup>6</sup> ISO/IEC Directives, Part 2. Principles and rules for the structure of ISO and IEC documents

# 2.

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## European efforts for the certification of digital assets

Digital health and social assets have great potential to facilitate the management of the population's health and well-being; and their evaluation and subsequent certification of these allows to ensure their quality, good use, and benefit from the people who use them. In Europe, application certifications are currently carried out at the national or regional level, with different evaluation criteria in each case. There are many efforts coming from different regions of the European Union and from different Health Systems to promote these applications among citizens and achieve a common framework of trust within Public Systems.

The European Commission, through the project **Label2Enable**<sup>7</sup>, is promoting a standard certification based on technical specifications **CEN ISO/TS 82304-2**<sup>8</sup>, focused on mobile applications, with the aim of having single certification criteria throughout Europe, eliminating the difference in assessment domains between countries and regions, and establishing a quality label with cross-border recognition. CEN ISO/TS 82304-2 establishes 74 criteria grouped into four evaluable domains of the quality label: **Healthy and Safe, Easy to Use, Secure Data and Robust Build**, which allow a global assessment of the app based on a final result obtained by each domain. This label is mirrored with other indicators already established throughout Europe such as **Nutriscore**<sup>9</sup> and **Energy efficiency in household appliances**<sup>10</sup>.

Different initiatives have been launched in Catalonia to help citizens choose trustworthy digital assets based on their evaluation. The iSYS Foundation established its **iSYS Apps ranking**<sup>11</sup> for patients and professionals, based on a method of evaluating mobile health applications based on objective variables to give users guidance on **Popularity, Trust and Usefulness**. At the beginning of 2016, the TIC Salut Social Health Foundation (FTSS) introduced the **Mobile application certification process** to guarantee the quality and reliability of health and wellness applications, based on 120 criteria grouped

into 4 blocks (*Clinical contents and functionality; Usability, accessibility and design; Data security and privacy; and Technological robustness*). This process arose as a result of the need to evaluate mobile applications in the field of health and social care in the Catalan territory, in order to bring them closer to the public.



**Figure 1:** CEN ISO/TS 82304-2 quality label

<sup>7</sup> Projecte Label2Enable. More information: <https://label2enable.eu/>

<sup>8</sup> CEN ISO/TS 82304-2:2021, "Health software – Part 2: Health and wellness apps – Quality and reliability".

<sup>9</sup> NutriScore. More information: [https://www.aesan.gob.es/AECOSAN/docs/documentos/publicaciones/seguridad\\_alimentaria/INFOGRAFIA\\_NUTRI-SCORE.pdf](https://www.aesan.gob.es/AECOSAN/docs/documentos/publicaciones/seguridad_alimentaria/INFOGRAFIA_NUTRI-SCORE.pdf)

<sup>10</sup> DIRECTIVE (EU) 2023/1791 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 13 September 2023.

<sup>11</sup> iSYS Foundation. Catalogue of Apps. Access: <https://www.fundacionisys.org/es/apps-de-salud/catalogo-de-apps>

**3.**

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# **Asset information**

A product, process or service that aims to improve the health or well-being of a person or population needs a series of specifications, instructions or information to be defined with regard its purpose - also called “intended use” - as well as benefits and risks and target population, among others.

It is important to show the public, including users of the solutions and healthcare professionals, **the characteristic features of the developed digital asset**, so that they can have at their disposal all the relevant information that allows them to know its functionalities, the user profile it is aimed at, among others, and can assess whether its use can bring them a benefit or entail a risk. Therefore, indicating what the asset can do and what it cannot do is key to identifying its characteristics that allow it to be classified and determine the risk it entails for the person, as well as other essential aspects to guarantee its quality, reliability and trust.

### 3.1 General information

As general information, the application must specify the name and identifying features it uses (icon, etc.), the operating systems and platforms on which it is supported (depending on whether it is an app, Web or WebApp, etc.) and the languages in which it is available. It must also provide information about the manufacturer and **owner of the solution**, a telephone number or contact email and the sources of funding, promotion and sponsorship of the solution. With regard to languages, all those assets aimed at the population of Catalonia must be available in the **Catalan language**.

As for the indispensable information that every person using a digital asset must be able to identify, it is necessary to start with the **intended use** of the asset, and explain the specific motivation for the health problem or the service offered. It is also necessary to include the profile of the person or audience to whom it is addressed (**intended users**); the **benefits or advantages** that the use of the digital asset can bring, emphasising the fact that its **functionalities** can **prove useful for people** in terms of saving time, acquiring knowledge, improving control and monitoring their health

status, among other factors, depending on its intended use.

Finally, it is necessary to highlight other aspects such as **age restrictions** for the use of the digital asset clearly and concisely, as well as all the individuals or bodies that, from the beginning or at some point in the process, have participated in the development of the solution.

### 3.2 Information to define the risk of the asset

In order to determine the quality of the digital asset, it is necessary to first define what risk it entails for the user who will use it. This classification makes it possible to determine the requirement applied when evaluating it. For this reason, there are three key parameters that directly affect the classification of a digital asset in the public domain, which are the use of sensitive data, the intended use and the impact on the population. The following table shows the different levels of each parameter.

<b>Use of genetic data</b>	CAP [Primary Healthcare Centre]	Local/Generic	Total
<b>Risk according to intended use</b>	Low	Moderate	High
<b>Impact on the population</b>	Small	Moderate	Potential

- —————> +

- **Use of sensitive data:** determines the level of sensitivity in accordance with the personal data that the asset processes and that may put the person’s privacy at risk, subject to the application of the General Data Protection Regulation (GDPR). For this reason, it is necessary to specify whether the asset collects sensitive user data, whether the processing is local or generic and whether they are transmitted outside the application.
- **Risk according to intended use:** the intended use establishes the purpose of the application: to inform, communicate, diagnose, support diagnosis or clinical

decisions, make calculations to determine diagnosis or treatment, among others. This parameter is decisive when it comes to having an accurate and complete definition of the intended purpose of the application, which will allow us to conclude whether or not it is a health product.

The technical specifications **CEN ISO/TS 82304-2** list the intended uses of health and wellness applications, applicable for all digital health and social assets. The table below has been adapted to show this list, as well as the health risk identified by the user for each intended use:

INTENDED USE	Description	Associated risk
<b>Health System Services</b>	Assets that improve the efficiency of the Health System, but that do not include direct and measurable results of individuals.	<b>Low</b>
<b>Information</b>	Assets that provide information and resources aimed at anyone with a specific health or wellness condition.	<b>Low</b>
<b>Simple monitoring</b>	Assets that record health or wellness parameters to create diaries without sending the data to third parties.	<b>Moderate</b>
<b>Communication</b>	Assets that facilitate communication between users and health professionals, for example, with video consultations or chats.	<b>Moderate</b>
<b>Preventive behavioural changes</b>	Assets that prescribe changes in the user's habits to improve their well-being.	<b>Moderate</b>
<b>Own management</b>	Assets that provide tools to manage one's own health, including recording symptoms, accessing medical reports or consulting prescribed medication.	<b>Moderate</b>
<b>Research</b>	Assets that collect data for studies or scientific research, with the aim of better understanding health problems and their solutions.	<b>High</b>
<b>Treatment</b>	Actius que ofereixen tractaments per a condicions de salut específiques o que donen suport a les decisions terapèutiques.	<b>High</b>
<b>Active monitoring</b>	Assets that directly record health parameters and transmit the data to health professionals, without input from the user, to control the disease.	<b>High</b>
<b>Calculation</b>	Assets that perform calculations that affect decisions in health control.	<b>High</b>
<b>Diagnosis</b>	Assets that use data to diagnose or guide the diagnostic decision made by the health professional.	<b>High</b>

- **Impact on the population:** establishes the degree of penetration of the use of the digital asset in the population of Catalonia based on various demographic factors (age, gender, lifestyle, genetics, access to health services, socio-economic situation, environmental surroundings) and how this use can help in the development of prevention and health management strategies within the System. The value can be **small** (less than 2% of the population); **moderate** (between 2% and 10% of the population) and **high** (above 10%).

The combination of these three parameters determines the risk of the asset and, therefore, defines the requirement in its evaluation.

**It should be noted that within the same solution there may be several assets that collect sensitive data, have several intended uses (for example, relational assets may have health system service assets and self-management) or have a variable impact on the population. Under these assumptions, the solutions will always be evaluated following the criteria of the asset with the highest risk.**

### **3.3 Digital solutions as a healthcare product**

Digital solutions in health that can be considered a health product are often called medical applications (or Mobile Medical Apps) while the rest are called health and wellness applications (or Health and Wellness Apps). The intended use is essential to determine whether or not a solution is a health product: if its intended use is to **diagnose, support diagnosis or clinical decisions, perform calculations to determine diagnosis or treatment, or be used for any medical purpose, the application could be considered a healthcare product.**

It is crucial to identify during the design phase if the digital asset under development is a healthcare product and what benefits the provider can offer through it, since, if so, it is necessary to adhere to the current legislation, which includes rigorous security controls

comparable to analogue solutions to guarantee, in this way, the safety of the patient. At present there are two regulations that harmonise all regulations relating to health products (**Regulation EU 2017/745, on health products or MDR<sup>12</sup>, and EU Regulation 2017/746, on in vitro diagnosis or IVDR**).<sup>13</sup>

Regulation (EU) 2017/745 defines a health product as:

**Health product: any instrument, device, equipment, computer program, implant, reagent, material or other article intended by the manufacturer to be used on people, separately or in combination, for any of the following specific medical purposes:**

- <Diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of a disease;
- Diagnosis, monitoring, treatment, alleviation or offsetting of an injury or disability;
- Research, replacement or modification of anatomy or of a physiological or pathological process or condition;
- Obtaining information through in vitro examination of samples from the human body, including donations of organs, blood and tissues, and that does not exert its intended main action inside or on the surface of the human body by pharmacological, immunological or metabolic mechanisms, but which may contribute to the function of such mechanisms.

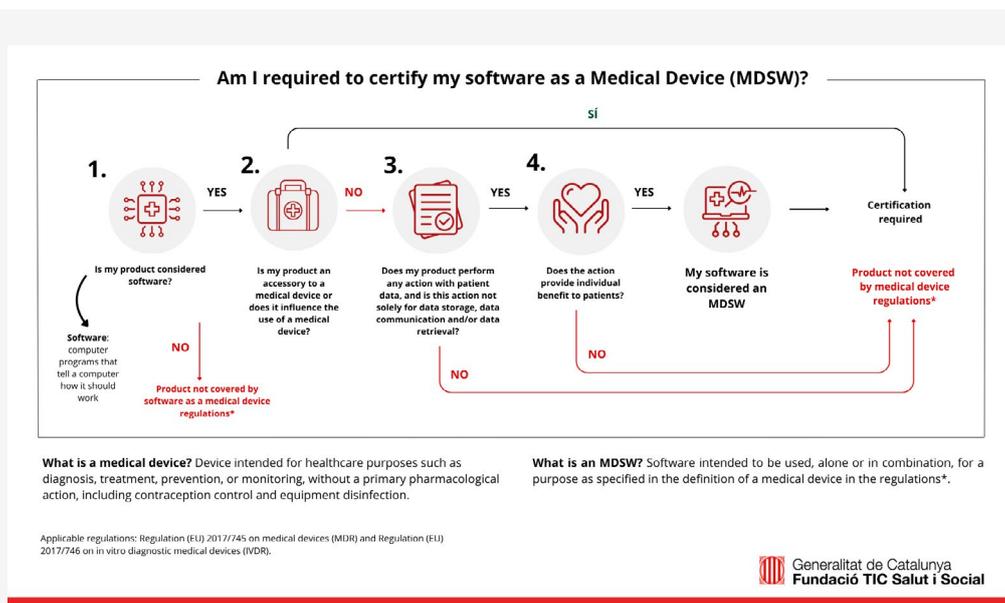
Following the definition of EU Regulation 2017/745, a digital solution can be a health product depending on the purpose of its use, or the intended use, so you must be very careful when designing the product. A classification of health products is stipulated in **Class I, Class IIa, Class IIb, Class III depending on the intended use and the** associated impact they have; for this reason, a detailed description needs to be made of the digital solution that one wants to develop.

<sup>12</sup> Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on health products, amending Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. 1223/ 2009 and which repeals Council Directives 90/395/CEE and 93/42/CEE.

<sup>13</sup> Regulation (EU) 2017/746 of the European Parliament and the Council, of 5 April 2017, on in vitro diagnostic health products and by which Directive 98/79/EC and Commission Decision 2010/227/EU are repealed.

The following scheme makes it possible to discern whether the solution is a health product

or not and its class.



**Figure 2:** Indicative algorithm for the classification of digital solutions as a Health Product according to the EC (EU) 2017/745 regulation

For more information on the regulation, see the **guide MDCG 2019-11**<sup>14</sup>.

All health products must have a **Unique Identifier number for Devices** (or Unique Device Identification, UDI)<sup>15</sup> and thus be able to be included in the **European centralised register of health products** (EUDAMED, acronym of European Database on Medical Devices)<sup>16</sup> so that it is available to the public. In addition, the notified bodies must provide a greater number of clinical data and research, and therefore, the products must comply with more post-marketing monitoring requirements - they go through a re-certification process and are subjected to strict monitoring, as well as unannounced audits—.

The Regulation also targets all agents involved in the arrival on the market of a health product or service (manufacturer, authorized representative, importer or distributor). They are also **guarantors of compliance with regulations, traceability and surveillance**.

Mobile applications considered a health product can act as an accessory to a health product or directly convert the mobile platform into a health product. On the contrary, **if the application only stores, files, transmits, performs simple data search, or presents data results without altering or manipulating them, it will not be considered a healthcare product.**

In this case the application will be considered a Health and Wellness App, and will only have to meet the requirements set out in this guide.

In any case, **the same solution** may or may not be a health product depending on the **intended purpose**.

<sup>14</sup> MDCG 2019-11. Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 - MDR and Regulation (EU) 2017/746. MDCG endorsed documents and other guidance

<sup>15</sup> Unique Device Identification (UDI). More information: <https://health.ec.europa.eu/>

[medical-devices-topics-interest/unique-device-identifier-udi\\_es](https://ec.europa.eu/tools/eudamed/#/screen/home)

<sup>16</sup> EUDAMED. Access: <https://ec.europa.eu/tools/eudamed/#/screen/home>

### EXAMPLE 1

**May or may not be a Health product:** a solution to monitor heart rate, if it is indicated exclusively for sports use, will not be a health product; on the other hand, the same application intended for medical use may indeed be a health product.

### EXAMPLE 2

**Yes Health Product:** a solution that transforms data from wearables into graphs or electrocardiograms; since it processes the data obtained from the user, it would be considered a health product. So would calculators that take into account clinical factors of the user.

### EXAMPLE 3

**Not a Health Product:** those solutions whose intended purpose is to improve communication between patients and healthcare staff, which allow storing of and searching for patient data or which allow the visual display of information, by carrying out searches, and whose purpose is not medical benefit, are not classified as patient health products.

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## Health content and functionality

The clinical and functional content of an asset is its fundamental part; it makes up its reason for being, what adds value and must distinguish it from the rest of the solutions. For this reason, it is crucial to recognise its great importance and provide it with the quality and reliability necessary to obtain **healthy and safe assets**. In this sense, it is also necessary to consider the benefits and health risks that the solution may bring, and ensure that it follows the line of ethical principles.

To develop this section, all the requirements established in the CEN ISO/TS 82304-2 technical specifications, focused on mobile applications and previously mentioned, have been taken into account, as well as the requirements established in the Mobile Applications Service of the ICT Social Health Foundation.

## 4.1 Content quality

It is essential to ensure that the clinical and functional content of the digital asset is relevant and reliable, and aligned with scientific evidence and current medical practice, in order to provide the asset with sufficient quality to be used by the public.

In this sense, the following aspects must be taken into account, both when preparing the content and when displaying it.

- **Content relevance:** it is necessary to ensure that the content offered is of interest to the user profile to which it is addressed, and that it can provide them with useful functions. Otherwise, citizens will lack interest in using it. For this reason, it is necessary to be clear about the objective of the solution and, if possible, encourage co-creation with end users.

- **Clear objective.** The use of the solutions must address at least one of the intended uses described in the previous section and must provide a benefit to the user. Possible benefits include the acquisition of knowledge (information), saving time (efficiency), improved control or monitoring of the state of health (quality), among others. Below is a table with the entire list of benefits.

- **Co-creation.** It is highly recommended to include potential users of the solution from the early stages of solution design and planning in order to ensure that the solution is useful to them and brings maximum benefit to them.

- **Content reliability.** To ensure the reliability of the content, we need to take into account the scientific evidence, the participation of experts and the review of the contents.

**The term health interventions (or health actions) refers to all those active functionalities of the digital asset that promote benefits for the health of its users based on their data. Active functionalities must be based on scientific evidence, and may have been programmed automatically through algorithms and/or require the action of a healthcare professional. Passive functionalities such as the provision of health information and administrative management are excluded. The WHO has published documentation containing the entire list of digital and clinical interventions.**

- **Scientific evidence.** It is essential to build product content with solid scientific evidence. For this reason, it is necessary to indicate the sources of information for the contents collected in the solution, including the reviewed scientific literature, in accordance with some of the regulations for the publication of bibliographic references (Vancouver, APA, AMA, etc.). It is necessary that health recommendations are made only on the basis of existing evidence, and that the clinical data systems used have recognized reliability and validity. This includes clinical language, measurement scales, vaccine schedules, normal ranges, etc. It should be borne in mind that measurement systems may vary depending on the territory.

If the healthcare interventions contained in the asset have been automatically programmed through **artificial intelligence algorithms**, it is essential that the reliability of the algorithms can be demonstrated through evaluation metrics (accuracy etc.), among other aspects. Transparency to users with these metrics will be necessary. This aspect is discussed in more detail in section 7.2 *Artificial intelligence algorithms*.

**- Participation of experts.** It is vital that health professionals, public bodies, scientific societies, professional associations and associations, among others, have collaborated in the development of the asset content, and that the contents have subsequently been approved. This information must be communicated to the intended users, also indicating the people responsible for it. Providing complementary curricular information such as the entity to which the professionals belong, their training and clinical speciality indicate transparency and inspire confidence among the general public. Having a multidisciplinary team, with specialists in the solution being developed, adds much more value to the asset. This is why it is recommended that you have specialists within the development team who can provide this confidence.

**- Review.** It is necessary to indicate the date of creation or last revision of the contents of the solution in the digital markets or of the solution itself, in order to be able to assess its validity, current validity and reliability. It is necessary to consider the need to review and update the contents periodically according to the changes and/or modifications established in the scientific evidence, providing robustness and consistency to the asset.

Additionally, it is recommended to supplement the content with self-help elements such as video tutorials, guides or frequently asked questions section to ensure that the functional and clinical

content is used and interpreted in the intended way. It is also advisable to incorporate contact mechanisms for users, which allow them to resolve doubts about functionality and clinical recommendations that the asset may generate. Contact can be facilitated by email, phone, chat, contact form, etc.

## 4.2 Health benefits and risks

The use of health and social assets can bring various benefits, but also risks for the health and well-being of the users. For this reason, it is essential to alert users that the solution and its contents are **not intended to replace the services offered by healthcare professionals**, and indicate that the support of professionals is necessary to obtain a benefit from the asset, whenever appropriate. It is also necessary to make them aware of the risks that their use may entail.

- **Benefits.** First, it is essential to describe the benefits in health and well-being that the solution can bring, as well as the **health interventions** applied to achieve the benefit. A series of important aspects are listed below:
  - Describe the benefits in health and well-being derived from the use of the application, based on the existing scientific evidence.
  - Cite available evidence to support the benefit, preferably peer-reviewed scientific literature. The asset will have more value if it has been developed with public information sources.
  - Give information about the health interventions applied to achieve the benefit.
  - Provide information on the financial costs of obtaining the health benefit. The asset will have more value if it has been developed with public funding sources.

The World Health Organization (WHO) **classifies the challenges in digital health**<sup>17</sup> in eight categories that are made available to the reader as a starting point to understand how a digital asset can benefit citizens. These align with the organisation's care strategies<sup>18</sup>.

<sup>17</sup> WHO. Classification of Interventions in Digital Health v1.0. More information: <https://www.who.int/publications/i/item/WHO-RHR-18.06>

<sup>18</sup> WHO. Principles of health benefit packages. Access: <https://iris.who.int/bitstream/handle/10665/340723/9789240020689-eng.pdf?sequence=1>

BENEFITS	DESCRIPTION
<b>Information</b>	Positive effect on the delay in the notification of events, lack of reliable data, blockages in communication, lack of access to data and insufficient use of data among others.
<b>Availability</b>	Positive effect on the insufficient provision of supplies, services, equipment or health professionals.
<b>Quality</b>	Positive effect on the experience of people with health needs or health problems or informal carers, as well as poor skills or low quality of guides or poor adherence to them.
<b>Acceptability</b>	Positive effect on the lack of alignment of local regulations or programs.
<b>Good use</b>	Positive effect on low demand for a service, geographical inaccessibility, low adherence to treatments or loss of follow-up.
<b>Efficiency</b>	Positive effect on the management of work flows, lack of referral or inadequate referral, planning or coordination, delay in the provision of care or in transport.
<b>Cost</b>	Positive effect on the high cost of manual processes, the lack of effective allocation of resources, the expenses of people with health needs or health problems or the coordination of payment.
<b>Accountability</b>	Positive effect on the lack of transparency of commodity transactions and the poor performance of accounts between the levels of the health sector and the population.

- **Risks:** on the other hand, one needs to bear in mind the risks associated with the use of the application. Therefore, it is essential to perform a risk **analysis and indicate the risks present and contraindications to users of the product**, including the possibility of misuse of the application and possible adverse effects. It is necessary to:

- Implement measures to control and minimise risks arising from digital assets.
- Determine whether the residual risks are acceptable for the use of the asset by the public.
- Provide information to users about the need for professional approval to use the asset, if applicable.
- Have a process to collect and review problems and incidents.

Information or data to estimate risks can be obtained from published standards, scientific or technical research, field data,

usability testing, clinical evidence, research or simulation results, expert opinions, external quality assessment schemes, etc.<sup>19</sup> The manufacturer of the asset must identify and document the known and foreseeable risks to the intended users, both under normal and error conditions through the introduction and use of the health application.

Health risks may include overconfidence, disproportionate attachment, and addiction to a health app or manipulation that affects human autonomy. A technique for identifying risks can be functional risk analysis, which considers the consequences if the asset is lost (i.e. if it is not available when required), is incorrect (if it is available but performs an action unwanted) or is inappropriate (if it works according to the intended use, but does not adapt to the circumstances of the moment).

<sup>19</sup> Adapted from ISO 14971:2019

Some examples of risk associated with each intended use are as follows:

INTENDED USE	ASSOCIATED RISK
<b>Health System Services</b>	Deterioration of system services (delayed service delivery, inadequate work-flow management, etc.).
<b>Information</b>	Shows incorrect or biased information, lack of quality or reliable data.
<b>Simple monitoring</b>	Tracking errors, insufficient use of data and information.
<b>Communication</b>	Poor transmission of health information, inconsistent data by text or multimedia.
<b>Preventive behavioural changes</b>	Incorrect prescription; bad practice.
<b>Own management</b>	Bad management of health condition.
<b>Research</b>	Incoherent hypothesis based on biased data.
<b>Treatment</b>	Incorrect prescription; bad practice.
<b>Active monitoring</b>	Tracking errors, insufficient use of data and information.
<b>Calculation</b>	Incorrect or miscalculation.
<b>Diagnosis</b>	Incorrect or misdiagnosis.

In addition to the previous points, we need to bear in mind the current regulations regarding **health products**, given that digital solutions can also be covered by this regulation. Therefore, **it is necessary to evaluate the intended use of the solution and the associated risks** to determine if it falls within this definition. If so, the solution needs to pass the health product regulations before making it available to the public (see section **3.3. Digital solutions as a healthcare product in this guide**).

## 4.3 Social benefits

The Catalan Health System is promoting integrated social and health care. In this sense, the ICT Social Health Foundation promotes networking in the areas of health and social

welfare; therefore, all solutions are urged to use methodologies that have not only a health but also a social approach.

Digital solutions can have an implicit social impact — providing information that is difficult to access for the population, providing access to insufficient services or equipment, reducing the costs of certain processes, easing family burdens, improving non-professional care, promoting community action, etc. —, or explicit, including integrations between the two areas of work that make it easier for them to share information and coordinate the efforts of professionals.

It is also recommended that the social impact of digital solutions has been assessed by research articles.

## 4.4 Ethics

Respect for internationally recognised human rights and fundamental ethical criteria must always be at the forefront of the development and application of technology. For the case of digital health and social solutions, it is essential to consider, first of all, the most elementary principle of bioethics: the respect for the **dignity of the person**, based on a comprehensive and humanist approach to health care. From this fundamental principle arise **the four basic principles of bioethics<sup>20</sup>: autonomy, beneficence, non-maleficence and justice**, which are described below, adapted to the present case.<sup>21</sup>

The ethical aspects of the use of the digital solution need to be analysed, with the relevant documentation and, if applicable, it is recommended that the digital asset has been approved by an independent ethics advisory/committee.



### Principle of autonomy

People must be able to deliberate on their personal goals and act under the direction of the decisions they can make. In this sense, the user of digital solutions must be one by conviction, never by professional obligation, for example. For this reason, it is also necessary for the digital solution to establish terms of use regarding the objectives of the solution, the benefits and risks it brings, the types of data that will be requested, returned or evaluated, among others, that allow the user to decide autonomously about their consent, what is called informed consent. The user must be able to give their approval through safe, clear and transparent verification processes.

Finally, this principle also applies to all decisions that may have an impact on the health and well-being of the person, that is to say, it is necessary to inform the user of all their therapeutic possibilities.

### Principle of beneficence

Moral obligation of people to “do good”, that is to say, to cure evil and promote good or well-being as far as possible, both to individuals and to society as a whole, and especially in the field of health and well-being. Therefore, the asset must be designed for this purpose. The functionalities implemented in the asset must have been designed to benefit the patient, that is to say, they must be effective and safe.

### Principle of non-maleficence

It is based on the maxim *primum non nocere*, that is to say, “above all, do no harm”. Not to cause and prevent harm, nor to cause pain or suffering. This is why it is necessary to carry out an analysis of the possible risks arising from the use of the asset, minimize them and evaluate the residual risks or arising from its use. In practice, the balance between benefits and risks must always be in favour of the benefits.

### Principle of justice

On the one hand, all people, simply because they are, have the same dignity and, therefore, deserve the same consideration and respect.

This includes rejecting discrimination on any grounds, be it disability, gender, sexual orientation, racial or ethnic origin, etc. On the other hand, the health and well-being resources provided must be equitable and fair for all, in accordance with the dignity and rights of people. It must be possible for all those who need it. All people have the right to comprehensive healthcare and can benefit from digital solutions as long as this principle is covered and digital tools complement it.

However, it must be borne in mind that our

<sup>20</sup> García-Perez, M.A., “The principles of bioethics and social insertion of the medical practice”, 2006.

<sup>21</sup> CAMFIC. The 4 basic principles of Bioethics. Access: [http://gestorweb.camfic.cat/uploads/ITEM\\_540\\_EBLOG\\_1848.pdf](http://gestorweb.camfic.cat/uploads/ITEM_540_EBLOG_1848.pdf)

society is diverse, with a part of the population who find access to or use of technology difficult, for various reasons. For this reason, it must be considered that the majority implementation of these resources could represent a discriminatory

digital gap for many and another form of inequity and inequality. In this sense, it is necessary to maintain the possibility of performing the essential services provided by technology face-to-face in health or social centres.

# 5.

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## **Accessible design and usability**

The **General Directorate of Digital Services and Citizen Experience**<sup>22</sup> has public web resources where one can find principles, procedures, guides and regulations on mobile applications. An example is the **Style guide for mobile apps**<sup>23</sup>, where we find accessibility, usability and style requirements for all applications that are part of the Catalan public ecosystem. Following these general guidelines, the current document expresses the specific health requirements established by the Department of Health for digital assets by SISCAT and addressed to citizens.

## 5.1 Accessibility

Accessibility in the digital sphere includes all the practices that ensure that all information, both on the network and in solutions, as well as the use of technological devices, are within the reach of the greatest number of users, regardless of its conditions, characteristics or capabilities. Therefore, **universal use** maximums are assumed for all assets that provide service in the public system.

The international body in charge of promoting

Internet accessibility is the World Wide Web Consortium (henceforth, W3C), in its working group Web Accessibility Initiative (hereinafter WAI). The organisation publishes a series of accessibility standards collected in the guides **Web Content Accessibility Guidelines (WCAG 2.1)**<sup>24</sup>. Regarding legislation, all digital assets must meet the requirements set out in Royal **Decree 216/2023**, of 7 September. In addition, to ensure compliance with the legislation, the Generalitat de Catalunya assesses the accessibility of digital assets through the European standard **EN 301 549 V3.2.1**.

Digital assets must allow users to locate, identify and perform their functions regardless of physical, cognitive or sensory abilities. That is why it must contemplate use without vision or with limited vision, without hearing or with limited hearing, without voice, without colour perception, without excessive photosensitive stimuli or with limitations of learning, language or cognition.

The following usability and accessibility criteria have been defined:

CRITERIA	Description
<b>Physical accessibility</b>	It guarantees that people with functional diversity can access health services. This may include orientation facilities to facilitate the identification of physical elements, such as ramps for wheelchairs and tools for people with visual or hearing impairments.
<b>Digital accessibility</b>	It ensures that digital platforms, such as websites and mobile applications related to health, are accessible to people with visual, hearing or motor disabilities. This involves using accessible coding, responsive design and help tools such as screen readers.
<b>Language and communication</b>	It ensures that health-related information is available in multiple languages and that communication is clear and understandable to people with different levels of education and language skills.
<b>Ease of use</b>	It assesses how easily people can use health services, including navigating web pages, understanding instructions and performing specific tasks without undue difficulty.
<b>Inclusive design</b>	It considers the design of health services to ensure they are inclusive and adapted to the needs of people with various abilities and health conditions.

<sup>22</sup> General Directorate of Digital Services and Citizen Experience. More information: <https://atenciociudadana.gencat.cat/ca/inici/index.html>

<sup>23</sup> Gencat apps style guide. Access: <https://atenciociudadana.gencat.cat/web/>

[content/manuals/serveis\\_mobils/Guia-apps-Gencat-2021.pdf](content/manuals/serveis_mobils/Guia-apps-Gencat-2021.pdf)

<sup>24</sup> The World Web Consortium (W3C), "Web Content Accessibility Guidelines (WCAG) 2.1", W3C Recommendation, 2023.

## Accessibility requirements

The assets available in La Meva Salut must satisfy the **four principles of accessibility** in order to guarantee universal and inclusive access for everyone. The four principles are **perceptibility**, the interface must present the information in such a way that it is perceptible by users; **operability**, interface components and navigation must be usable; **comprehensibility**, it must be possible to understand the information and the operation of the interface, and **robustness**, the content must be robust enough to be reliably interpreted by a wide variety of user agents - including assistive technologies.

Below is a collection of accessibility requirements and good practices that synthesize national and international standards, as well as the consensuses that derive from them.

### Perceptibility

- **Typography.** A Sans Serif font must be used<sup>25</sup>. The body text size must be a **minimum of 14 points** and it must be possible to expand it by 200% without the need for assistive technology. It is recommended that the line length does not exceed 75 characters per line.

The relationship between font size and spaces is the following:

- Between letters it must be 0.12 times the font size.
- Between words it must be 0.16 times the font size.
- Between lines it must be at least 1.5 times the font size.
- The space between paragraphs should be twice the size of the font.

- **Contrast in text.** The colour contrast between the primary text and the background should ideally be 7:1 for texts — or 4.5:1 for texts larger than 18 points (14 bold) —. However, a colour contrast between the primary text and the background of 4.5:1 — or 3:1 for texts larger than 18 points (14 in bold) — is allowed.

- **Contrast in other elements.** For images in text, it is recommended not to use them in any context except when they are essential, as is the case with logos. If used, however, **they must always observe a minimum ratio of 4.5:1**. Interface components, such as buttons and graphic objects, must present a minimum ratio of 3:1 to adjacent colours.
- **Textual alternatives.** Important information will be communicated in text format and audiovisual resources will serve to add value to the textual content. It is necessary that the non-textual content has a textual alternative, which serves the same purpose, except in cases where it is essential not to present it, in which cases a descriptive identification of the content must be included. The <alt> attribute is the resource with which this practice is achieved.
- **Subtitles and audio description.** As well as in text, it is necessary to present alternatives for video and audio content (subtitles, audio description, interpretation in sign language or other audiovisual alternatives). **Subtitles and audio description are required for recorded audiovisual media** and recommended by live audiovisual media. Captions must be optional and editable and the time difference in which they are presented and the content they complement cannot be greater than 100 ms. The audio description must also be optional and be synchronized with the content it complements.
- **Flashes and flickers.** Flashes or flickers can produce convulsions, which is why the **application must not present more than three consecutive flashes or flickers**. Also, avoid large regions not having this feature.

### Operability

- **Position of interactive elements.** The useful interaction area must be presented on the screen in such a way that it is easy to interact with it. The central space of the screen is the natural space for interaction, which becomes more complex the closer to the edges.

<sup>25</sup> Sans serif fonts do not have lines that project at the ends and enable better readability.

## Operativitat

- **Click area.** The **buttons** and elements to interact with must be at least 9 x 9 mm and leave a separation between elements of 8 px<sup>26</sup>. Icons must have a size of 48 px, between the element and the padding area. It should also be taken into account that it must be possible to interact with both the right and left hand and that the ends of the screen are less accessible.
- **Response time.** It is necessary that users have enough time to complete the actions that require the use of the applications. Whenever the user performs an action, they must receive a response - sound, animation or message. The waiting time cannot exceed 5 seconds to avoid generating frustration in the user. If the action requires a longer waiting time, an element must appear on the screen indicating that some action is being executed so that the person is aware of it.
- **Adaptation and psychomotor adaptation.** The content must adapt to the psychomotor context of the user. This includes avoiding or providing alternatives to double-tap, time-held tap, and keyboard combinations to access certain functionality. You must use the same language with words, phrases and concepts that are familiar and adaptable to the context and purpose of the application. It is necessary to use universal conventions that are familiar and known by the user.
- **Gesture control.** If the device allows gesture control, for example, magnification or scrolling (or swipe), it must be implemented in a way that is understandable for the user and always with alternatives - for example, with buttons - that perform the same function.

## Comprehensibility

- **Clear and coherent texts.** You must use simple and easy to understand language, use simple and short sentences. It is also necessary to use consistent tags that describe the function of the elements of the

asset, using standardized language (such as using the tags “copy”, “save”, “close”) that is consistent in all sections. Likewise, these requirements must be applied to links, the purpose of which will be described in the text.

- **Structure and hierarchy.** A structured, minimalist and clean design of the asset is promoted to obtain the information clearly and quickly. In order to discern key information, proper use of headers, titles, and subheadings is necessary. The headers have two functions: to introduce the content and mark the hierarchy; therefore, it is important to make a visual difference and identify them with tags (in html, <h1> is used for the page header and headings and subheadings <h2> to <h6> to divide and organise content) .
- **Information and relationships.** The structure in which the information is presented and the relationship between the sections must be able to be determined by assistants or be available in text form. The sequence of information must be meaningful and not depend on sensory characteristics such as colour, shape, size, orientation, sounds, visual location...
- **Data entry.** Use focus indicators, delimiters that separate each element of the form, with sufficient contrast. For those fields that the user must complete repeatedly, it is recommended to enable an auto-complete function. It is also necessary to make visual marks (colour, icons, changes to the text, informative text...) to indicate errors in the form, to make a summary of the errors once the form is finished, and to ensure that the sending of data is reversible.

## Robustness

**Brand language.** Asset elements have start and end tags, are organized according to specifications, do not contain duplicate attributes, and identifiers are unique. Status messages can also be determined by assistive technologies.

**Name, function and value.** For all asset elements, the name and function must be

<sup>26</sup> px: píxels

determinable with technological assistants. The states, properties and values that can be assigned by the user must also be able to be determined with wizards.

### **Resources for accessibility**

Operating systems already offer many accessibility options to improve the user experience, and it is important to ensure that the application to be developed is compatible with them. In order to ensure accessibility through screen readers are “VoiceOver”<sup>27</sup> for iOS and “TalkBack”<sup>28</sup> for Android.

The language used must be plain, facilitating the understanding of the content for any user profile. Technicalities should be used only when strictly necessary. That is, when similar terms do not exist or when the fact of using non-technical terms can lead to confusion.

**In the event that documents are planned to be downloaded from the digital solution, it must be taken into account that these documents must also be accessible. In this case, the accessibility requirements can also be found on the Digital Services and Citizen Experience website.**

## **5.2 Usability and user experience**

In computer engineering, usability is the degree to which a computer tool ensures effectiveness and efficiency in achieving its goals. It also includes a series of criteria determined so that users can use it comfortably and intuitively.

### **Good practice for usability**

It is recommended that digital assets be based on four principles to improve usability: **navigability**, the ease with which a person can navigate through all the application interfaces; **readability and coherence**, the elements of the text must be easy and simple to interpret; the **organisation and prevision**, the functional specifications must be explicit and well structured and the **user experience**, the elements related to the interaction that make the perception

positive.

Below is a collection of good practices for usability.

### **Navigability**

- **Locate the information.** The application must offer resources and an optimal design that allows information to be located. Be able to answer questions like: “Where am I?”, “Where have I come from?”, “Where can I go?” they help to have good navigability.
- **Efficiency and effectiveness.** The application must present an intuitive, fast and simple interaction. It is recommended that users can access all the information in the application in a maximum of 3 steps (3 click rule). In any case, this rule will not be necessary as long as the navigation is clear and consistent, and that at all times it is reinforced to the user that the path is correct. It is also relevant to minimize the learning process to use the application, and guide it step by step through a tutorial.
- **Interactive area.** It is recommended that all buttons, links and interactive areas have the appearance of what they represent through shape, colour and size must follow consistent codes established in the universe of the platform. Avoid confusing functions, such as beeping a button multiple times to access its function.
- **Visibility and status.** The application must let the user know in which part of the structure they are and know the status of the current process. This information must be clear and must be provided in a reasonable amount of time. With these actions we enhance the feeling of control and familiarity with the application and help to avoid or correct errors.
- **Appropriate design (or affordance).** It is urged that the appearance of the elements of the application represent the function for which they are designed. It is pertinent, for example, that a button has a distinguishable appearance, that the text fields in a form are perceptible to know which fields must

<sup>27</sup> VoiceOver Screen Reader for iOS. More information: <https://www.apple.com/es/accessibility/vision/>

<sup>28</sup> TalkBack Screen Reader for Android. More information: <https://support.google.com/accessibility/android/answer/6283677?hl=ca>

filled in, that symbols and icons follow universal conventions of appearance, that the messages of errors are visible and obvious.

## **Readability and consistency**

- **Minimalist design.** The design of the interface should be as simple and practical as possible, try to minimize banal options and redundant information that can generate stress, noise on the screen and wrong decision-making. We urge you to follow the guidelines of the **Style guide for digital solutions**<sup>29</sup>.
- **Colour.** The use of colour can be used to organize the content within the application. It is advisable to use the “60-30-10” rule, where: 60% is the main colour (for example a background colour that helps reading), 30% is a secondary colour (that helps to complement and give visual contrast) and 10% is a colour to highlight elements (links, buttons and important elements). It is urged to use colours following universal conventions (green and red to denote success and error) and to use colours that provide high chromatic contrast.

## **Organization and forecasting**

- **Content organisation.** The content of the application can be structured in different ways depending on the final objective: hierarchical organization, which includes a main screen from which the rest of the pages are accessed; linear, which structures the information in successive pages that can be accessed through the page immediately before—or after—; hierarchical linear, which contemplates a mixed model, or network, which does not contemplate a specific structure and it is possible to access the pages regardless of where you are.
- **Planning ahead.** It is necessary to generate some previous functional specifications in order to satisfy all the needs of the users. It is advisable to describe the specific functions, avoid technical details if not

strictly necessary and avoid redundancy. It is also important to detect and minimize the possible errors that the user may make to avoid future frustrations.

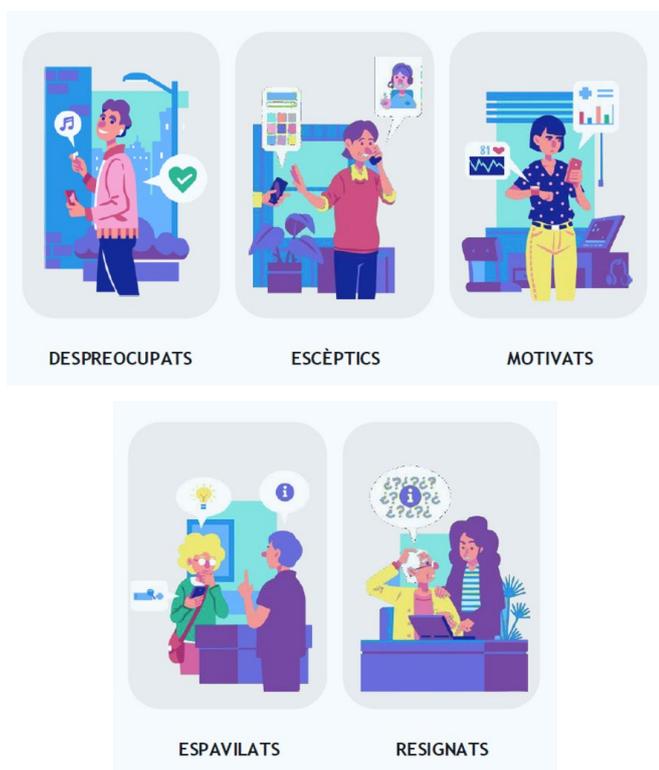
- **Flexibility and adaptation.** The application must ensure that it can be used by novice and expert users; therefore, the advanced features of the application should not be necessary to make good use of it. Help and documentation. The application must be intuitive, for this reason it must not need documentation in order for the person to be able to use it. However, it is necessary to provide support through a FAQ section or help icons.

## **Using digital archetypes to adapt the user experience**

The **digital archetypes** (attitudinal segments of SISCAT users regarding the use of digital health assets related to the System itself) are conceptual representations that group the population based on their attitudes, beliefs, behaviours and needs when interacting digitally with the healthcare system, beyond their demographic characteristics. The Citizenship, Innovation and User Department of the Catalan Health Service (CatSalut) has created a set of digital archetypes with the aim of better understanding the motivations, barriers and expectations of the System’s users in relation to digital solutions and, thus, being able to improve or offer new services and functionalities appropriate to their needs and interests.

Currently, 5 different digital archetypes have been identified: **carefree, motivated, smart, sceptical and resigned**. Each archetype has been defined based on the combination of two main characteristics: their needs when interacting with the healthcare system and their digital skills.

<sup>29</sup> Style manual for digital solutions. Accessible only to professionals from the Department of Health.



Given that the preferences identified for each archetype are considerably different, it is proposed to digital asset developers that they adapt the design of their asset according to the archetype(s) that are believed to be in the majority among their users.

To access documentation on the different digital archetypes, email [oficinamobilitat@ticsalutsocial.cat](mailto:oficinamobilitat@ticsalutsocial.cat).

## 5.3 Language and communication

From the Department of Digital Services and Citizen Experience, it is requested that in order to give effect to the rights and duties of citizens, it is essential to make use of clear communication and plain language. Plain language is a simple and efficient writing style that allows the reader to easily understand the written text, which is based on the use of concise and clear expressions, an orderly linguistic structure and good document design. Clear communication is aimed at the entire population, regardless of age, literacy level, location, financial resources, etc. It is based on a series of writing rules that facilitate the understanding of the texts, as well as models

of comprehensible writing and an appropriate graphic design.

**There are 3 pillars to achieve clear communication: vocabulary, structure and graphic design.**

Regarding **vocabulary**, language needs to be used that citizens understand. It is vital to use common, understandable and precise language in standard Catalan, and to use short and simple words. Although it must possess a high level of linguistic correctness and informative rigour, you must always bear in mind that you are talking to citizens. Use neutral language.

One also needs to take into account the tone (formal and distant, or close) with which the texts are written, which will depend on the type of service or digital solution and the relationship established with the recipient. Each communication medium has a specific style, so you can go from more formal models (for example, for content on the web) to notifications on the mobile phone with messages of a fresher and closer tone. It is recommended that, when we address the public, the form to be used is “tu” (second person singular). However, you can also use the form vós (second person singular that agrees with the second person plural) in cases where the relationship is formal.

As for **structure**, always try to write short and concise texts where the sentences follow the syntactic order, the ideas are structured in lists and the punctuation marks are used correctly.

Regarding **graphic design**, follow the international standards of typography, size and line spacing; as well as the alignment of the texts, and the use of bold, italics, underlining and capital letters.

All the necessary material can be found at the **Citizen Help and Information website**<sup>30</sup>, where there is the **Clear Communication Guide**<sup>31</sup>, or you can consult the **Guide on clear communication for government authorities**<sup>32</sup>.

<sup>30</sup> Generalitat de Catalunya - Government of Catalonia. Atenció Ciutadana [Information and Help for Citizens]. Access: <https://atenciociutadana.gencat.cat/ca/comunicacio-clara/>

<sup>31</sup> Generalitat de Catalunya - Government of Catalonia. Atenció Ciutadana [Information and Help for Citizens]. Clear Communication Guide. Access: <https://>

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<sup>32</sup> Barcelona City Council. Let's be clear. Clear communication guide for administrations. Access: <https://bcnroc.ajuntament.barcelona.cat/jspui/bitstream/11703/128460/3/GuiaComunicacioClara.pdf>

# 6.

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## Secure data and privacy

Security in the world of software often mistakenly takes a back seat, prioritising the number of functionalities or ease of use. The security of applications is related to the security of the data they manage, and therefore, it is key to do everything possible to guarantee both the security and privacy of the data, as well as its traceability.

All digital solutions that manage personal data must apply the specific regulations. It is also important to understand that security should be taken into account not only during the software development, but is a continuous process of improvement that must be carried out throughout the life of the application. Moreover, it is necessary to assess the security aspects from the **first phases of the project**. It is recommended to have a **security expert**, whether internal or external, who assesses the security needs of the project.

## 6.1 General Data Protection Regulation (GDPR)

The **General data protection regulation (GDPR)**<sup>33, 34</sup> regulates in Europe the processing of personal data, their use, and the circulation of these data. The GDPR applies to all companies, organizations, bodies and institutions that process data of European citizens.

The GDPR has been fully in force since May 2018, and has brought about a significant change in the duties and obligations of those responsible and in charge of the processing of personal data. This Regulation has been supplemented with the approval of Organic Law 3/2018, of December 5, on the protection of personal data and guarantee of digital rights (LOPDGDD). These laws, which can be consulted on the website of the **Spanish Data Protection Agency (AEPD)**<sup>35</sup>, not only regulate technical aspects related to data protection, but also include aspects related to the rights of users that must be guaranteed, or the consents that must be requested to carry out the processing of personal data.

The main aspects are presented below, as a summary.

### Personal data

The GDPR defines personal data as any information related to an identifiable person, who can be identified directly or indirectly by reference to an identifier. Examples of personal data include a person's name, address, GPS location, health information or monetary income.

Within personal data, the **GDPR differentiates** those that are considered **sensitive data** requiring special **protection measures**. They are regulated by article 9 of the GDPR, which, at the outset, establishes a general prohibition of processing, without prejudice to some exceptions.

The **general prohibition of processing** of these data is without effect if any of the circumstances of article 9 of the GDPR occur, such as having explicit consent or involving processing linked to issues of personal health or public health. Another important aspect to consider is to determine, on the one hand, the **data controller**, and on the other, the **data processor**.

- **Data controller.** The physical or legal person, public authority or any body which, alone or together with others, determines the purposes and means of data processing.
- **Data processor.** The body, natural or legal person that processes personal data on behalf of the data controller.

### Data treatment

**Data processing** covers a wide range of operations on personal data, whether manual or automatic, including the **collection, recording, organisation, structuring, storage, adaptation and alteration, retrieval, consultation, use, transmission and dissemination**.

<sup>33</sup> Data protection in the EU. More information: [https://ec.europa.eu/justice/smedataproduct/index\\_en.htm](https://ec.europa.eu/justice/smedataproduct/index_en.htm)

<sup>34</sup> 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)

<sup>35</sup> Spanish Data Protection Agency (AEPD). More information: <https://www.aepd.es/>

## **Rights of the data subject**

One of the key aspects of data protection regulations is to grant all natural persons the various rights and powers in relation to the processing of their personal data, starting with the **right of information and then the right of access, rectification, erasure, restriction, portability, objection and no-automation**. Therefore, when processing a subject's data, the following key aspects must be guaranteed:

- **Clear and explicit consent:** It is necessary to have explicit consent to process personal data. The consent form cannot be ambiguous and must use plain and comprehensible language. It is necessary, for example, to put a box to consent to each of the processing that will be done of the data and it is not useful to include a generic "I accept the terms and conditions of use". Consents prior to the regulation that do not comply with this point must be requested again. In the case of children under the age of sixteen, consent must be provided by a legal guardian, and this age can be reduced locally in some states to thirteen years.

*From the FTSS, in addition, it is recommended that a specific consent be made for the case of dependent people's data.*

- **Right to information:** the right to information is part of the essential core of the right to the protection of personal data and is related to the principle of transparency, which the GDPR has strengthened.

**The information must be provided in a concise, transparent, intelligible and easily accessible manner, with clear and simple language, especially when it is addressed to a minor.**

**This information can be conveyed in combination with standardized icons that must be machine-readable and that provide an easily visible, intelligible and clearly legible overview of the intended treatment.**

- **Right of access:** the data subject must have access to all their data in a friendly

and understandable format, together with additional information detailed in Article 15 of the GDPR (such as the purposes of the processing). The right of access is another part of the **principle of transparency** enshrined in data protection legislation, so that data controllers are transparent about the data processing they conduct, as well as about who controls the data, for what purposes, how to access it and how data subjects can exercise their rights over their personal information.

- **Right of rectification:** according to art. 16 of the GDPR, subjects must be able to request the modification of false or inaccurate personal data, including those obtained through other sources. The data subject must obtain the rectification of their data in **the term of one month**.
- **Right to erasure or right to be forgotten:** as indicated in art. 17 of the GDPR, it is necessary to ensure that all the data of a person is physically deleted if he so requests, and to stop transmitting them to third parties, without unjustified delay. This right will apply as long as it does not compromise others such as freedom of expression.
- **Right to restriction of processing:** this right allows the affected person to request that their personal data not be used for certain treatments. In this case, all the data of the subject is deleted in a logical way, making them not visible, in any way, from the application. (art. 18 of the GDPR).
- **Right to data portability:** the affected person must be able to receive the personal data that he had provided to data controller, in a structured, commonly used and machine-readable format, and transmit them to another person in charge. Therefore, it is necessary to be able to export all data in a structured format, such as JSON or XML, although others such as CSV can also be used. (art. 20 of the GDPR).
- **Right to object:** as per art. 21 of the GDPR, the affected person can object at any time, for reasons related to their personal situation, to a certain treatment of their personal data.

- **Right not to be subject to automated individual decisions, including profiling:** this right refers to the fact that no-one must be subjected to a decision based solely on automated processing, that is to say, without human intervention, including profiling, which has legal effects or affects him or her in a significant way. (art. 22 of the GDPR).
- **Report processing activities to local data protection authorities of each country or region.**
- **Data minimisation:** only request those data that are strictly necessary for the specific processing that is conducted. This principle, which can also be called proportionality and minimal intervention, is related to the principle of confidentiality, which refers to the expression of the right to personal privacy.
- **Keep data only as long as necessary:** when the data is no longer necessary for the purpose for which it was collected, it must be deleted. There are exceptions if you need to keep them for other legal reasons.
- **Each type of processing requires separate consent:** each type of processing carried out on the data, or if it is later decided to process the data for a new purpose, requires a specific consent.
- **Notify users if their data are transferred outside the European Union.**
- **Reporting intrusions:** those affected and the supervisory authority must be notified of intrusions that may affect the rights or freedoms of individuals. Notification must be made as soon as possible, preferably before 72 hours have elapsed.

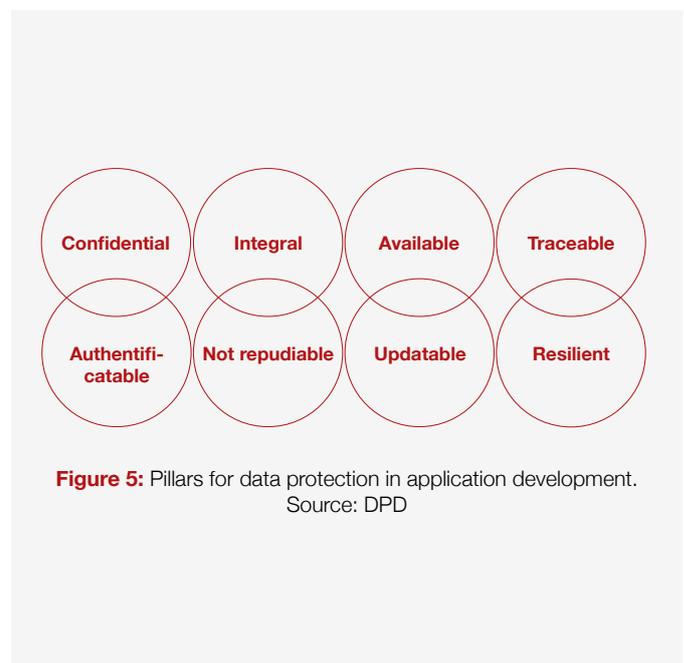
## 6.2 Security measures applicable to health information systems

Considering the risks posed by the processing of special category personal data, such as

personal data or data relating to health, the **Office of the Data Protection Officer (DPO) of Health**<sup>36</sup> of the TIC Salut Social Health Foundation has made a summary of the security measures relating to data protection that must be complied with in the development of applications.

Although the GDPR does not establish a list of security measures applicable to the type of data subject, it is necessary to evaluate the associated risks prior to each treatment and choose the model of good practices in information security that will be used for specifying the measures to be implemented.

In the case of the public sector, the first additional provision of the **LOPDGDD**<sup>37</sup> establishes that the **National Security Scheme** (ENS)<sup>38</sup> will include the measures that must be implemented in the case of processing personal data, to avoid its loss, alteration or unauthorised access. The scheme is based on the following pillars:



**Figure 5:** Pillars for data protection in application development. Source: DPD

- **Confidentiality.** Information will only be accessible to legitimate recipients. To guarantee this principle, it is necessary to ensure encryption, at rest and in transit, ensure secure erasure and use efficient anonymization and pseudo-anonymization techniques. An example to ensure confidentiality would be to encrypt

<sup>36</sup> Health DPO. More information: <https://ticsalutsocial.cat/dpd-salut/>

<sup>37</sup> Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos Personales y garantía de los derechos digitales (LOPDGDD). Accés: <https://www.boe.es/eli/es/>

<https://www.boe.es/eli/es/2018/12/05/3/con>

<sup>38</sup> Real Decreto 311/2022, de 3 de mayo, por el que se regula el Esquema Nacional de Seguridad. Accés: <https://www.boe.es/eli/es/rd/2022/05/03/311>

the sending of information with secure protocols such as TLS if the application communicates with external systems. All secure communications are also required to be conducted with servers that are identified by valid **digital certificates**.

- **Integrity.** The data will be accurate and consistent during storage and processing. In order to guarantee this principle, it is necessary to know the data collection and production systems, follow the rule minimisation principle, make periodic copies of the file systems, use encryption algorithms and key-value mapping algorithms (*hash functions*).
- **Availability.** The data must be accessible for a specific time by the people or user entities. To guarantee this principle it is necessary to activate the load balancing of Data Processing Centres (CPD), replicate the information and capture the states (or snapshots) periodically, constantly monitor alerts and systems performance to detect problems and risks, and structure information correctly.
- **Traceability.** The data must guarantee a record of data activity longitudinally over time. To guarantee this principle there needs to be a **log**<sup>39</sup>, which may include the login of each user, the date and time of each processing, program, service or application.
- **Authenticity and Authorisation.** The information entered into the systems must be truthful. To guarantee this principle, access and user permissions must be controlled, access policies must be in place, each user must be assigned a unique identification with specific functionalities depending on the role they play, or secure password policies must be established. An example to ensure authenticity would be to use alternative user authentication systems like **Oauth 2.0**<sup>40</sup> to facilitate access with credentials from other services. If your own credentials are used, you must make it mandatory for them to meet minimum requirements of length and complexity, and it is essential to save these encrypted data on

the server. The possibility of validation using biometric elements such as fingerprints can also be assessed.

- **No repudiation.** The participation of the parties in a communication must be provable. To guarantee this principle, the receiver must have evidence of the sending by the issuer and vice versa.
- **Up to date.** The data must be of good quality, valid and up-to-date. To guarantee this principle, it is necessary to verify the data before entering it, periodically request verifications from the owners of the data and use alerts for old data.
- **Resilience.** Data storage and processing systems must be repairable when incidents occur that affect their viability. To guarantee this principle, it is necessary to evaluate the infrastructure and the data contained, it is necessary to take measures to guarantee protection, it is necessary to have attack monitoring systems and to develop problem resolution plans that have strategies for the rapid restoration of the affected services. Two examples of tools to ensure resilience would be:
  - **Hacking prevention.** If the application works with a database, it is susceptible to an **SQL injection** hack. It is one of the most common types of attacks and can involve the loss, corruption or theft of data. This attack consists of entering SQL code into the data entry parameters, such as a field to put the password on the login screen, so that the query made to the database is modified by being able to perform the actions whatever the attacker wants. To avoid this, it is important to validate all text strings that are used in actions against the database, preventing the introduction of SQL code into them.
  - **Conduct a penetration test** (*pentesting*) to verify that it is not vulnerable to known attack types. To perform a complete penetration test you can follow several guides, such as the

<sup>39</sup> Log management. National Cybersecurity Institute. More information: <https://www.incibe.es/sites/default/files/contenidos/politicas/documentos/gestion-logs.pdf>

<sup>40</sup> OAuth 2.0. More information: <https://oauth.net/2/>

one performed by **OWASP**<sup>41</sup> (Open Web Application Security Project), a global non-profit organisation focused on improving software security.

## 6.3 Impact assessment related to data protection (AIPD)

As indicated in the GDPR, in the event that sensitive data is processed on a large scale (as is the case with a large part of digital assets in health and social), it is necessary to carry out an impact assessment, a procedure that aims to identify the risks with respect to the rights and freedoms of people related to the processing of data, as well as the preventive measures to control and minimize these risks.

The Office of the Data Protection Officer of the TIC Salut Social Health Foundation has made available the **AIPD tool**<sup>42</sup>, developed and based on the model of the **Catalan Data Protection Authority (APDCAT)**<sup>43</sup>. The tool has been adapted to the specific needs of the health sector to evaluate the processing of personal data in research and innovation processes. It is intended, thus, to contribute to homogenising and standardising the methodology and criteria for carrying out the evaluation task in health entities. First of all, it allows you to carry out a self-assessment to detect risks in the processing of personal data and their mitigation, using a simple and understandable language. In addition, the AIPD provides examples and definitions in order to identify the actors involved in the process, describe the types of processing and measure the risks, with the aim of establishing an action plan and measures to avoid them.

It is the owner's responsibility to ensure that a data protection impact analysis is carried out when there is a probability that, due to its nature, scope, context or objectives, it may represent a high risk for the rights and freedoms of individuals, especially in cases involving the use of new technologies. The AIPD tool makes it possible to support the data controller and the agents involved in decision-making through automated proposals, and allows a detailed analysis of the life cycle of the personal data

involved in all stages of the project.

On the other hand, in accordance with the provisions of the General Data Protection Regulation (GDPR), the Catalan Data Protection Authority (APDCAT) has created and published a non-exhaustive list of data processing categories data on its website. This list aims to facilitate the identification of data processing cases that could require an impact assessment for data controllers. In most situations where a processing meets two or more criteria in the list, it is considered necessary to carry out the AIPD. The more criteria the processing meets, the risk associated with the processing increases, and the certainty of the need to carry out an AIPD is consolidated.

Below are the list of vulnerable processing or risk indicators, adapted by the Data Protection Department (DPD) of the TIC Salut Social Health Foundation according to the needs related to the health sector. Treatments involving:

- The profiling, evaluation or assessment of people.
- The making of automated decisions or that contribute to them.
- The systematic and comprehensive observation, monitoring, tracking, geolocation or control of the data subject.
- The special categories of data (data relating to convictions or criminal offences, or data to determine the financial situation...).
- The use of biometric data.
- The use of genetic data.
- The association, combination or database registration link of two or more processings with different purposes or managed by different managers.
- Vulnerable people who are at risk of social exclusion.
- The use of new technologies or an innovative use of established technologies that prevent data subjects from exercising their rights, using a service or executing a contract.

<sup>41</sup> Open Web Application Security Project (OWASP). More information: [https://wiki.owasp.org/index.php/OWASP\\_Unified\\_Pentesting\\_Framework#tab=Main](https://wiki.owasp.org/index.php/OWASP_Unified_Pentesting_Framework#tab=Main)

<sup>42</sup> AIPD tool. More information: <https://ticsalutsocial.cat/djpd-salut/eina-ajpd/>

<sup>43</sup> Catalan Data Protection Authority. More information: <https://apdcatal.gencat.cat/ca/inici>

Secure application development of the Cybersecurity Agency of Catalonia<sup>44</sup>. In addition, the APDCAT has a guide for developers focused on *Privacy by design and by default*<sup>45</sup>, based on the AEPD guidelines.

## 6.4 European Health Data Area

The European Commission is working on the **European Health Data Space**<sup>46</sup> as one of its key commitments in the provision of health care services in Europe. This new framework will allow people to control their health data, both in their country of origin and in the other member countries, fostering a single market for digital health services and products. The European Health Data Space establishes an efficient, reliable and consistent framework for using health data in the field of research, innovation, policy and law making, while guaranteeing European data protection regulation.

The European Health Data Area has three main objectives: to empower people giving them better digital access to their health data in any of the 27 countries of the European Union; **to free the data economy** by fostering a true single market for digital healthcare services and products; and **establish strict rules** for the use of de-identified health data for research, innovation, policy development and regulatory activities.

Some of the benefits that the European Commission highlights about the plan for each of the following groups:

- **Citizens:** will have control of their health data, with security and privacy. They will be able to share their data with health professionals in member countries in a common European format. They will also be able to add information, rectify errors and find out how their data is being used.
- **Health professionals:** they will have faster access to patient health data from member countries, reducing the administrative burden.

- **Research staff:** they will have access to a large volume of high-quality health data. Access will be less expensive and more effective.
- **Political and regulatory representatives:** they will have faster and more transparent access to non-identifiable health data that allows them to be used for the benefit of public health.
- **Companies in the health sector:** they will be able to access new markets thanks to the standardisation of the process. They will have access to non-identifiable data to use in favour of innovation.

<sup>44</sup> Cybersecurity Agency of Catalonia, "Secure application development", 2023

<sup>45</sup> APDCAT. Privacy by design and by default. Developer guide. Access: [https://apdcatt.gencat.cat/web/\\_content/03-documentacio/documents/](https://apdcatt.gencat.cat/web/_content/03-documentacio/documents/)

[guiaDesenvolupadors/GUIA-PDDD.pdf](#)

<sup>46</sup> European Health Data Area. More information: [https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space\\_es](https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space_es)

**7.**

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# **Robust technology and performance**

## 7.1 Technological requirements

The provider must ensure the smooth operation of the application during its use, in the registration and installation of the application, in its use in the foreground and in the background, when consuming network resources and in events scheduled

### Installation

To ensure proper operation during registration, both the installation and de-installation of all required components must be ensured. It is necessary to inform the users of all the required or desirable technical specifications in a remarkable way in order to be able to carry out the installation.

### Recording

If data recording is necessary, the user must be informed, checks must be run to ensure that the data entry is correct, and mechanisms must be provided for the recovery of identifiers and passwords.

### Plans, processes and standards

To ensure good performance of the application, procedural plans, configuration management and verification plans must be provided for. A standard operating procedure must be established that ensures service coverage during peak demand, as well as a maintenance process that contemplates the incorporation of new functionalities, error correction and the impact on security of modifications between others. It will also need to include a configuration management plan, a verification and validation plan - which includes inspection, analysis, demonstration, simulation, testing and certification of components and protocols - and achieve a set of coding standards that follow conventions, use appropriate compilers, and establish good error tracking.

### Operational specifications

To ensure good performance, the application cannot crash or freeze, or fail with prolonged use or in cases of suspending and resuming its activity. It must also ensure correct recovery on context changes and cannot affect other system functions if it runs in the background.

### Resource and network consumption

The application must not consume excessive resources, neither of the system nor of the network. It must ensure that database resources are properly shared. Must be able to operate in flight mode or when experiencing network lags and loss of connection. It must also be able to operate in pause mode and resume download interruptions.

### Scheduled events

The application must ensure the correct behaviour within the term of a scheduled event. In a state of suspension, the program must correctly resume the activity. It must request the necessary permissions to access the various services on the device, which are published and described. With all this, the application will generate action monitoring in an external system.

### Software used in development

The software used in the development of the application must come from reliable libraries, or its stability must be ensured. This is also necessary if artificial intelligence algorithms are used in the development of the application.

To obtain more information on how the management of public health information is carried out in a centralised, global and cohesive manner and to know how this management of control processes in access, management and exchange is carried out with other systems/ services of health-related entities, you can refer to the SISCAT Information Systems Master Plan<sup>47</sup>.

<sup>47</sup> Ministry of Health, "SISCAT Information Systems Master Plan. Building together a digital health strategy for Catalonia", 2017.

## 7.2 Artificial intelligence algorithms

The application software may rely on the use of artificial intelligence algorithms and, in this case, it is essential that the technical effectiveness and performance of the algorithms can be demonstrated through the training data and evaluation metrics used.

### Training data

The type of training data used, its origin, the sample size and the proportions assigned to the training, test and validation sets must be indicated. It will also be appreciated that an analysis of the representativeness of the population sample used is provided in relation to the users and the intended uses.

### Evaluation metrics

It will be necessary to provide metrics for evaluating the algorithm (for example, accuracy, among many others) in order to demonstrate its effectiveness. It will be necessary to describe from which data the metrics were obtained (simulated data, real data, data included in training, etc.) and what volume. Transparency to users with these metrics will be considered good practice.

**The Guide to evaluating digital health technologies that include artificial intelligence (AI)** established by the Agency for Healthcare Quality and Evaluation of Catalonia (AQuAS) and the Health/AI Programme, led by the TIC Salut Social Foundation, provides more detail on this aspect, as well as other aspects that are important to take into account.

For more information on the use of artificial intelligence in digital assets, please consult the **guides offered by the Health/AI Program**.

## 7.3 Interoperability standards

Interoperability is the ability to share information among systems or devices without losing its meaning. It guarantees access to information regardless of where it has been recorded and promotes its reuse, minimising blind spots and ensuring continuity of care. Interoperability must be both syntactic and semantic, which is why we have communication standards and terminologies.

- The HL7 (Health Level Seven) communication standard defines a messaging protocol for exchanging information between applications. The use of this standard is governed by the use of defined messages that transport information between centres.
- The terminologies SNOMED-CT, SERAM, SEMN and LOINC, among others, are coding systems for medical or healthcare information with a specific code that allows applications to uniquely recognise the information.

Digital assets must provide all potential users with specifications and implementation guides for both the Application Programming Interfaces (or APIs) and the terminology used. They must also have verification mechanisms for test identification at the ends (or endpoints), as well as ensure that users can access their data and export it in a comprehensible way.

In order to expand the information on the communication standards you can refer to the **website of the interoperability department**<sup>48</sup> of the TIC Salut Social Foundation.

<sup>48</sup> Interoperability Department of the TIC Salut Social Health Foundation. More information: <https://ticsalutsocial.cat/que-fem/interoperabilitat-i-tecnologies/>

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## **Availability of access to digital assets forma La Meva Salut**

Allowing access to SISCAT's digital health assets from La Meva Salut is a crucial step towards more complete and personalized assistance.

Currently, *La Meva Salut* has a wide range of health services, such as the possibility to view and download clinical reports, diagnoses, the medication plan and results of clinical analyses and tests, in addition to booking appointments with primary care and access to various digital health services that facilitate better management and control of citizens' health. Expanding the availability of digital services and resources within these spaces, offered from different digital solutions, would provide more personalised care and promote equity throughout the territory.

In this sense, it is clear the need to have digital resources available at SISCAT centres in order to facilitate the management and information flow of the centre itself, as well as the monitoring of patients. However, the adaptation of digital assets and services to the criteria set out in this guide, as a step prior to incorporation into the La Meva Salut ecosystem, must be understood as a commitment to quality, capacity and diversity of service.

Currently, the "Other Services" section of La Meva Salut is the point of connection with digital hospital solutions and other relational services from SISCAT providers. The section is under constant review, with assets that evolve and change, some disappear and others can become central assets with a transversal service vocation, as is the case with the primary care eConsult. Thus, the objective of the Ministry of Health is for "Other Services" to become the space to access all the selected digital assets from a single point, with the aim of obtaining an ecosystemic view of SISCAT's digital assets and facilitating - its use by citizens. At the same time, "Other Services" will allow the collection of data through the mConnecta platform, which will become another part of the Electronic Health Record (HES).

*It is important to highlight that the evolution of the "Other services" section will continue to be worked on by the Department in order to provide a more cohesive and effective digital health experience for all citizens.*

**Any digital asset that wants to integrate into La Meva Salut must ensure that does not duplicate any services already offered<sup>49</sup>.**

**This will prioritise simplification of use by the user and achieve consistency in the offering of digital services in the System.**

<sup>49</sup> La Meva Salut. Serveis. Accés: <https://lamevasalut.gencat.cat/web/cps/ajuda/serveis>

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# 10.

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## Annexes

## 10.1 Annex I: International directives

### Health product

- (EU) 2017/745 of health products (MDR)
- (EU) 2017/746 of in-vitro diagnostics (IVDR)
- Declaration of Conformity (EC)
- Law 14/1986, of 25 April, General Health

### Health benefits and risks

- ISO 13131:2021 Health Informatics – Telehealth services – Quality Planning guidelines
- ISO 14971:2019 Medical devices – Application of risk management to medical devices

### Accessibility and usability

- Royal Decree 1112/2018, of 7 September, on accessibility of websites and applications for mobile devices in the public sector
- EN 301 549 V3.2.1. Accessibility requirements for ICT products and services

### Security of the data

- European Data Protection Regulation (GDPR)

### Technological robustness

- UNE-EN 62304:2007/A1:2016 Medical device software. Software life-cycle processes
- IEC 82302-1:2016 Health software – Part 1: General requirements for product safety

## 10.2 Annex II: Reference guides

### Health product

- MDCG 2019-11 Guidance on Qualification and Classification of Software in Regulation 2017/745 – MDR and Regulation (2017/746) – IVDR

### Health benefits and risks

- Classification of digital Health interventions v1.0 (WHO/RHR/19.06)

### Ethics

- Health inequalities and eHealth report

### Accessibility and usability

- Web Content Accessibility Guidelines 2.1 (WCAG 2.1)
- PAe Guide to Accessibility
- Mobile Applications (Apps)

### Security of the data

- Ref 8/2021. GDPR and Security in Applications and Systems



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