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INCORPORATING INNOVATIVE MEDICAL TECHNOLOGY

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Expert contributors to this Guide

Coordinators

Ramon Vilallonga, Magda Campins

Editorial team

Josep Arimany-Manso, Rosa Burgos, Andrea Burón, Oscar Camara, Magda Campins, M. José Campo, Xavier Canals, Raquel Cànovas, Marta Ciércoles, Raquel Cumeras, Sara Hernández, Núria Martí, Míriam Méndez, Begonya Nafría, Alexandre Perera, Marc Pérez Pey, Anna Sala, Maria Sala, Carlos Sisternas, Ramon Vilallonga, Rosa Vivanco

Document reviewers

Francisco Araújo
Arnau Cuadras
Iolanda Jordan
Francesc López-Seguí
Clara Prats

Technical coordination

Anna Mitjans. Corporate Projects Manager of the College of Physicians of Barcelona
Marta Ciércoles. Head of Press and External Media of the College of Physicians of Barcelona

Editorial committee of the Good Practice Guides

Jaume Padrós. President of the Governing Board of the College of Physicians of Barcelona
Gustavo Tolchinsky. Secretary of the Governing Board of the College of Physicians of Barcelona
Antoni Trilla. Member of the Governing Board of the College of Physicians of Barcelona
Magda Campins. President of the Ethics Commission of the College of Physicians of Barcelona

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College of Physicians of Barcelona
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Design and layout

Carlos Ortega

Translation

Gemma Ruffino

The *Good Practice Guide* series is a periodical publication of the College of Physicians of Barcelona that has been issued since 1991 and is characterised by being:

- A continuous medical training tool that promotes the professional development of physicians for the benefit of the public.
- A clinical practice guide that promotes good practice and occupational risk prevention.
- A medicolegal tool that protects both the public and the medical professional.

Contents

Introduction

It is with great pleasure that we present this *Good Practice Guide for Incorporating Innovative Medical Technology* of the Council of Medical Colleges of Catalonia, an essential document for all those health professionals committed to excellence and the continuous improvement of health care. In the case of this Guide, it is an initiative of the Good Practice Working Group of the Interdisciplinary Group of Health-Related Professionals (GIPS). This group was created to promote the interaction of professionals from different disciplines with the aim of being pioneers in clinical innovation and research focused on patient needs and achieving the best health, scientific and academic results. We are honoured to share with you what we hope is valuable tool that addresses the typology of medical technologies and the use and knowledge that are derived from them.

This Good Practice Guide represents a significant contribution to the field of biomedicine and the sciences that revolve around medicine and the patient. In its seven chapters, the application of new technologies in the medical context is explored and debated, as are the implications and challenges that they bring with them. The document includes the fundamental aspects that define good practice for healthcare professionals in the development, proof of concept, bringing to market, regulations and use of new technologies.

This Good Practice Guide represents a significant contribution to the field of biomedicine and the sciences that revolve around medicine and the patient.

The first chapter establishes the foundations of the concept of medical technology and offers a clear vision of its importance and impact on clinical practice. The second analyses the utility and applicability of these technologies and underlines the virtues and the benefits they bring to patients and health professionals.

Research and the development of medical technologies is the central theme of the third chapter. In this section, the need for a rigorous and ethical focus on the exploration of new advances is addressed, as well as the importance of scientific validation and patient safety in this process.

The fourth chapter focuses on the use of new technologies in healthcare practice and examines how these resources can optimise clinical outcomes, improve efficiency and facilitate professional decision-making. It therefore invites us to reflect on the use of new technologies in healthcare practice. At the same time, it addresses the ethical, deontological and regulatory issues that this use entails.

Chapters five and six are dedicated to exploring the ethical aspects of the communication of results and place emphasis on the importance of the transparent and responsible dissemination of information generated by new technologies. Finally, the seventh chapter offers us the opportunity to learn about the experience in the Catalan public health system in the development and evaluation of technology in the field of health, a valuable perspective for understanding the local context and its particularities.

With this Guide we aim to stimulate dialogue and reflection on the good practice of healthcare professionals in the use of new technologies. **Medical technologies are a fundamental element of the healthcare system since they help professionals provide better quality care to patients**. We hope that this contribution will be a source of inspiration and a reference for those who work in the healthcare field and for all those interested in this area.

1. Concept of medical technology

A medical technology is any device, equipment or software that is used in the prevention, diagnosis, prognosis, treatment or rehabilitation of a disease or condition. This includes everything from the simplest technologies, such as a thermometer or a pregnancy test, to the most complex, such as a positron emission tomography (PET) scanner, an artificial intelligence-based algorithm for data processing or a surgical robot. Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices of 5 April 2017 includes these medical technologies as medical devices.

Who are the users of a medical technology? This depends on the type of technology and its purpose. Some medical technologies are intended for healthcare professionals, while others can be used by patients in their own homes. They can also be specific to a particular use, such as a knee prosthesis or a respiratory assistance device.

The development of a medical technology is a complex process that usually involves many different actors, including scientists, engineers, healthcare professionals and companies in the sector. The process usually starts with basic research to develop new devices or products and then goes through stages of design, development and testing of prototypes. If the medical technology is successful, it must be approved by regulatory bodies for its commercialisation.

The development of a medical technology usually involves many different actors, including scientists, engineers, healthcare professionals and companies in the sector.

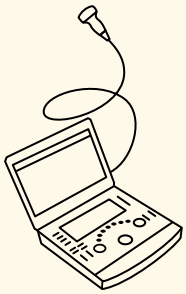
Medical technology can be protected in various ways, depending on the type of technology and its purpose. Patents are a common option for protecting new medical technologies, as they give the holder the exclusive right to manufacture, use and sell the technology for a specified period of time. Other forms of protection include trademarks, copyrights and industrial designs.

When it comes to filtering the protection of a technology, entities such as the notified body for Spain, the National Center for Certification of Health Products (CNCps) of the Spanish Agency for Medicines and Health Products (AEMPS), and regulatory agencies such as the European Medicines Agency (EMA) in Europe or the Food and Drug Administration (FDA) in the United States are responsible for regulating medical devices to ensure that they are safe and effective. **This implies the need to carry out a clinical evaluation through studies to guarantee the safety and efficacy of medical technologies before their commercialisation**. Specific requirements for medical devices, such as warning labels or instructions for use, can also be established.

2.

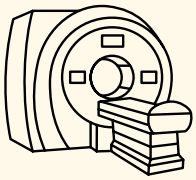
Utility and applicability of technology

Medical technology encompasses a wide range of products, resources and devices that contribute to improving healthcare and clinical outcomes. Types of technology include:



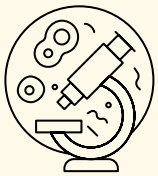
Medical devices: Medical devices or healthcare products encompass a wide range of tools and devices used for diagnostic and therapeutic purposes. This includes everything from vital signs monitors and electrocardiography devices to prostheses and biomedical implants. In addition, advances in wearable technology, such as smartwatches and heart rate monitors, have enabled the continuous monitoring of health and well-being. Some European countries have already incorporated digital health applications (DiGA) that can be used to improve the treatment of a wide range of diseases by imparting information, providing context or guiding patients through exercises.

Electronic patient information systems and electronic health records (EHRs): This technology allows for the efficient management of patient information, facilitating the access to and exchange of clinical information between healthcare professionals. In addition, EHR systems offer features such as medication reminders, abnormal results alerts and data recording for research that may be included in the category of health products.



Medical imaging: Imaging technologies, which are also included in the healthcare product category, such as computed tomography (CT), magnetic resonance imaging (MRI), ultrasound and digital radiography, allow detailed images of the inside of the body to be obtained for the diagnosis and monitoring of diseases. In addition, the use of advanced imaging techniques, such as positron emission tomography (PET) and molecular imaging, has improved the early detection of lesions and the development of personalised therapies.

Software and tools for visualisation, processing, treatment and analysis of data and images. This includes the classic tools of statistics and mathematics and also mathematical modelling, such as artificial intelligence and big data.



I***n vitro*** **diagnostic devices (IVD)**: these are intended to provide information based on the analysis of biological samples (blood, saliva, urine, etc.) and allow the monitoring of diseases, establish compatibility for transplants or predict congenital diseases. They are healthcare products that, due to their specificity, are subject to their own regulation (IVDR).

Regarding the current applications of technology in the field of health, numerous examples can be found. The use of information systems and EHRs has improved the coordination of care, clinical decision-making and the operational efficiency of health centres. Telemedicine has allowed access to health care in rural and remote areas, as well as the monitoring of patients over long

distances. Imaging technologies have improved the accuracy of diagnosis and disease monitoring and have permitted more precise and personalised interventions. Medical and *in vitro* diagnostic devices have facilitated the early detection of health problems and have improved the quality of life of patients with various conditions.

Regarding the measurement of the economic, medical and health impact of technologies, numerous studies have been carried out to evaluate the benefits and costs associated with their implementation. It has been shown that the use of information and EHR systems can improve the efficiency of clinical processes, reducing errors and the costs of repeating examinations and tests. Telemedicine has shown economic benefits thanks to the reduction of travel and hospital admission costs, in addition to improving access to health services. Imaging technologies have contributed to improving the early detection of diseases and have reduced the costs associated with more invasive or aggressive treatments.

Many technological advances have been shown to have a positive impact on both economic efficiency and improved medical and healthcare outcomes.

Finally, medical devices have improved the quality of life of patients and reduced the costs associated with hospitalisations and medical complications. **The current healthcare system would not be possible or sustainable without the use of these technologies**.

Thus, the utility of technology in the field of health is broad and diverse and embraces different types of technologies that are currently applied in areas such as patient information management, telemedicine, medical imaging, and medical devices, among others. These technological advances have proven to have a positive impact on both economic efficiency and improved medical and healthcare outcomes.

3. Research and development

3.1. Process from idea to commercialisation

The innovation process in medical technology is, in many ways, similar to that in any other sector. However, as with medicines, this is a regulated sector and, for an innovation to be successful, it must include the following aspects:

The first step is to ensure that the generation of an innovative idea that responds to a real problem or an unmet medical need.

Subsequently, it is important to consider from the beginning the protection, clinical, technical, regulatory and business aspects of the project and evaluate the risks of each in order to have a chance of success.

The protection of the innovation can be done through mechanisms such as patents, utility models, industrial design, copyright, intellectual property registration or other forms of protection.

The clinical and technical studies necessary to apply for regulation and CE marking will depend on the type of medical device (MD) or *in vitro* device (IVD) and its category (or class) depending on the risk to the patient and the nature of its use:

Low risk	MD class I – IVD class A
Medium risk	MD class IIa or IIb – IVD class B or C
High risk	MD class III – IVD class D

High-risk or disruptive products require a very high level of rigour in their evaluation and quality control, as well as clinical research to demonstrate their safety and efficacy [1].

Before a medical technology can be marketed and widely used, the relevant regulatory approval must be obtained. Regulatory aspects must include the Medical Device Regulation (MDR) [1] or *In Vitro* Devices Regulation (IVDR) [2], but also others such as the General Data Protection Regulation (GDPR) and regulations applicable to the specific product and activity for which it is intended, also depending on the market it is intended to target. Thus, if the product is software that includes artificial intelligence (AI), the Artificial Intelligence Act (AIA) [3] will need to be applied.

The flow of the development cycle of a medical technology is shown below [4]:

Need/idea (TRL 1-2)	Proof of concept/feasibility (TRL 3-4)	Validation Evaluation/clinical research (TRL 5-6)	Validation of solution Approval and certification (TRL 7-8)	Commercialisation (TRL 9)
Generation of the initial idea, based on scientific research and clinical knowledge, that provides solutions to medical needs identified by more than five professionals	To turn the concept into tangible technology	Validation of the efficacy and safety of the technology	Optimisation and refinement of the technology based on the results obtained during testing and validation	AEMPS licence.
Intended purpose of the product	Establishing the project plan.	Implementation of a quality system.	Transfer to production	Obtaining CE marking
Identification of similar products on the market	Creation of prototypes, new algorithms or methods	Functional product	Technical documentation (Annex II and III Regulation)	Manufacturing first series
	Optimisation and refinement	Preclinical tests according to applicable technical standards	Quality system (ISO 13485)	Marketing plan
	Feasibility analysis	Validation in a representative environment followed by validation in a real environment	Application for CE marking to the NB	Preparation for practical implementation and widespread use in the medical field
	Objective of technology	Clinical research		
	Functionality	Approval CEIm, AEMPS and health centre		
	Principal characteristics			
	Competitive advantages compared with other solutions			
	Patent application or intellectual property registration			

Figure 3.1 Steps from an idea to commercialisation. The European TRLs (technology readiness levels) are specified [5]. Abbreviations: AEMPS, Spanish Agency for Medicines and Health Products; CE, European Conformity; CEIm, drug research ethics committee; NB, notified body; ISO, International Organization for Standardization

The two most critical points in the process are clinical research (which, depending on the risk and degree of innovation of the MD, will last more than a year) and the regulator to obtain the CE marking (see 3.4) with an average duration of a year and a half. Both have a significant cost that may require obtaining financing.

Apart from clinical evaluation and regulation, it is also necessary to carry out an economic assessment through cost-effectiveness and economic impact studies of the medical technology. The costs of the technology will be assessed, as well as the benefits it provides in terms of improving the health and quality of life of patients.

The regulations governing medical devices require the manufacturer to maintain a post-marketing monitoring process in order to keep the product up to date with the regulations (with the state of the art) and its use, monitoring possible incidents and complaints (with reactive measures) and the effective-

ness of its use (with proactive measures). The results of this monitoring form part of the technical documentation.

How are new medical technologies introduced to healthcare centres?

New medical technologies can be incorporated into healthcare centres in two ways:

- **If the technology does not have approval for clinical use (CE marking)**, it can be used experimentally, through clinical research or scientific studies and only in a research context, with the approval of the drug research ethics committee (CEIm) of the health institutions and the AEMPS.
- **If the technology already has approval (CE marking)**, an assessment of the impact, benefit, risk and cost of the technology will be carried out by the healthcare management of the centre, following the medical technology evaluation processes.

The validation and evaluation process may vary depending on the type of medical technology and the specific regulations applicable in each country or region.

In medical technology research, there are a series of **recommendations to follow that can be useful in reducing biases**:
Include data for the development of completely independent technologies and validation
Multicentre and randomised studies
Complete patient data, covering a wide spectrum in terms of gender, race, phenotype, age, socioeconomic factors, etc.
Taking into account the aspects of equity, responsibility and transparency of technology
Good practices: ● Increase and improve data diversity ● Data sharing: include citizen participation ● Document and communicate biases ● Organise and standardise databases, following the FAIR (findable-accessible-intraoperable-reusable) principles whenever possible

In order to **validate and reduce the risk of the technology it is necessary to**:
● Follow verification and validation standards from standardisation bodies (ISO, IEC, UNE, etc.), regulators such as the European Commission, FDA, EMA or other relevant bodies
● Definition of the specific question that the technology answers
● Definition of the context of use: who will use the technology and how
● Risk assessment (consequences if the technology gives erroneous information or works incorrectly)
● Establish that the risk–benefit is acceptable

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- [7] Royal Decree "por el que se regulan los productos sanitarios para diagnóstico in vitro" [regulating health products for in vitro diagnostics], *https://www.sanidad.gob.es/normativa/audiencia/docs/RD_Productos_Sanitarios_invitro.pdf*.

3.2. The role of research ethics committees and data ethics committees

Research ethics committees play a crucial role in ensuring the protection of the rights, safety and well-being of participants in clinical trials and in the ethical review of medical research. Their composition and functions are regulated by *Royal Decree 1090/2015, of 4 December, regulating clinical trials with medicinal products*, the *drug research ethics committees and the Spanish Registry of Clinical Studies (RD 1090/2015)*, which distinguishes two types of ethics committees:

a. **Research ethics committee (REC)**: independent body with a multidisciplinary composition, whose main purpose is to ensure the protection of the rights, safety and well-being of subjects participating in a biomedical research project and to offer them public assurance through an opinion on the corresponding documentation of the research project, taking into account the views of lay people, in particular patients or patient organisations.

b. **Drug research ethics committee (CEIm)**: Committee on Ethics of Research which, in addition, is accredited in accordance with the terms of RD 1090/2015 to issue an opinion in a clinical study with medicines and in a clinical investigation with healthcare products.

Ethics committees are linked to academic and research institutions, government agencies and health authorities. In the development or validation of technological tools in the medical field that imply access to patient data, there is a mandatory intervention of these committees, who will approve and vali-

date the ethical and legal viability of the project by reviewing, among other aspects, the study plan, informed consent, justification for the need for complementary tests, the capacity of the principal investigator, insurance coverage associated with the study and the procedures for action and communication in the event of an adverse event. When evaluating new technologies, the participation or advice of experts in the technological fields to which the technology being evaluated belongs should be included.

Research ethics committees must include among their members a data protection delegate or, failing that, an expert with sufficient knowledge of the General Data Protection Regulation (EU - 2016/679) (seventeenth additional provision of Organic Law 3/2018, of December 5, on the protection of personal data and guarantee of digital rights).

Additionally, **data ethics committees** have been created to verify that requests for access to large volumes of data (usually in cases of data reuse for research purposes) comply with the institutional guidelines set by the data controllers. These committees do not exist in all institutions and are not mandatory, but they are useful in helping to ensure that the data access process and its exploitation are carried out correctly and agilely. To ensure this, it is important that there are representatives from different areas and departments, including, for example, the department of information systems or innovation or a representative from the legal department. The Government of Catalonia has a Data Ethics Committee, a collegiate body of a consultative and cross-cutting nature at the service of the Administration of the Government of Catalonia and its public sector.

Data ethics committees may have among their functions the provision of clinical data and technical support during the preparation of a project proposal, as well as in its subsequent execution.

It should be noted that the proposal for a European Regulation to create the European Health Data Space provides for the creation of health data access bodies that will be responsible for granting access to electronic health data for secondary use and that will be designated by each state. The intervention of this body will be mandatory.

From the point of view of data protection regulations, complying with the principle of privacy by design, when projects are presented to these committees a data protection impact assessment must be carried out in which the elements detailed below will be analysed and which must also be described in the project protocol:

a. **Compliance with data protection principles.** It is necessary to ensure that data processing complies with the principles established in Article 5 of the European Data Protection Regulation, such as necessity, minimisation, proportionality or transparency.

b. **Determination of the data flow and the roles of the parties**. It is necessary to define which entity or entities will be constituted as controllers, joint controllers or processors, as well as the data communications that occur, including international transfers.

c. **Determination of the legitimate basis that justifies access to the data,** in accordance with the provisions of Articles 6 and 9 of the European Data Protection Regulation. For example, in the case of public institutions, the public interest in the use of data for research purposes justifies the use of healthcare data in compliance with certain guarantees such as pseudo-anonymisation.

d. **Finally, it is necessary to describe the security measures that will be applied**, including, for example, those derived from the application of the National Security Scheme.

The impact assessment is a tool that will help design the project taking into account data protection regulations and will prevent the project from being halted by the research ethics committee or the data ethics committee once it has been designed for not complying with the requirements of the data protection regulations.

3.3. The role of health technology assessment agencies

Health technology assessment is a **multidisciplinary process that uses explicit methods to determine the value of a health technology** at different points in its life cycle. The purpose is to inform decision-making processes in order to promote an equitable, efficient and high-quality health system.

In Spain, the *RedETS* network of health technology assessment agencies was created in 2012 (RD 16/2012). This network is made up of seven regional agencies (*SESCS*, *IACS*, *Bioef-Osteba*, *AVALIA-T*, *AETSA*, *AQuAS* and AETS) and one state agency (*ISCIII*), who work in a coordinated manner, with a common methodology and under the principle of mutual recognition and cooperation. RedETS' mission is to evaluate new techniques, technologies or procedures, including medicines, on a mandatory basis and prior to their use in the National Health System as part of the Common Portfolio of Services, taking into account: the safety, efficacy, efficiency and therapeutic utility of the technologies; healthcare alternatives; less protected or at-risk groups; social needs and the economic and organisational impact. This network follows an annual workplan proposed by the autonomous communities and prioritised by the Commission on Benefits, Insurance and Financing (CPAF) of the Ministry of Health.

3.4. The CE mark

European legislation on medical devices establishes the obligation of CE marking for these products in two regulations:

- MDR, Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC; in force from 26 May 2021 [1].
- IVDR, Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU; in force from 26 May 2022 [2].

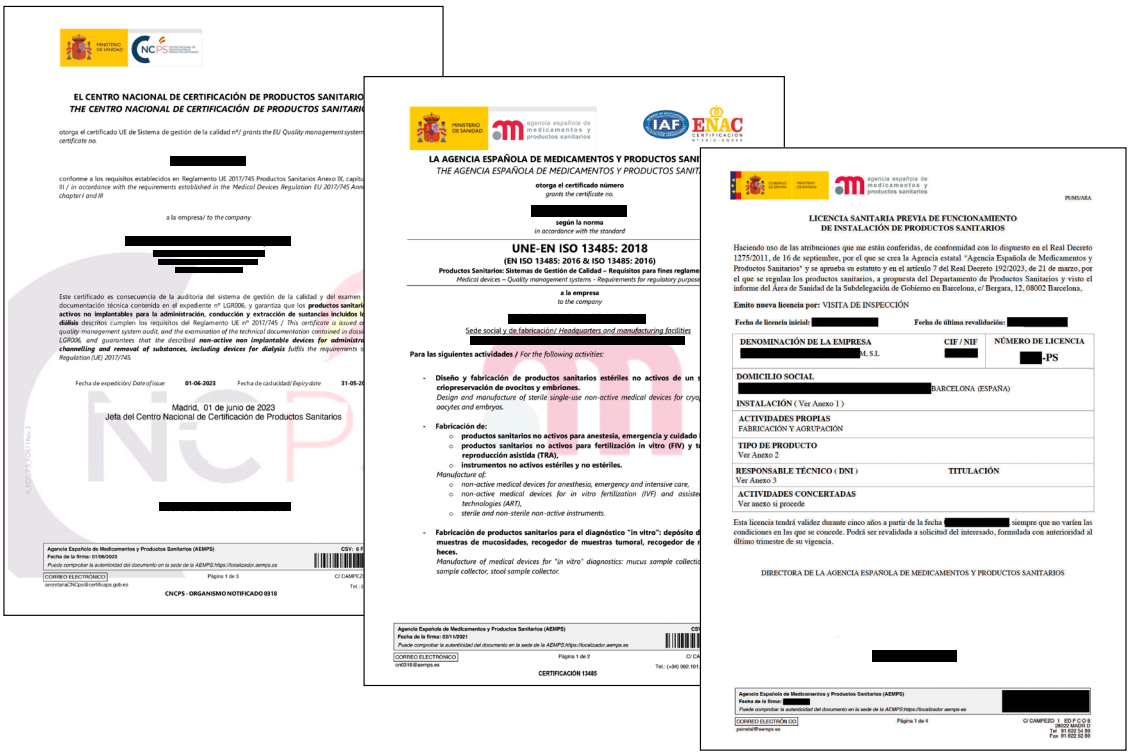
As these are regulations, they are applicable throughout Europe and do not require transposition into national legislation as the previous directives they repeal did. In order to establish additional national requirements, there is Royal Decree 192/2023, of 21 March 2023, which regulates medical devices, and Royal Decree 1662/2000, of 29 September, on medical devices for *in vitro* diagnostics [3] (regarding which *there exists a draft amendment that has not yet been approved* [4]). These requirements include the need for a prior licence, a responsible technician — in addition to the person responsible for compliance

with the regulations (MDR-IV requirement) — and marketing communications for manufacturers, importers, consolidators and authorised representatives. For manufacturers of custom products and distributors, registration in the autonomous communities is also required.

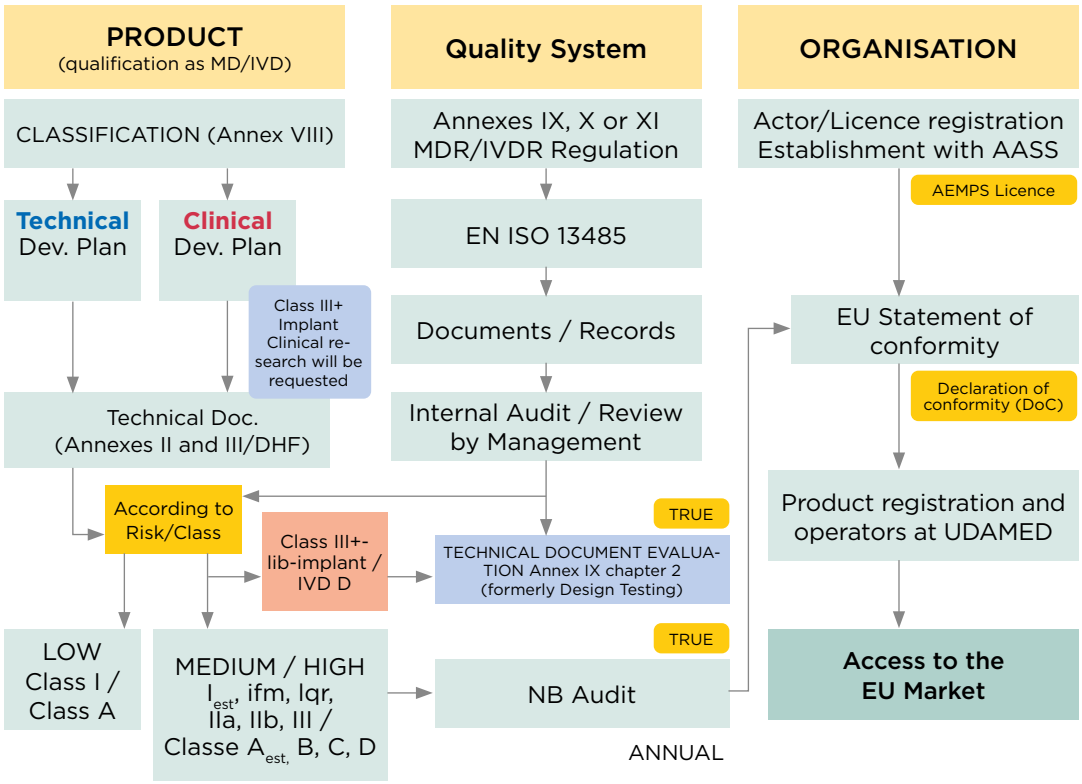
These are the essentials for obtaining the CE mark: the technical documentation, the quality system and the records and licence.

The steps for obtaining the CE mark are:

1. Product qualification and classification.
2. Establishment of technical documentation.
3. Implementation of a quality system.
4. Application for AEMPS manufacturer licence.
5. Application for conformity assessment to a notified body (NB).
6. EUDAMED Registration and AEMPS Marketing Registration.



The following diagram shows the process to follow:



The qualification of the product, that is, checking whether this regulation applies to it, is carried out by analysing whether it complies with the definition of a medical device, with that of an accessory or whether it is in the Annex XVI list for MDR [1] or whether it complies with the definition of an *in vitro* diagnostic product or IVD accessory [2].

The regulations of medical devices establish a classification based on risk. Thus, MDR distinguishes products of class I, IIa, IIb and III, while IVDR establishes classes A, B, C and D in order of increasing risk, as explained in Section 3.1. In the case of medical software, qualification and classification may be more difficult to establish and for MDR, Annex III of the document establishes that all software that provides information to support clinical decision-making is at least class IIa; therefore, it requires intervention by a notified body [7].

In a case including artificial intelligence and involving patients, the training of the algorithm must be carried out as clinical research with the approval of a CEIm and of the AEMPS. Currently, the European data space is being developed, including data from different national initiatives. This will allow this training to be carried out with a large number of items of data and thus improve the safety and effectiveness of medical software.

Medical technology, which is a medical device according to the MDR or IVDR regulations, must go through the conformity assessment process including, for higher risk products, the intervention of a notified body that issues a certificate of conformity.

Conformity assessment is the procedure by which it is demonstrated whether a product meets the requirements of the MDR or IVDR regulations (Art. 2.40 MDR and 2.32 IVDR).

These products will be safe and effective and will not compromise the clinical condition or safety of patients or the safety and health of users nor, where applicable, of other persons, provided that the possible risks associated with their use are acceptable in relation to the benefit they provide to the patient and are compatible with a high level of safety and health protection, taking into account the generally recognised state of the art (annex I.1 MDR).

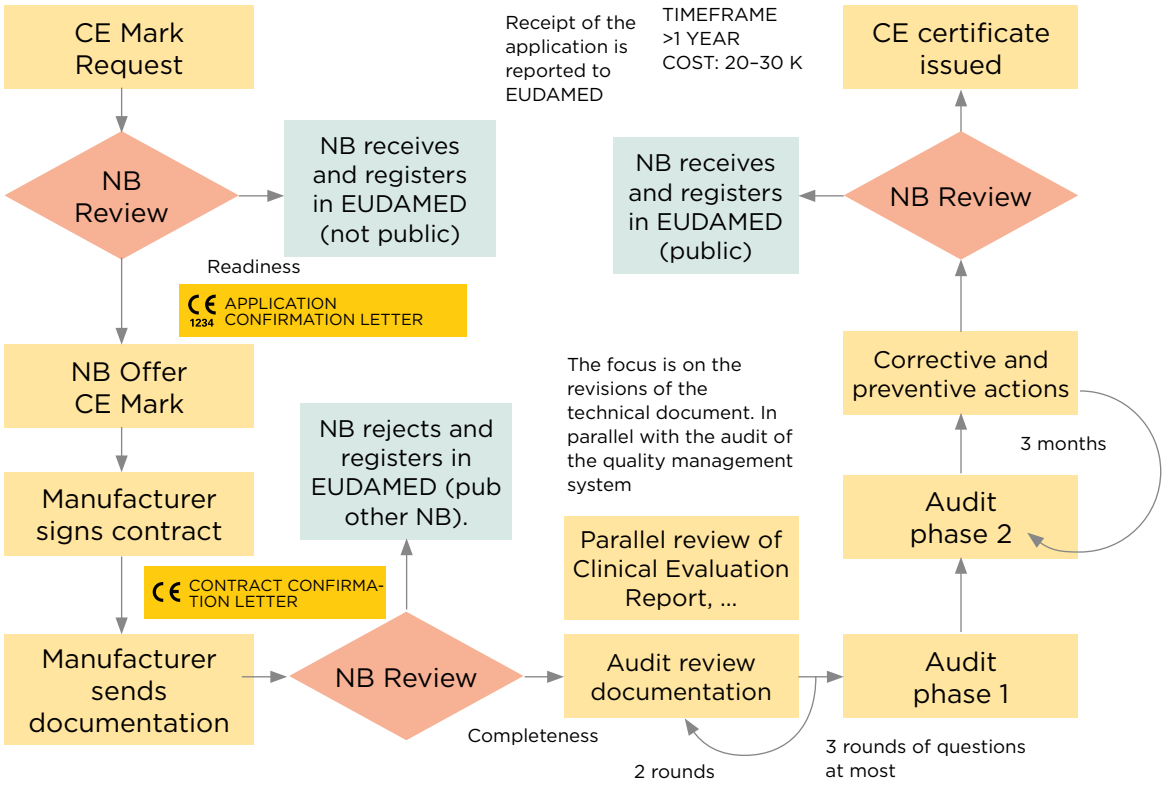
The technical documentation is established in the regulations (specifically in annexes II and III) and includes the description of the product, the intended purpose, the labelling and instructions for use, design and manufacturing information, general safety and performance requirements of Annex I, risk analysis (according to ISO 14971), preclinical testing (according to harmonised standards and the state of the art), clinical evaluation and research and post-marketing surveillance data.

In this assessment, the technical documentation (according to Annexes II and III MDR or IVDR), the quality management system (according to ISO 13485) and the registrations and licences (AEMPS and EUDAMED) are reviewed, by the manufacturer itself for low-risk products (classes I or A), and by a notified body for the rest (for example, the Spanish CNCps 0318).

Depending on the classification of the product, different assessment routes can be followed. The most typical is that of Annex IX of MDR/IVDR, which includes the design of the product.

Products that have passed this assessment can be consulted in EUDAMED [8], except for custom-made products, clinical investigational products and in-house manufactured products. The time for this assessment is one year from the date the application is submitted to the notified body and the cost is around €20,000–€30,000 per product family.

The conformity assessment process follows the following flow chart:



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4. The use of new technologies in healthcare practice

4.1. The role of healthcare institutions

It is essential to highlight the crucial role that healthcare institutions in Spain and Catalonia play in the adoption and use of new technologies in healthcare practice. These institutions, such as hospitals, health centres and other healthcare entities, are responsible for promoting an environment conducive to the effective integration of the new technologies.

In Spain, there is a strong commitment on the part of healthcare institutions to be at the forefront of technological innovation in the field of healthcare. Programmes and initiatives have been established to promote the implementation of new technologies in healthcare centres, these have included the digitisation of patient records, telemedicine, artificial intelligence and other advanced technological solutions.

In Catalonia, specifically, healthcare institutions have also promoted initiatives to deepen the use of new technologies in healthcare practice. Collaborative projects have been created between healthcare centres, universities, research centres and other agents in the sector to develop innovative technological solutions that improve patient care and optimise available resources.

Institutions in Spain and Catalonia have played a key role in establishing regulatory and normative frameworks to guarantee patient safety and privacy in the use of new technologies. Security protocols and data protection policies have been established to ensure that health information is treated confidentially and appropriately.

In addition, institutions have been pioneers in evaluating the effectiveness and efficiency of new technologies in healthcare practice. Studies and analyses have been carried out to understand the impact of new technologies on improving clinical outcomes, patient quality of life and the efficiency of the healthcare system.

These healthcare institutions in Spain and Catalonia have assumed a fundamental role in the use of new technologies in healthcare practice. With their commitment to innovation, appropriate regulation, patient protection and evaluation of results, the institutions contribute to improving the quality of healthcare and advancing towards a more technological and efficient future in the field of healthcare.

One of the important aspects would be to emphasise the importance of user training in medical technology, where institutions and industry have a shared responsibility, as well as the need to carry out technical, corrective, evolutionary and legal maintenance of medical equipment.

4.2. The role of healthcare ethics committees

The healthcare ethics committees (HECs) are consultative and interdisciplinary bodies at the service of professionals and citizens to guide their actions in the conflicts of values, ideology and morals that healthcare practice can give rise to. The fundamental objective of the HEC is to promote that professional actions occur within a framework of respect for the dignity of the person and human rights, considering that this attitude is the foundation of good healthcare practice.

The HECs act in accordance with the four principles of bioethics (non-maleficence, beneficence, autonomy and justice). In particular, they ensure that

the patient's autonomy and freedom of thought, conscience, religion, opinion and expression are preserved in their sphere of action. The composition of the HEC members is regulated and accredited by the General Directorate of Professional Regulation and Health Regulation of the Department of Health. The HECs follow the deliberative process as a procedure for resolving conflicts.

The great development of the new technologies applied to health has increased concerns, not only about the ethical implications of their research and development, but also about their implementation in clinical practice. The main ethical issues have to do with equity, in the sense that, potentially, new technologies could generate or increase inequalities in health care. The need for the patient to take an active role in the operation and provision of the functionality of the technology may result in some sectors of the population being excluded. Another controversial issue is the right to privacy, in the context of data collection and analysis and the use and application of artificial intelligence, which cannot ignore the patient's right to informed consent.

Undoubtedly, new technologies can raise new ethical questions that HECs, who deal with clinical issues, are not accustomed to handle. From a bioethical point of view, when applying new technology, it is necessary to reflect deeply on the ethical aspects of the direct consequences of healthcare technology, but it is also necessary to take into account the potentially unwanted effects, placing respect for the privacy and autonomy of people at the centre of healthcare. That is why it is important that these committees be interdisciplinary, including technical and clinical profiles.

4.3. Participation of patients and members of the public in the incorporation and implementation of new technologies

The incorporation of health or medical technology is reinforced by the systematic consideration of the perspective of the patient, their families and members of the public in general. Their vision allows us to help and facilitate the development of new technologies for the benefit of their health. It is also necessary to consider the identification and description of possible conflicts or problems in the application of the technology and which results are really important for patients.

Patients and people in their immediate environment have the unique experience of living with diseases and know the impact on their quality of life. They can express their preferences and needs and collaborate in the design and development of technologies and in their evaluation. Through this collaboration they can provide a valuable and essential perspective on the consequences, intentional or not, of current or future health technologies. Patient involvement also contributes to equity, as it allows us to understand the diverse needs of patients facing a particular health problem and balance them with the demands of a healthcare system that aims to distribute resources fairly among all users.

> The culture of participation allows for increased transparency and credibility of the process and fosters a sense of belonging and responsibility.

Below, quality standards are proposed for patient participation in the health technology assessment process:

I	Health technology assessment organisations should have a strategy that describes the processes and responsibilities of those working in them.
II	These organisations should designate adequate resources to ensure this involvement.
III	They should also provide training on how to involve and incorporate patient perspectives throughout the technology assessment process.
IV	Patients and patient organisations should also have the opportunity to participate in training to empower themselves and better contribute to the assessment.
V	Patient involvement processes should be reviewed periodically, taking into account the experiences of all those involved, with the aim of continuously improving them.
VI	Communication strategies should be in place to reach a wide range of patients.
VII	Timelines should be established to ensure that patient input can be obtained.
VIII	Patients' perspectives and experiences need to be documented and the influence of patient contributions on conclusions and decisions reported.

Health technology assessment can be considered the path from scientific evidence to decision-making. Patient opinions contribute to finding the right path to ensure that decision-making is rational. By taking into account patients' needs, preferences and experiences, it is possible to improve patient satisfaction, identify unmet needs, improve adherence to treatments and ensure safety.

In short, the public play an active role in different stages of the conceptualisation, development and application of new technologies, providing their perspective, needs and feedback to ensure that medical technology is efficient, innovative and patient-centred. This allows the technology to be better adapted to individual needs and improves its usefulness in clinical practice.

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5. Ethical, deontological and regulatory implications

5.1. Information for the patient

In accordance with article 6 of *LLEI 21/2000, de 29 de desembre, sobre els drets d'informació concernent la salut i l'autonomia del pacient, i la documentació clínica* [Law 21/2000, of 29 December, on the rights of information concerning the health and autonomy of the patient, and clinical documentation], information and obtaining informed consent form part of all healthcare and research processes.

The physician must inform the patient of the treatment or procedures to be carried out, as well as of the research project in which he or she is asked to participate, and this also applies to the use of or research into new health technologies. This task cannot be delegated to other professionals nor to administrative staff. The patient's right to refuse a diagnostic test, treatment or participation in a research study must be respected, once he or she has been informed in an comprehensible manner.

Whenever the execution of a research project modifies the usual practice in the care of a patient, this person must be informed and must give prior consent through his or her signature or that of a legal representative. The information given to the person must precede the signature of the document accepting participation in the project. This information must be given in the most understandable terms and respecting the patient's cultural values. The patient must be provided with a document specifying the potential benefits and risks of participation in the study, and the name of the person who provided the information. The patient must be given the necessary time to consult the proposal and to make a free and voluntary decision, and can stop participating in the study at any time.

Informed consent is a patient right that is part of all medical acts and of the process of information, communication and decision-making between the physician and the person being treated. In order to fulfil the ethical and legal duties of the professional and respect the patient's autonomy, it is essential to inform the patient and obtain consent. The medical record is the space to record the information and consent processes, without prejudice to the fact that in the cases provided for by law, the corresponding informed consent document must also be signed (available in Catalan *).

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5.2. Data protection

We understand digital health as the transformative capacity of digital technologies, aimed at members of the public / patients, healthcare professionals, healthcare service providers and other agents involved. The digitalisation of healthcare services can bring enormous benefits to the relationship between

the healthcare professional and the patient by facilitating the tasks of professionals and empowering the patient, who can become an active agent in the treatment of his or her illness or condition. However, given the wide range of applications in the healthcare field, it can sometimes be difficult to recommend an application due to distrust or lack of knowledge about its suitability and guarantees.

Therefore, the use of apps, wearables, sensors, etc. can generate a series of risks of regulatory, ethical and deontological breaches that may be unknown to the professional and that must be faced to minimise them, until acceptable risk levels are reached and the advantages offered by digital technologies can be fully exploited.

- ☑ The health applications used by professionals must be validated by the organisation itself or official institutions in order to recommend them to patients with confidence and guarantees.
- ☑ It is essential that apps be reviewed based on professional criteria, with content validation, reliable sources of information, usability criteria, accessibility and guarantees of privacy and security in relation to health data.

Health apps must:

- ☑ Be evaluated and identified as appropriate solutions for each case, taking into account the patient's conditions or the healthcare process.
- ☑ Have accessibility criteria so as not to exclude certain vulnerable groups in their use and present an appropriate design to guarantee universal and inclusive access to people who are disabled.
- ☑ Respect patient autonomy. The use of applications should never replace the face-to-face relationship between professional and patient when this is necessary.
- ☑ Comply with data protection regulations.
- ☑ Comply with health product regulations, if applicable.
- ☑ If the patient's consent is collected for the use of the application, it must be kept in the terms and conditions that it was given.
- ☑ The information must be provided in a concise, transparent, intelligible and accessible manner, using clear and simple language, especially when addressed to a child.
- ☑ Provide all security guarantees, aligning with the requirements of the entity. In this sense, entities must implement security measures adjusted to the level of risk of the data processed, having, among others, an IT infrastructure that minimises the risks of external attacks, clear data access protocols and robust pseudonymisation and anonymisation processes.

5.3. Confidentiality and access to medical records

For some time now, medical records (MRs) have been computerised and partially interconnected between centres, which makes them much more accessible. New technologies are often associated with systems for the display of and the information transfer with the MR, which can be one-way or two-way. For this reason, it is important to remember that the MR is a confidential doc-

ument, **to which only authorised personnel directly involved in the healthcare of the patient to whom it refers have access**. Any professional who accesses it without the patient's authorisation and if there is no justified reason for doing so could be responsible for committing an offence against privacy, which could lead to imprisonment. The patient's authorisation is not required when access is made at the request of a court, for epidemiological reasons or for planning and evaluating the quality of care, among others. The integration of new technologies that involve computer connections with the MR must be reviewed in this regard.

On the other hand, **patients have the right to access their MR and obtain a copy** of the data contained therein if they request it. This copy, however, does not necessarily have to be complete, as for reasons of confidentiality some data such as subjective annotations made by professionals or the personal data of professionals or third parties may be omitted under the provisions of Law 21/2000, of 29 December, on the rights of information concerning the health and autonomy of the patient and clinical documentation (Article 13).

New technologies should help not only to facilitate the transfer of information and improve access by authorised professionals (and, where applicable, by the patients involved), but also to monitor and prevent unauthorised access.

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5.4. Conflicts of interest

A conflict of interest is a combination of conditions in which professional judgement regarding a primary interest tends to be unduly influenced by a secondary interest (*Thompson DF. Understanding Financial Conflicts of Interest. NEJM 1993;329:573-576*). In the field of medicine, secondary interests can have different origins, most of which can be related to the incorporation of medical technology:

- **Economic:** industry payments, company incentives in contradiction with the patient's interest, referrals of consultations from public to private care for personal gain or for a third party.
- **Non-economic:** professional prestige (if the desire for recognition negatively influences professional conduct), emotional (if there is excessive involvement with patients who are friends or relatives), institutional (an uncritical defence of the institution where one works), ideological (related to religious beliefs, moral convictions or political ideas), defensive medicine (if the fear of a complaint is detrimental to the patient's interest).

It is very important to educate health professionals in the management of conflicts of interest, recognising their existence, differentiating between induction/temptation and acceptance. In the event of acceptance, it must be decided whether it is necessary to make a public declaration of the conflict, carry out a prior review by an expert committee or to abstain, in the case of an irresolvable conflict.

Medical students assume the ethical principles of their profession in the Hippocratic oath, taken at the end of their degree. Throughout their professional career, in their practice, they are subject to the rules of the Code of Ethics (*https://www.ccmc.cat/pdf/DG_Deontologia_CAT.pdf*) and must be aware

that conflicts of interest can also affect them when integrating medical technology. Equally, there are increasingly similar initiatives for other health professionals, such as biomedical engineers (*https://www.upf.edu/web/biomedical-engineers-pledge/about*), which are especially important for developing new medical technologies considering the potential consequences for society in general and the patient in particular.

In the Code of Ethics of the Council of Medical Colleges of Catalonia (CCMC), the following rules stand out in relation to conflicts of interest:

- **Rule 9**: The physician must maintain transparency regarding potential conflicts of interest that may arise in his or her professional activity with respect to any relationships with the healthcare, pharmaceutical and other industries related to the health sector.

- **Rule 66**: The physician, when establishing a treatment, must base it on the benefit for the patient and the correct use of healthcare resources and must not be influenced by inappropriate restrictive measures or by incentives, invitations, subsidies or other aids. The relationships that each physician maintains with the healthcare and pharmaceutical industries must be transparent and must be made clear in the event of a conflict of interest.

- **Rule 136**: Medical fees must be decent and fair. No physician may accept direct or indirect remuneration or benefits in any form, whether in the form of a commission, as a propagandist or as a supplier of clients or for reasons other than commissioned work. Dichotomous practices are also not ethically acceptable.

These rules should be extended to all professionals who work with people's health, regardless of their field (health or technology).

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5.5. Public–private collaboration

The development and incorporation of tools, platforms and technological solutions in the field of health is increasingly structured through contractual formulas based on public–private collaboration that aim to **promote research and innovation**. This can involve health centres, research centres, universities, industry, etc.

This collaboration is often essential for the complementarity that is usually provided by the public part, often more related to the research aspect, and the private part, which is closer to the market. That is, an initial technological idea (low technology readiness level (TRL)) can have contributions from public and private centres until the product reaches the end users (high TRL).

Likewise, mechanisms for innovation and technology transfer to public bodies must be fostered, which give rise to the creation of startups, as well as technology licences to companies that will develop the technology and bring it to the market. In line with this framework, mechanisms are promoted that aim at facilitating accessibility to the data that the implementation of these projects requires. This use of data, whether primary or secondary, must be realised in compliance with data protection regulations and, in this sense, it must be borne in mind that:

- The purpose of the projects in public–private collaborations is mainly research and innovation, with the requirements established in this regard by the European Data Protection Regulation and by Organic Law 3/2018, of 5 December, on the protection of personal data and the guarantee of digital rights.
- Given the diversity of the entities that participate, it is particularly relevant to define the roles with which they act, establishing mainly whether they are responsible or in charge of processing, since each type of relationship requires compliance with different requirements.
- It is essential to specify the people who have access to personal data, also taking into account the centre or entity from which the actions will be carried out and verifying that the accesses are included in their scope of action and within the functions they perform. Regarding the legitimation for the use of data, in most cases it will be given by the consent of the data owner.
- The necessary technical and organisational measures must be applied. In the use of digital tools, traceability, periodic verification of access and the realisation of adequate pseudo-anonymisation of data where necessary are especially important. Compliance with the requirements established in the case of devices that are healthcare products must also be verified.
- It is essential to know the requirements of the technological tools that are used and the consequences of their use or implementation in the internal systems of the centres in order to avoid security problems that could compromise personal data.

In order to guarantee that the outlined actions are carried out within the framework of data protection regulations, it is essential to implement data protection from the design stage onwards in public–private collaboration projects and to keep it updated throughout their development.

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5.6. The relationship with industry

Medical technologies emerge from the intersection of the fields of basic sciences and engineering, generating wellness technologies, diagnostics, medical devices and digital health solutions.

The transfer mechanisms of these technologies can be categorised into:

a) licensing contracts to consolidated companies;

b) collaborative R&D&I projects; and

c) creation of technology-based companies, called spin-offs or startups depending on the context and the founding mechanisms.

Technology transfer is, in fact, a process that consists of several phases, which are not always consecutive: **research, evaluation, valorisation, prototyping,**

industrial/intellectual protection strategy, product development, validation and commercialisation, among others, which establish a bridge between need and market.

Once on the market, it must also be taken into account that if this technology is to be financed within the health system through the common (Ministry of Health), complementary (autonomous communities) or hospital portfolio, it must be evaluated by the relevant agencies (AQuAS, RedETS) or by the healthcare centre itself. For this reason, it is recommended that the development of the technology be considered within the perspective of the life cycle and to orient the different phases in this sense.

Catalonia has unique characteristics with respect to entrepreneurship and the promotion of talent. These characteristics have a very significant impact on technology transfer via public–private collaboration and the migration of technologies from the public to the private sector.

Recently, solutions have become available for this promotion of technology to the medical technology industry, catalysed by private initiatives (such as incubators or accelerators such as Ship2B, BSTARTUP, WAIRA or ANTAI, among others), public initiatives (such as CRAASH Barcelona, promoted by Biocat, Barcelona Activa, The Collider or CIMTI), associations (such as Barcelona Health Hub and TechBarcelona) or network initiatives funded by the Agency for the Management of University and Research Grants (AGAUR) and promoted by research entities such as the i4kids network, led by the Sant Joan de Déu Research Institute, or the Xartec Salut network, led by the Biomedical Engineering Research Centre (CREB) of the Polytechnic University of Catalonia (UPC). In all initiatives, research groups play an important role and provide a bridge to the medical technology market.

In terms of economic impact, these startups have generated nearly 1,720 million € during 2022, being almost 17% of initiatives involved in medical technologies. Despite the impact of the pandemic, the profits of these companies have been stable and they have employed more than 19,000 qualified professionals. It is interesting to assess the capital invested in the sector by public and private entities. Considering the period from 2017 to 2023, the total capital invested in Catalonia is 1,094.3 million €, 89% of which is of private origin.

The Catalan spin-off/startup fabric is shaping up to be one of the most emerging and dynamic in the country, despite the differences in public and private investment compared with other regions, European ones above all.

This fact is possibly the result of several factors:

a) Structural factor specific to a spin-off as a transfer mechanism where we see incentives to attract funding and advance TRL levels more efficiently compared with universities or research centres.

b) Taking advantage of talent from universities and research centres (directing this talent to technology-based companies is more attractive than losing it to other countries).

c) Collaboration between public and private sectors, together with the clinical environment, improving the relationship between groups and centres with companies and hospitals, promoting joint research projects and unique programmes such as industrial doctorates or R&D&I networks.

This has allowed the attraction of foreign investments that increase the competitiveness of the territory and make it attractive for the health sciences ecosystem.

Barcelona has become a centre of innovation and entrepreneurship, also attractive for startups from various industries, with the medical technology sector at the forefront.

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5.7. Professional civil liability

The growing use of technology in medicine has a significant impact on the healthcare liability regime when understood as a whole. A correct approach to this regime requires us to distinguish two major areas. The first is the liability that derives from the incorrect use of technologies by the physician in the different ways described, that is, the physician uses technology inappropriately in the medical act and this causes harm to the patient. The second area is the liability that derives from a malfunction or abnormal operation exclusive to the technology applied in healthcare.

	Healthcare responsibility understood as a whole:
☑	Liability arising from incorrect use of technologies by the physician
☑	Liability arising from malfunction or abnormal operation exclusive to the technology applied in healthcare.

The first area is subject to what is known as the subjective liability regime based on proof of the physician's fault based on the *lex artis* criterion — the standard criterion of correct medical action agreed upon by the scientific community. That is, if it is proven that the physician has used technology incorrectly in the medical act and that damage has been caused to the patient, the physician must compensate for this damage through his or her civil liability policy — even, in the worst case, and very exceptionally, incurring criminal liability. In short, the classic civil liability regime of the physician applies: the patient must prove the physician's fault in the inappropriate use of technology in the different forms, the causal relationship and the damage.

On the other hand, in the second indicated area of liability, that derived from a malfunction or abnormal functioning of the technology applied to healthcare, at the moment the most usual would be for the liability regime regulated by the regulations of consumers and users to be applicable — always referring

to the most frequent case, civil liability. This implies applying a much stricter and more protective regime for the patient, given that it is a regime based on a clear tendency towards the objectification of liability, that is, that the holder or owner of the medical technology is responsible for the damage caused to the patient, with the sole exception of fortuitous events or force majeure. In these cases, the damage will be compensable without the need for the patient to prove fault to an extreme degree. If it is proven that the damage has been caused by the incorrect functioning of the applied medical technology and there has been no fortuitous event or force majeure, the damage must be automatically compensated.

Therefore, the usual procedure will be that the owner or holder of the technology – be it a physician, a clinic, a hospital, etc. – must compensate the patient for the damage caused without the need to prove fault. All this is without prejudice to the fact that, if it is proven that the damage is the responsibility of the manufacturer or distributor of the technology, this will be the one ultimately responsible in an objective manner. The most common approach will be for the patient to direct his or her claim against the owner of the technology that was used and that the latter, in turn, takes the same action against the manufacturer or distributor — without prejudice to the fact that action may be taken against the manufacturer or distributor directly if it was aware of the issue.

This growing use of technology in healthcare may lead to an expansion of the strict liability regime described in healthcare. This situation is of concern to the CCMC's Professional Liability Service, which is always alert to possible changes.

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6.

Ethical aspects in the communication of results (dissemination and transparency)

The generation of scientific knowledge and its dissemination are an inherent part of healthcare. The communication of results to the scientific community, whatever form this may take, encourages debate and allows the development of new hypotheses. Likewise, dissemination to the population is essential so that citizens are informed of scientific progress.

This activity must not lose sight of the fact that **values such as honesty, respect, prudence, transparency or commitment are fundamental**, since all biomedical research is based on a relationship of trust between citizens, researchers, institutions and industry.

In advertising the results of medical research and the introduction of new technologies, the message cannot contradict the values of the medical profession, create false expectations nor trivialise the healthcare relationship with superficial promotions. The principal investigator is the one who must authorise the publication of the results, which must include the list of professionals who have contributed to the project, the centre or centres involved, the grants received and potential conflicts of interest, as well as the tasks carried out by each of the participants. In scientific publications — written, oral or visual — no name or detail that allows the identification of the subject of the experiment may be used, unless in unavoidable cases the interested party, after careful information, gives his or her explicit consent, as provided for in Rule 93 of the Code of Ethics.

Likewise, as is well established in the Code of Ethics, the physician must take special care in disseminating the results of research in the media and must try to avoid that they lead to misunderstandings or generate false hope in patients, especially in those affected by diseases for which a proven, effective solution has not been found (Rule 94). The dissemination of information on professional activities or those of a health and scientific nature must be careful, especially when this affects the population in a general way. The information must be truthful and understandable and based on objective, reliable, identifiable and verifiable sources (Rule 130). It is necessary to act with caution, considering the repercussions it may have on the audience for whom it is intended, and avoid the appearance of advertising, as well as the endorsement of products without proven health benefits (Rule 131).

The Spanish Network of Agencies for the Evaluation of Health Technologies and Services of the National Health System (RedETS) has established as one of its main strategic axes the systematisation and transparency of all processes, from the identification and prioritisation of technologies to be evaluated, to work procedures or the publication and dissemination of results.

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7.

The experience of the Catalan public health system in the development and evaluation of technology in the field of health

The health innovation ecosystem in Catalonia is mature, dynamic, in continuous growth and generates great opportunities for industrial transformation. According to the *Informe de la BioRegion 2023* [BioRegion Report 2023], it has the ingredients to position it as one of the leading health innovation hubs at the European level.

The BioRegion of Catalonia brings together a combination of companies, research centres and organisations, hospitals, universities, administrations and support agents who work in this strategic sector. It currently contributes 7.9% to Catalonia's GDP and employs nearly 6.5% of the population. It has 91 research entities and nearly 1,400 companies, nearly 500 of which are startups and scaleups.

However, the innovation generated in Catalonia is not easily implemented in the system. In other words, although the health system has a great capacity to generate innovation, the mechanisms for adopting it can clearly be improved and result in an impact on the sustainability of the system itself.

One of the main challenges for innovation to be implemented in the system is evaluation. Evaluation and implementation require clear and agile mechanisms and roadmaps that allow us to know the needs of the system, define its criteria, determine the value of the technologies and, finally, know the cost of the value provided by the new technology.

In October 2022, in Catalonia, the Commission for Innovation and Transformation of the Health System was created to promote innozvation in the sector and its application to the system. Within this framework, the Subcommission for the Adoption of Innovation in the Health System was created, coordinated by Biocat, with the mission of:

- Establishing a clear and agreed model for promoting innovation in the health system.
- Facilitating highly complex public–private collaboration projects and innovation collaborations with a clear orientation towards generating value.
- Promoting the deployment of innovations in processes and services generated by the health system.
- Defining the strategy for the use, programming and execution of projects through the various public procurement instruments for innovation or other alternative instruments for adopting innovation.
- Ensuring the correct coordination of the various existing instruments for promoting and adopting innovation.

Some examples of adopted innovation projects are:

- The Digital Health Validation Center (*https://ehealthvalidationcenter.santpau.cat/web/public*) created by the Hospital de la Santa Creu i Sant Pau.
- The One Step Stroke project of the Vall d'Hebron Hospital, which has involved the European Regional Development Fund (FEDER), the Operational Programme 2014-2020 of Catalonia that promotes innovative public procurement projects within the framework of SISCAT (Integrated Public Health System of Catalonia), as well as private companies.

- The Unit of Excellence in Diabetes, an innovative public procurement project with AQuAS as consultants, financed through the Department of Health with FEDER funds, of the Hospital Sant Joan de Déu.

The operational plan for access to innovation in the Catalan health system includes among the benefits of its implementation:

- Responding to the priority health needs of the population.
- Contributing to improving the health status and quality of life of people.
- Contributing to the equity, modernisation, quality, efficiency and sustainability of the health system.
- Contributing to the development of the life sciences and health sector in Catalonia.
- Improving the competitiveness and attractiveness of the health system and companies in the sector in the international environment (Pla Operatiu d'accés a la innovació al Sistema de Salut de Catalunya) [Operational Plan for Access to Innovation in the Health System of Catalonia]. Available from: *https://scientiasalut.gencat.cat/handle/11351/10435*)

It is key to design and build consensus on the processes and instruments necessary to promote innovation and streamline adoption mechanisms to transform the healthcare system, within the regulatory framework of medical and digital health technologies, as well as data processing, with a clear orientation towards generating value and improving people's health and well-being.

Among the functions of the **Catalan Agency for Health Quality and Evaluation (AQuAS)** is the evaluation of the structure, processes, new healthcare or service provision models, health technologies and information and communication applied to healthcare, and the results of healthcare interventions, analysing their variability and quality, identifying best practices in the clinical field, working closely with healthcare system professionals, and promoting optimal clinical practice and the efficient use of resources. It is for this reason that AQuAS works closely with the Department of Health and the Catalan health service to make the Catalan health system high quality, efficient, equitable and sustainable. One of the latest initiatives in which evaluation is of particular relevance is the *Artificial Intelligence in Health Program in Catalonia*, where AQuAS, together with the Tic Salut i Social Foundation, evaluates the challenges that arise in the market to provide solutions to health problems that need them, such as, for example, support for the diagnosis of *diabetic retinopathy*.

Conclusions

This Guide has addressed fundamental aspects of good practice for healthcare professionals for the development, proof of concept, market introduction, regulations and use of new technologies. New medical technologies are a current and inevitable pivot of progress and future for the benefit of excellence and continuous improvement in healthcare. This Guide aims to help and guide professionals and should be a first step for the GIPS Good Practice Working Groups and the Council of Medical Associations of Catalonia.

Medical technologies, such as robotics, artificial intelligence and telemedicine, have emerged as potentially transformative tools in the provision of healthcare services. With the capacity for more precise diagnosis, personalised treatment and improved efficiency, these innovations seem to unlock the potential for better and more effective healthcare. However, their use is not without challenges, as we have seen. Everything surrounding new medical technologies implies a degree of complexity and the need for order, transparency and ethics.

As we conclude this exploration of new medical technologies and their interaction with clinical practice, healthcare institutions, health policies and, above all, patients, we find ourselves in a dynamic and often challenging landscape. New medical technologies offer exciting opportunities to improve the quality of healthcare, but at the same time they raise fundamental questions about their utility, ethics and implications for medical practice.

To ensure that these technologies truly benefit patients and improve health outcomes, an interdisciplinary approach will be required.

In this Guide we have addressed one of the crucial issues, which is the need for regulation and transparency in the adoption of new medical technologies. The absence of adequate regulatory frameworks can expose patients to unnecessary risks and raise questions about the safety and quality of services.

The relationship between technology and clinical practice is complex. Professionals connected to health, whether they provide care or not, have to make important ethical decisions about how and when to use new technologies. The protection of patient data, confidentiality and professional civil liability are crucial issues that must be addressed in an appropriate and coordinated manner between the various professionals and fields involved. Likewise, the participation of patients and members of the public must be a central point in the future, a new focus in the conceptualisation of new technologies. This will force us to open the door to greater participation by patients, their families and the general public. Access to medical information and the possibility of collaborating in clinical decisions are important steps towards more patient-centred medical care. However, this raises questions about the communication of results and transparency in the dissemination of medical information.

The constitution of the new data committees, a challenge for the coming years of health institutions, will be a fundamental pillar of a system guaranteeing the implementation of new medical technologies. Globalisation allows the exchange of ideas and innovations, opening up new opportunities to learn from international experiences and improve medical practice.

Catalonia, as an example of a health system, illustrates the different ways in which new medical technologies can be implemented at a regional level. Good health policies and resources for research, innovation and business will have to be sought and promoted.

The future of new medical technologies is exciting and, at the same time, complex. To ensure that these technologies truly benefit patients and improve health outcomes, an interdisciplinary approach that includes professionals linked to health (healthcare professionals, engineers, biotechnologists, biophysicists, etc.), information systems professionals, regulators, and patients will be required. Ethics and transparency must be fundamental pillars of the adoption of new technologies, and open communication with patients is essential.

In this journey towards a more promising future for new medical technologies, we can observe the challenges and opportunities that present themselves. The complexity of this intersection between science, ethics, regulation, and clinical practice should not be underestimated, but neither should it slow down research nor the adoption of technologies that can positively transform the way we manage health and disease. The Good Practice Working Group of the Interdisciplinary Group of Health-Related Professionals (GIPS) must promote a balanced approach aimed at achieving a healthier future, where new medical technologies are used responsibly to improve the lives of many people. This complex and exciting task is a shared responsibility of all those committed to improving health and well-being.

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Good Practice Guides

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Paseo de la Bonanova, 47. 08017 Barcelona
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