# Healthcare Workforce and Organisational Transformation with AI – Enacting Change

Think Tank Round Table Meeting Proceedings

**Spain**

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THINK TANK

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# Context for the selection of the 2020 Round Table Series Topic

In March 2020, a joint report between EIT Health and McKinsey & Company "Transforming healthcare with AI: the impact on the workforce and organisations" was launched which aims to contribute to the debate surrounding Artificial Intelligence (AI) in healthcare but going a step further in helping to define the impact of AI on healthcare practitioners, and the implications of introducing and scaling AI for healthcare organisations and healthcare systems across Europe.

With AI in healthcare being a fast-moving field, the report provides a unique vantage point from the frontline of healthcare delivery and innovation today, and the latest view from a wide array of stakeholders on AI's potential, the real state of play today, and what is holding us back from widespread uptake and adoption.

As the report takes a broad pan-European perspective, identifying levers for change at the personnel, infrastructural and environmental levels, further exploration of how these findings and recommendations could be translated at a national level is warranted.

Through this Round Table Series, national-level decision makers representing key stakeholders that play a role in developing and implementing AI approaches at scale within existing national healthcare systems were identified to provide opinion and potential solutions that could be applied to support practitioners and providers to fully embrace the potential of AI.

# Objectives of the National Round Table Meetings

In each of our seven locations, by reviewing the national infrastructural context, educational and health systemic structure, we aim to:

- Validate the relevant barriers and enablers, as indicated within the report, for the successful adoption of AI at the Member State (MS) level, whilst also identifying similarities and differences between countries.
- Identify how to improve "on the ground" impact of AI by specifying obstacles to overcome and opportunities to maximise within the defined domains.
- Outline a national (MS level) "plan-of-action", indicating individuals, organisations, bodies or other relevant vehicles to accelerate and expedite integration of AI to drive workforce capability and organisational receptivity.

In addition, it will be useful to look at the role the EU could play in encouraging greater adoption of AI in healthcare.

# Agenda and participants: Spanish Round Table

Hosted by: EIT Health Spain.

Moderated by: Esther Paniagua, journalist.

Other participants: A full list of meeting participants can be found in Appendix 1.

2020 Round Table Series Co-Chairs:

- Charlotte Stix – former Coordinator for the European Commission's High-Level Expert Group on Artificial Intelligence
- Zineb Nouns – Physician, Medical Education Specialist and HR Manager
- Farzana Rahman – CEO, London Imaging Network

## Discussion topics

The agenda for the Round Tables was developed following a review of the EIT Health and McKinsey & Company report "Transforming healthcare with AI: the impact on the workforce and organisations" and with the input and advice of the 2020 Think Tank Round Table Co-Chairs.

- **Session I**

  Validate the relevant barriers and enablers as indicated within the EIT Health and McKinsey report for the successful adoption of AI at the Member State level, whilst also identifying similarities and differences between regions

- **Session II–V:**

  Identify how to improve "on the ground" impact of AI by specifying obstacles to overcome and opportunities to maximise within these six domains:

  1. **Clinical leadership**
  2. **Rethinking education and skills and investment in new roles and talent**
  3. **Regulation and policy making**
  4. **Funding and reimbursement**
  5. **Strengthening data quality, governance, security and interoperability**
  6. **Liability and managing risk**

Outline a national (MS level) 'plan of action' to accelerate and expedite integration of AI to drive workforce capability and organisational receptivity

# Session I: Validate the relevant barriers and enablers for the successful adoption of AI at the Member State level

## Synopsis of participant survey results

A survey was sent to all participants prior to the Round Table meeting to gather feedback on the situation in their country regarding AI and healthcare in relation to the six domains identified in the joint EIT Health and McKinsey & Company report.

**Introducing new technologies**

Participants noted that other strategic technological initiatives, such as open data and open source, have already been successfully introduced in Spain. The same should be true for AI, however as advances in the technology industry are taking place at a rapid rate, it is desirable to have a clear road map for all stakeholders before 2030.

Without a doubt, the starting point should be a clear definition of what is understood by AI, as the impact that is achieved by its introduction will depend on this premise. Round Table participants considered that the umbrella of AI should include all-natural language processing with a component of machine learning and deep learning, as described below.

Alongside this, the specific characteristics of the Spanish healthcare system need to be considered. Factors such as the country's demographic profile (marked by population ageing), the characteristics of the diseases that affect citizens (notably complex chronic diseases), or the lack of connection between the various (regional) health systems add pressure when innovative solutions are introduced. Therefore, *prioritisation* becomes the main factor to consider, as well as the *timetable* and *rate* of introduction.

**Investing in data**

Once Spain has a clear commitment, regulation will be required for all the components involved, which are broken down very clearly in the EIT Health and McKinsey report and addressed individually in the following sections. Although the role of the authorities is fundamental, one idea that emerged from the Round Table discussions was to use a bottom-up process that requires abandoning the traditional 'medical' approach focused on investing in drugs, equipment and products, and to begin thinking in terms of data.

Participants highlighted that digital systems involve intensive data exploitation. Consequently, it would be worthwhile proposing that health organisations construct and use a standardised database with universal access (open-source AI). However, inevitably, attention will then focus on data privacy and interoperability, aspects that will be reviewed in more detail later in this document.

Spain has already made significant advances in this respect, for example there are banks of aggregated medical images. Therefore, these attempts to construct datasets could help to

develop the algorithms that are needed on the road to joint, uniform implementation of AI-based solutions.

To implement AI in healthcare effectively, a suitable methodology for deployment is needed but this must be combined with the necessary human talent with appropriate education and skills. In this regard, a lack of academic structures that help to exploit health data were detected, as well as a deeper understanding of the application of the existing regulatory framework. This will be discussed in more detail in the corresponding sections.

**Making AI a current reality**

AI will never be – and it not intended to be – a substitute for the health professional, rather it is a way to expand their capacity and contribute to improving the efficiency of healthcare systems. Based on this premise, participants concluded that a significant change in mindset is required on many levels so that AI is seen as a current reality, rather than something that will happen in the future.

## Discussion of outcomes

From discussions at the Round Table meeting, it was apparent that participants considered that all domains identified in the joint EIT Health and McKinsey & Company report are closely interrelated. As a result, it is difficult to avoid the fact that the different domains overlap with each other in some way.

**Clear EU guidelines are needed**

The initial discussions focused on how to scale-up the application and integration of AI. This is a challenge for Spain, considering the three territorial levels at play: European, national and regional in the autonomous communities. If what is sought is minimum uniformity of criteria, it will be impossible to scale up AI effectively without clear guidelines set out by the European Union and promoted at national level.

To help achieve this, Spain should position itself so that it can occupy relevant posts in the main European initiatives on the creation of data spaces, which are currently held by German and French organisations. Examples of these initiatives are the International Data Spaces Association and Gaia-X.

**National initiatives**

For Spain specifically, it would be beneficial to have use cases that are focused on how to make the most use of AI and that describe what challenges it can contribute to overcoming.

The structural changes required to introduce AI applications into healthcare within Spain are not inconsequential, as is does not just require technological changes. The aim is also to incorporate new models that facilitate the governance of existing data within the Spanish healthcare system. One suggestion arising from the Round Table discussions was to implement AI through innovative public procurement that provides shared benefits.

**Simplicity and clarity as a starting point**

In a country like Spain, it would be appropriate to start by setting small goals and then continuing to learn and expand upon them. Participants considered that it was important to establish a set of

basic metadata with obligatory compliance at a national level. This would give the starting signal for fruitful integration of AI into healthcare. AI can be considered as another form of healthcare product, so appropriate regulatory pathways must be sought, as well as the synergies needed to facilitate training, investment and sustainability of the system.

A change in terminology was also suggested. This nuance would mean no longer referring to 'artificial intelligence' but instead using the term 'hybrid intelligence', as the endpoint is to try to implement systems based on machine learning and deep learning.

**Patient and citizen empowerment**

Now, more than ever, it is essential that the patient it put at the centre of all activities relating to their health. AI initiatives should start from the patient's needs and not from the doctor's speciality. The aim should be to empower citizens as the owner of the data, and jointly seek solutions for people, based on citizenship and society.

**Barriers to AI implementation**

One barrier that Spain will need to address urgently is the disruption caused by sharing data. This aspect can be a difficult issue for the Spanish government, where reservations often arise when new models are suggested. In addition, Spain suffers from a low level of digital literacy, an obstacle that will be overcome once the roadmap is clear and actions are taken to facilitate digital literacy, with specific educational programmes.

It is essential that there is an open, transparent debate regarding which particular model to follow: centralised versus federal (decentralised). The technology industry is not used to using centralised, monolithic models. Given that these companies are important companions on the path to AI integration, partnerships with them should be encouraged, not feared.

Likewise, neither should the regulation of this roadmap be feared – in Spain there is already an existing regulatory framework which is adequate, so this should be used to help translate AI applications into reality. Inspiration can be taken from experiences of other EU Member States and the USA.

Drawn from their different areas of knowledge and experience, Round Table participants' opinions on immediate applications of AI that could feasibly become a reality were:

- As it is important that innovations reach the patient, one idea would be to apply AI solutions that are focused on chronic patient self-care.
- A good AI algorithm can calculate the radiation dose that a patient should receive; this would free up healthcare workers' hours which could be translated into quality face-to-face medical care.
- AI could support the transition from chronic to acute care settings.
- Something that is currently still a long way off for Spain: health professionals are already proposing deep learning networks for the diagnosis of rare diseases.

# Sessions II–IV: How to improve 'on the ground' impact of AI

For each of the six domains below, Round Table participants discussed and developed a list of actionable recommendations. They identified the people who need to be involved and proposed the actions that need to be taken, in order for these to be realised.

## 1. Clinical leadership

### Challenges and barriers: What is not working/what needs to change in this domain?

**Clear guidelines**

To be able to lead a change of such magnitude, it is vital to have standards, a shared code or language that explains which data should be collected, how they are coded and how they are shared. The European Commission should take a more directive role in generating communication mechanisms through a unified protocol so that computing systems understand each other. The Digital Europe Programme is a positive step. However, it is essential to define its scope and be able to roll it out at a Member State level.

**Dedicated time for innovation**

The demands of the medical profession, and the need to stay up-to-date on clinical developments and publish proactively, leaves little room for healthcare workers to dedicate time to digital innovation. A formal framework for this purpose is demanded from Spain in the form of dedicated, paid time for healthcare workers for ongoing learning and innovation. This would not only have an impact on accelerating the introduction of AI but would also lead to the emergence of individual leadership through agents of change.

**Knowledge builds confidence**

Without a doubt, knowledge equates with confidence. It would therefore be valuable to start by mapping digital innovation hubs (DIH, also called centres of excellence) to determine the innovation capacity of each territory. Equally, it is fundamental to obtain feedback from users regarding the design of applications.

AI algorithms should be developed through a methodology that includes a 'by design' explanation, so that health professionals can understand their functioning and be confident in using them.

**Multidisciplinary teamwork**

It was suggested that in this era of change, there may no longer be a place for thinking in terms of hyper-specialisation. Collaboration between multidisciplinary teams should prevail, alongside support provided by staff from a range of disciplines, and the creation of new profiles for managing and leading projects.

## What is working well and best practices identified in this domain

### Existing successful projects and positive experiences

> One advantage that participants highlighted among health professionals in Spain has always been their willingness to collaborate. Multidisciplinary collaboration has always appeared stimulating to them, while recognising the importance of the primary incentive: developing a product whose use can be scaled up (utility of the innovation).

### Best practice examples

> The collaboration between different fields of medicine is an everyday reality, for example in transplant cases, which demonstrates that there is no specific aversion in healthcare to change or to multidisciplinary working.

> Technology companies see no disadvantages to collaboration either: when they see utility, they will commit to scientific progress.

## Key Points

> In terms of clinical leadership, the proposal from Round Table participants was to promote an open innovation ecosystem with clear communication channels, with time to dedicate to this learning and innovation that will subsequently be translated into quality time for the patient.

> It was recognised that none of these advances will be possible without involving the private sector and academia and generating the required synergies.

## Proposed actions and recommendations

> Design some kind of test bank within the health context (like a 'sandbox' model), a channel of innovation that eliminates concerns about risk and promotes learning and the common good, for the benefit of the patient, which is the final aim of all medical interventions.

> The importance of having a common coding system should not be overlooked (lobbying Europe is essential).

| Clinical leadership | |
|---|---|
| **Action** | **Target Stakeholder(s)** |
| Facilitate the creation of a sandbox-type environment or test bank in the healthcare environment. | Start-ups; integrators; developers; risk managers; legislative bodies |
| Promote digital innovation hubs to enable mapping and structuring the innovative capacity of the region. | Healthcare systems; software suppliers; insurers |
| Accelerate concept testing (test before investing). | Management of health centres |
| Promote multidisciplinary teams. | Clinicians; technologists; management of health centres |
| Allow dedicated time for innovation activities within the professional career development of healthcare professionals. | Healthcare systems |

## 2. Rethinking education and skills and investment in new roles and talent

### Challenges and barriers: What is not working/what needs to change in this domain?

**Lack of knowledge and training**

Healthcare professionals often lack knowledge and training in certain digital competences. It is crucial that they understand how technological processes work and how the practical application of an AI algorithm is developed.

**Hybrid professions**

The healthcare sector needs to be prepared for the arrival of new job profiles that are hybrid in nature, more technical and focused on fairness of the algorithm. It would therefore be valuable in the academic sector for university degrees to include a stronger focus on basic digital skills and to provide greater flexibility in the selection of optional subjects. In Spain, university curricula are quite rigid, while in many European and US training institutions subjects and disciplines can be combined.

### What is working well and best practices identified in this domain

**Existing successful projects and positive experiences**

> There are generally positive outcomes when doctors and engineers have the opportunity to collaborate to develop innovations. However, there can be a difference in capacity

between qualified, working doctors and doctors in training. For qualified professionals, immersion in technical knowledge can be more difficult due to the demands on their time.

> The academic sector should promote the multidisciplinary nature of digital literacy, something that is already a reality in other countries, and a potential model to follow.

**Best practice examples**

> Currently in Spain, many initiatives are being implemented to provide education on digital technology and AI. There are already postgraduate courses in biotechnology, AI and automated learning and this progression should be continued while also increasing the flexibility in the choice of subjects.

### Key Points

> On the basis that it is impossible for someone to programme data that they do not understand and that healthcare professionals will base their belief in certain data depending on the way it is programmed, it is crucial to promote cooperation between doctors and programmers.

> The premise and starting point for AI applications is always the need of the clinician (who in turn is always focused on the benefits for the patient). Therefore, it is appropriate to establish frameworks of collaboration between health entities, such as large companies and SMEs, and with academia, so that development projects can be undertaken that resolve this need and enable solutions to be launched on the market once they have been properly tested. This approach is proposed in order to balance the commercial interests of companies with the impact on health outcomes or the efficiency of health systems.

### Proposed actions and recommendations

> Promote interdisciplinary training, stop thinking in an analogue way and shift to a knowledge-based model.

> The incorporation of hybrid roles will entail redesigning staff planning in health institutions, using a holistic approach and avoiding the fragmentation of professional interactions in the patient pathway (multidisciplinary working).

> Seek the political support required to put an end to purely commercial interests and pursue clear social benefits.

| Education and skills | |
|---|---|
| **Action** | **Target Stakeholder(s)** |
| Improve digital literacy. | Government/cities; health centres; doctors; engineers; users/patients |
| Promote co-development of innovations and non-exclusive models of collaboration between healthcare centres, research teams and the pharmaceutical industry/MedTech. | Doctors; engineers; users/patients; health centres; research centres; start-ups |
| Promote technical subject modules (such as medical computing) in medical school curricula and introduce interdisciplinary technological immersion activities for health staff. | Ministry of Education; Government; academic sector |
| Undertake a national study to determine what is being taught and how. | Collaboration of intermediate organisations |
| Redesign healthcare staff resource planning to account for new hybrid job roles. | Management of health centres |

## 3. Regulation and policy making

### Challenges and barriers: What is not working/what needs to change in this domain?

Instead of grouping all AI applications under the same umbrella, it may be more valuable to distinguish between the various uses of AI, given the different regulations and ethical considerations that are required in each case. It will be crucial to establish the concept of commoditisation of AI, in terms of treating it as another healthcare product, a concept that is not as regulated or as well-integrated as, for example, the adoption of medicines or medical devices.

**Simplifying the regulatory environment**

It is essential that the regulatory environment for AI is as simple as possible, as any added complexity in the already highly complex process of introducing AI into the healthcare sector could present a barrier to implementation. The EU General Data Protection Regulation (GDPR) came into force in Spain in 2018, however the difficulty lies in its application. A practical implementation guide which clearly defines the ethical, legal and operational model that should be followed for AI applications would be extremely beneficial.

**Continuous evolution requires regular assessment**

Spain lacks a flexible national regulatory body for the approval of its medical devices, along the lines of the European Medicines Agency for drug products. This is particularly true with regard to products and services related to AI. Auditability is an important factor to consider in regulation.

Algorithms learn and are automatically fed by inferences based on automatic learning. Hence, it is essential to review them periodically in order for them to improve incrementally so they do not become outdated. This also relies on health professionals' feedback.

**Expanding the scope of regulations**

In terms of data, Spain is subject to both European (GDPR) and Spanish data protection regulations. However, the Spanish Agency for Medicines and Medical Devices (AEMPS) needs impetus to be able to validate technological projects, including AI applications, as currently it does not include this type of innovation. In addition, it is vital that ethics, or rather the evaluation of ethical impact, is not overlooked in the regulatory process. This involves guaranteeing supervision by a human and generating reliable AI guides with the following premises:

- An algorithm itself cannot make a clinical decision
- It is essential to guarantee that the database is not biased before it is entered into the AI system
- They must comply with the key requirements of the European Commission ethics guidelines for trustworthy AI

## What is working well and best practices identified in this domain

**Existing successful projects and positive experiences**

- The 2018 GDPR supports the concept of proactive responsibility, with rights and guarantees for citizens. This means that the impact of processing the data of those involved is assessed before and after the event, and risk mitigation is an obligation.
- A good example of this is in the area of informed consent, where Spain has made considerable progress.

**Best practice examples**

- An example of good practice is the Spanish COVID-19 tracking app, Radar COVID, which has been used during the pandemic.
- Multidisciplinary teamwork, data sharing and central coordination are pivotal to the success of Spain's organ transplantation network, which operates effectively despite different regional healthcare systems. In this setting, a multidisciplinary team comes together to undertake technical assessment and an ethics committee contributes to the decision regarding organ distribution.

## Key Points

- Although regulations exist, clear guidelines on their implementation are lacking.
- For development of a novel treatment or device for use in the healthcare sector, a new requirement could be introduced that specifies the need to gain advice from a scientific committee or relevant expert. This is something that does not exist yet and could be developed in the framework of AI.

### Proposed actions and recommendations

- The quality of an algorithm needs to be certified in some way at European level. Three basic characteristics of an algorithm need to be guaranteed: it should have no bias, be predictable and be explainable (and its results be interpreted).
- It is important to establish legislation beyond the paradigm of the clinical trial, as in the future numerous, different assessment criteria will be used.
- The use of metadata needs to be regulated and then an ethical guarantee must be ensured for security. However, this area still needs to be explored, as the ethical criteria surrounding digital innovations are still in the development stage.

| Regulation and policy making | |
|---|---|
| **Action** | **Target Stakeholder(s)** |
| Create an innovation ethics committee, as used for clinical trials in hospitals, to validate algorithms. | AEMPS; research centres |
| Develop European regulations for how algorithms are developed. | European Union |
| Develop certification standards, equivalent to ISO standards, for the design of algorithms which include ethical criteria. | European Union |
| Publish implementation guidelines and checklists. | Regulating agencies |
| Ensure implementation of GDPR safeguards for data use. | Legislative bodies; Government |
| Undertake regular algorithm audits. | External agencies |

## 4. Funding and reimbursement

### Challenges and barriers: What is not working/what needs to change in this domain?

**Clarity of criteria**

Participants agreed that it is crucial to clearly define the reimbursement of AI-related applications. In the past, funding for research and development has focused on 'doing science' for its own sake rather than converting the findings into real innovations. Faced with the AI paradigm, the focus of investment should now be shifted. A model can be developed that is centred on the creation of software products in the healthcare sector, in which a process of continuous evolution and improvement is required, backed by users (healthcare professionals).

**Fragmentation and lack of adequate budgets**

Throughout Europe, healthcare is chronically underfunded, and funding is excessively fragmented. The inappropriate focus, poor of distribution of funding, and lack of adequate budgets for digital transformation are barriers that must be overcome in order to achieve uniform introduction of AI.

## What is working well and best practices identified in this domain

### Existing successful projects and positive experiences

- In the United States, the first cases have been published of reimbursement of AI tools by the Centers for Medicare & Medicaid Services, based on measuring the final benefit to the patient. Examples are an application that can diagnose a complication of diabetes that causes blindness and one that alerts a specialist when a brain scan suggests a patient has suffered a stroke.
- It is important that national and international success stories of impact studies of AI applications are widely communicated to (public and private) healthcare system payers to increase their visibility.

### Best practice examples

- In the area of funding of AI applications, the public–private partnership (PPP) system may be suitable. This system has had excellent results in other areas. It would be worth including insurance companies in this area of collaboration.

## Key Points

- For AI to be sustainable, it is important that Member States to promote funding schemes that make a clear commitment to digital transformation.

## Proposed actions and recommendations

- The concept of payment-by-results is common in the pharmaceutical sector, so the proposal of Round Table participants was to shift to a value-based funding model throughout the entire patient pathway, with payment according to service and results. The focus should not be on efficacy or efficiency, but on the value of the entire experience. This new model should be based on patient-reported outcomes (PRO). This will favour economies of scale and, with the help of the right technology, new sustainable models can be introduced.

| Funding and reimbursement | |
|---|---|
| **Action** | **Target Stakeholder(s)** |
| Implement value-based cost estimation and payment models (bundled prices for the whole care cycle). | National Health System Interterritorial Council (Consejo Interterritorial del Sistema Nacional de Salud - CISNS); Regional Government/Hospitals National HTA agency (Instituto de Salud Carlos III - ISCIII) and seven regional HTA organisations |
| Consider AI as another health product, and clearly define the reimbursement process. | Health authorities; Government; AEMPS; GuíaSalud |
| Incorporate organisational and budget changes to facilitate the incorporation of new innovative technologies. | Regional Government/Hospitals |

# 5. Strengthening data quality, governance, security and interoperability

### Challenges and barriers: What is not working/what needs to change in this domain?

Below is a breakdown of all the challenges Round Table participants considered were associated with this domain, particularly in relation to data ownership and accountability.

**Data and its governance**

AI cannot extract everything; it is fed by structured or classified information through metadata. Currently, the scope in Spain is quite limited. The alternative of anonymising data was not considered as a valid solution. With the enormous amount of data processed by the healthcare system (although still in a disaggregated way), people are still identifiable (it was noted that an IP address and a cookie are also personal data). In the future, we should talk in terms of pseudonymisation or encrypting of data in the interest of what is known as 'differential privacy'. The importance of advancing in citizen data governance has been highlighted in previous sections of this report, although logically the control and management mechanisms will be determined by the professionals.

**Interoperable shared space**

As mentioned previously, the Digital Europe Programme is underway but Spain needs to establish its own top-down approach. Systems must be able to connect, based on an interoperability standard that identifies them as reliable and enables them to share. Interoperability is more than

just connectivity: it represents an agreement on the registration and coding systems to standardise the interpretation of the data. Application of the European Interoperability Framework (EIF) would be beneficial here.

Gathering data and using data should be differentiated, as what predominates in AI applied to the healthcare sector are the use and final objective, and the consequences of a data leak or security breach in the health sector are irreparable.

### What is working well and best practices identified in this domain

**Existing successful projects and positive experiences**

> National datasets already exist, for example for organ transplantation (as mentioned above), the Spanish National Health Survey, and the Cancer Observatory.

> In Europe, the European Innovation Partnership on Active and Healthy Ageing is an initiative that should be highlighted. Data have been regulated to the fullest extent based on the principle of free movement of people.

**Best practice examples**

> The European Commission has adopted a Recommendation on a European Electronic Health Record (EHR) exchange format. This will allow secure sharing of EHR between Member States.

> The Connecting Europe Facility (CEF) has created a dataset with the aim of codifying it in a common standard.

### Key Points

> Europe is increasingly consolidating a common health data space. The aim is to create an ecosystem without barriers, with the patient empowered (data sovereignty) and infrastructures that enable this.

> A mechanism is needed for aggregating data from very diverse sources. It is likely that data will have to be made uniform, by mandate or through an agreement with the authorities of member countries, marking the minimum common fields and moving towards microservices and Application Programming Interfaced open markets.

### Proposed actions and recommendations

> Carry out periodic audits, with the required frequency, to verify that data meets the four essential characteristics: findable, accessible, interoperable and reusable (FAIR).

| Strengthening data quality, governance, security and interoperability | |
|---|---|
| **Action** | **Target Stakeholder(s)** |
| Standardise medical records at source. | Commitment of the interterritorial body of the Ministry and Departments of Health |
| Promote HL7-FHIR (Fast Healthcare Interoperability Resources)-type standards and encourage their implementation. | Autonomous communities and private suppliers |
| Distribute funds for development of data exchange mechanisms. | European Union |
| Make the clinical database for primary care interoperable. | Commitment of the interterritorial body of the Ministry and Departments of Health |
| Make a commitment to the citizen health file with services of value to citizens to promote adoption by the majority | Government; autonomous communities and private suppliers |

# 6. Liability and managing risk

## Challenges and barriers: What is not working/what needs to change in this domain?

### Obligation to make AI-based decisions

An AI system must be given the appropriate legal context. Whether it is obligatory to make decisions based on the information generated by AI systems needs to be defined. According to the code of medical ethics, 'no harm' must be done to patients. In the context of AI applications, it is therefore important to think about the impact of *not* using an algorithm: for example, what would happen if the system denies care to a citizen based on their medical insurance? It is also important that the principles of accountability and transparency are not forgotten.

### The key to success

The key is to successful AI implementation in healthcare is confidence, to the extent that only a system that generates confidence will end up being regulated and adopted.

It has been suggested that liability for an algorithm should be the responsibility its developer and/or the manufacturer of the technical equipment. However, as mentioned previously, AI does not replace humans, and humans will always be behind all decisions that affect the patient – the algorithm recommends, and the professional decides.

Cognitive computing establishes correlations with information that is totally unknown to the programmer once the algorithm advances on its own, so work needs to be done on the concept of building in 'safety by design' and 'ethics by design' to AI applications. The audits mentioned earlier will contribute to the management of risk as they represent a control and periodic monitoring of validity and clinical effectiveness of algorithms.

## What is working well and best practices identified in this domain

### Existing successful projects and positive experiences

> As in clinical leadership, it is important to promote synergies with technology industries that have experience with managing interoperability in order to take advantage of the fast pace of learning and implementation of technical solutions.

### Best practice examples

> It should be assumed that all technology entails an aspect of risk and that this risk is minimised by building confidence. The problem of possible algorithmic bias is important here as it can have an influence on the integration of AI. To ensure this is monitored, regular follow-up mechanisms should be implemented in real-world settings, similar to undertaking regular alcohol tests for target populations.

## Key Points

> Legislation must come from the European Union that establishes a risk threshold that policymakers can implement nationally. A national body or role could be established that would serve as a link for each autonomous community.

### Proposed actions and recommendations

> Two concepts are critical: the management of transparency and the explainability of the algorithm.

| Liability and managing risk | |
|---|---|
| **Action** | **Target Stakeholder(s)** |
| Implement a CE mark as for medical devices | European Union |
| Evaluate data and distribution of responsibilities | Regional evaluation agencies |
| Promote safety by design and ethics by design in the development of AI applications | External audits |

# Session V: Driving acceptance and utility of AI in healthcare

Structural changes are needed across the healthcare system so that the digitisation of healthcare does not proceed before problems and bad habits within the system are eliminated. A national plan for digital transformation is required that is agreed with all the autonomous communities: a National Agreement for Digitisation of Healthcare. A shared vision and path are required to direct these efforts.

Speed is a determining factor in the type of measures that are taken and how they are prioritised: the Spanish health system is under pressure due to population ageing and will suffer the consequences in the coming years. AI is an essential tool to help face this challenge.

After decades of reflection and advances towards digital innovation, concepts such as machine learning, deep learning, business intelligence, big data, open source, and acronyms such as ICT and DIH are commonplace. However, the level of penetration is still far from ideal. Therefore, in in Spain and other EU Member States, a call to action is necessary, to start a deep-rooted movement (more doers, fewer planners).

To speed up the integration of innovation of this calibre, health workers need a minimum level of literacy and clear guidelines.

It would help working professionals to have basic skills and tools, and to facilitate 'test bank' projects with controlled risk. For trainee health professionals, interdisciplinarity in digital competences becomes essential. In both cases, the idea is to promote a flexible, multidisciplinary learning environment in which health professionals are supported by IT experts and specialists in data analysis. In the near future it is likely that we will see the incorporation of new hybrid roles, for example experts in data management and analysis.

At the level of regulation, we should not forget human rights, or the social value of data focused on the common good.

Regarding funding, a suggested approach is to design assessment that can calculate reimbursement based on clinical effectiveness, and implement payment based on final benefit. This investment concept is very different to the traditional model.

In terms of the raw material of AI, the data, consensus is lacking on centralisation and regulation of access, as the idea is not to accumulate data but to use it, possibly through licencing for a specific period and use. Ethics and control audits also come into play in this setting.

It would be valuable to create a government department that facilitates the construction of AI tools, or a health council comprised of various institutions to define priorities, as well as a regional interlocuter in the case of Spain, to roll out initiatives. The starting point of the process could be something basic, such as algorithms to prioritise appointments in primary care or support tools for the indication of diagnostic tests. The next step could be more complex interventions such as personalised medicine supported by genomic data.

As we progress, it will be crucial to promote public–private collaboration for the exchange of ideas and good practices (collaboration between industry and the healthcare system), and it is worth

taking advantage of the common data space that to collate these ideas and scale-up to a European level.

One proposal is to establish the groundwork in schools, teaching citizens that everyone is the owner of their body and learning to understand and listen to it. This would sow the seed of citizen empowerment, which would lead to radical changes after a few decades.

In summary, AI is a means to an end, and it requires joint leadership, and strong, clear positioning by the authorities regarding regulation, ethics and investment (with political backing), as well as a solid, bottom-up approach. Only by doing this will AI be established as a social asset defined for the final benefit of the patient, which is the focus of all medical practice.

# Appendix 1: Round Table Meeting participants

EIT Health would like to thank the following participants for their input in the Round Table Meeting:

| Name | Organisation |
|---|---|
| **Esther Paniagua (Moderator)** | Journalist |
| **Alberto Estirado** | CIO, HM Hospitales |
| **Carolina García-Vidal** | Hospital Clínic – IDIBAPS |
| **Cristian Marti** | CSO and Founder, Methinks AI |
| **Daniel Alonso** | Artificial Intelligence & Big Data Partnerships Driver / EUHubs4Data coordinator, Technological Institute of Valencia (ITI) |
| **Itziar de Lecuona** | Associate Professor, University of Barcelona/Hospital Clínic |
| **Javier Quiles del Río** | Head of IT Department, SERGAS – Servizo Galego de Saúde |
| **Jesús Carrillo** | SAS – Regional Government of Andalusia |
| **Juan Fernández Ortega** | Director & Consulting Services Executive, Global, Cerner Corporation |
| **Julián Isla Gomez** | Chairman, Foundation 29<br>Data and AI Resource Manager, Microsoft<br>Committee Member, EMA |
| **Julio Lorca** | E-Health Development Director, DKV Seguros |
| **Marc Torrent Moreno** | Director, Eurecat - CIDAI |
| **Paloma Cabello** | Partner, Calligram |
| **Organisers and other attendees** | |
| **Cristina Bescos** | Managing Director, EIT Health Spain |
| **Laia Cendrós** | Communications Lead, EIT Health Spain |
| **Mara Belluco** | Event and Engagement Officer, EIT Health Spain |
| **Mayra Marin** | Think Tank Manager, EIT Health e.V. |
| **Sameena Conning** | Director of External Affairs, EIT Health e.V. |