Healthcare Workforce and Organisational Transformation with AI – Enacting Change

Think Tank Round Table Meeting Proceedings

France

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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: French Round Table

Hosted by EIT Health France.

Moderated by: Stéphanie Trang and Damien Gromier from AI For Health.

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 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. Individual feedback was not reviewed but the questions were used to stimulate discussion at the meeting. At the start of the meeting, all participants were asked: describe in one word what AI means. The following answers were received:

- Decision support
- Help
- Opportunity
- An accelerator
- The future
- Complementary
- Added value
- A solution
- A promise

In February 2019, a report was submitted to the French Senate by the deputy, Cédric Villani, and the senator, Gérard Longuet, regarding the main priorities that should be addressed by a national strategy of AI applied to health data. The main conclusions were as follows (extracted from the full report):

- The hearing highlighted the potential links between the future Health Data Platform and the digital health space, both provided for by the bill under consideration, and populating the platform (Hub) with pseudonymised patients' personal health data. In this regard, the patient representative emphasised how late France was.
- Furthermore, the proper use of data depends firstly all on the quality of data collection, the individual's trust in the system, and in particular the guarantee that access to data will be protected. This must remain entirely under the control of the public authorities, with an important role devolved to the CNIL (Commission Nationale de l'informatique et des Libertés, the French administrative regulatory body responsible for ensuring that data privacy law is applied to the collection, storage, and use of personal data).
- In addition, reforms to the financing of the health protection could constitute an opportunity to accentuate the qualitative dimension of the care, which will imply a requirement for quality of the recorded data (1 (*)).
- Regarding personal information, the compliance director at the CNIL proposed that the Health Data Platform make it their mission to better inform citizens, which was agreed by the Social Affairs Committee.

There are multiple challenges in meeting these objectives

- Firstly, there are technical challenges, as without a system that works well, nothing will happen. France has a heritage of medico-administrative information systems with the national health insurance database, SNIIRAM (système national d'information interrégimes de l'Assurance Maladie), but its infrastructure is aging. The interoperability of information systems is an essential factor. The permitted, if not compulsory, use of the social security number (INS (2 (*))) is a major element in this regard.
- There are also financial issues. The cost of the National Health Data System (SNDS), regardless of its expansion with the new Health Data Platform, has been estimated at several tens of millions of Euros, covering both the infrastructure and its maintenance. This follows a legacy of underinvestment in France.
- More generally, there is a need for skilled human resources. We find ourselves in a 'global digital shift', with a skills gap for technology professionals and a need for a cultural change in those whose professions it is set to transform.
- In terms of organisation, several participants queried the choice in the bill of the legal status of public interest grouping (GIP) for the Health Data Hub. The Department of Research, Studies, Evaluation and Statistics (DREES) recalled that the Minister of Solidarity and Health, Ms. Agnès Buzyn, had favoured this formula to guarantee citizens that the public status would predominate in this structure and that the State would be the guarantor of protection and management of health data.
- The public interest group the National Institute of Health Data (INDS) currently comprises the State, organisations that ensure representation of patients and users of the health system, producers of health data and public and private users of health data, including health research organisations.
- Referring to the GIP-CPS (professional health card), the GIP-DMP (personal medical file) or even the GIP ASIP-Santé, for which she was part of the constitution, Jeanne Bossi-Malafosse underlined that it was necessary to create a GIP to manage specific topics each time, although it was recognised that this form of governance entails complexity and delays in implementation.
- A consensus emerged among stakeholders, researchers, start-ups, lawyers and representatives of the administration, noting that an agile structure and governance were critical factors for the success of the Health Data Platform, which Article 11 of the bill proposes to create to succeed the INDS. It is certain that the large number of actors represented in the governance of GIPs constitutes a source of recurring roadblocks that it is imperative to avoid when developing the future Health Data Platform.

The purpose of the Round Table meeting in France was to identify both the measures already in force in France relating to the implementation of AI in the healthcare system, existing AI initiatives, and also to collect the point of view of decision-makers, funders, and stakeholders on the strategy to be implemented to facilitate the deployment and facilitate the adoption of AI in healthcare on a large scale in France and in the EU.

The meeting also aimed to identify the possibilities for collaboration between France and other European Member States with the prospect of creating synergies for a scaling up. The objective

was also to draw lessons from what is being undertaken in other European Member States that could be deployed in France to accelerate the large-scale deployment of AI.

Discussion of outcomes

The Round Table meeting highlighted the importance of acting at local, regional, national, or European level depending on the complexity of the subject being addressed.

1. **At healthcare organisation level**
   - The creation of departments or functions within hospitals dedicated to data processing.
   - Plan the creation of open desks dedicated to AI innovation with champions and ambassadors who could be made available to project teams working on AI.
   - Recruitment of new profiles dedicated to the processing of health data.
2. **At regional level**
   - Explore the possibility of pooling resources at a regional level, including IT resources to manage data storage, processing, aggregation, and centralisation in an interoperable manner.
   - Set up joint research units to encourage collaboration with clinicians from the start of AI projects. These teams could be located on university campuses or in start-up incubators.
   - It is important to encourage project leaders developing AI solutions to integrate the challenges of the health system from the outset through local public funding and based on practices in terms of security, interoperability, and data usage.
3. **At a national level**
   - It is important to encourage vocations very early on by promoting IT and data skills in the medical career path but also to attract talent from IT careers in the health sector.
   - More training on AI issues must be integrated into university courses for doctors. Conversely, it is important to familiarise data scientists with clinical questions.
   - Medico-economic evaluations should consider not only the medical benefit but also productivity gains of AI for healthcare organisations.
   - Support the development of data access platforms for start-ups.
4. **At European level**
   - Encourage data infrastructure initiatives such as Gaia X for a sovereign cloud, based on membership and not on coercion.
   - We should use the principles of the General Data Protection Regulation (GDPR) to create trust among citizens regarding the sharing of their health data within the framework of the European health data space.
   - Dialogue with the regulatory agencies for medicines and MedTech must be encouraged to understand the existing evaluation and validation mechanisms and adapt them for AI solutions.

- Create guidelines at the European level on good manufacturing practices for AI solutions using good norms and good standards guaranteeing good security and quality of health data.
- Similarly, it would be interesting to define frameworks and practices for the use of AI for pathology as well as the correspondence of terminology between European languages to facilitate semantic AI.

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?

Create multidisciplinary and transverse teams in hospitals

To ensure effective clinical leadership in terms of AI, multidisciplinary teams need to be created, based on mutual understanding. Doctors, data scientists, and CEOs of start-ups should no longer work in silos, but understand each other and work together for the same goal. The integration of open desks in open offices could support transverse collaboration on AI projects from the design phase.

Solutions using AI are designed to address issues that physicians encounter in their practices. Spaces dedicated to interactions between doctors, data scientists and patients could encourage the development of use cases that would bring added value to medical practices and improve the quality of life of patients, thus strengthening the entire ecosystem.

It is essential to ensure these centralised teams remain connected to centres of expertise, centres of excellence, services and laboratories in order to maintain contact with the field. Creating a critical mass, a viable infrastructure and a hybrid structure will allow teams to maintain their connection and commitment to services. Regulatory skills and know-how must also be integrated to catalyse the development of solutions.

Narrow the gap between clinical value of data and commercial ambition

Data – both from research and clinical settings – must be collected continuously, to improve the researcher–clinician–patient relationship and ensure transverse application. Research data should be viewed as having the same value as clinical data.

Access to sufficiently large databases outside the public domain is vital, to refine the accuracy of algorithms. Data interoperability, including informed consent, must be at the heart of the development and application of AI.

Successful AI projects – as seen in the UK, Sweden and Germany – arise from partnerships between clinical and hospital IT teams, where data storage, management, aggregation and integration are starting to be controlled and centralised, thereby minimising fragmentation. Internal communication between research teams and the creators of AI tools remains a major challenge. To ensure multidisciplinary working, bridges must be built between doctors, data scientists and developers to streamline the integration of AI into clinical teams.

The inclusion of clinical teams in AI project development will provide them with the opportunity to take scientific leadership by providing anonymised and easy-to-access open-source packages, performing simple tests with the technology team, and performing experiments with the first

sets of tests. Ultimately, they will be able to partner with institutions and engineers to create the final tool. Processing power should be centralised – the creation of a data processing function and department in the healthcare organisations is essential – because it is currently too dispersed in hospitals.

What is working well and best practices identified in this domain

Existing successful projects and positive experiences – Cross-links in research

- Collaboration with the AP-HP (CHU Ile de France) or in mixed research units is essential to discuss not only data from the clinic and the clinician–patient link, but also clinical research data – such collaborations have been seen to emerge since the COVID-19 pandemic.
- In California, from an early stage of in training, they bring together people who are likely to collaborate on a project, putting engineers, entrepreneurs, and young people in the same room as university doctors.

Best practice examples – Open Desks

- At the Institut Pasteur, one of the first initiatives was to create an 'open desk' policy, with designated places where researchers and doctors could interact with new experts recruited internally and collaborate around issues and problems that needed to be solved.
- When Owkin developed partnerships with the AP-HP and other institutions, places were created where people with different types of expertise, medical or data science, could meet.

Key Points

- Involve Key Opinion Leaders (KOLs) willing to free up their time and network to work upstream on AI-related projects.
- Financially incentivise KOLs and to obtain support from their employer to advance projects and scientific development.
- Ensure the proper use of Clinical Research and Data in a translational way and support collaboration of the Directory of the Information, Directory of Clinical Research and Innovation with clinicians.
- Develop an open innovation laboratory in each health facility and address the organisational challenges of bringing data set closer to the 'computing business' functions in hospitals.
- Build incubating multidisciplinary teams from the design phase and offer supporting open desks to AI projects teams.
- Integrate physicians/clinicians and representatives of patient/citizen associations into creating an AI solution at the earliest possible stage.
- Encourage data sharing from the initial stage of AI project development.

Proposed actions and recommendations

Clinical leadership	
Actions	**Target Stakeholder(s)**
Involve Key Opinion Leaders (KOLs) as 'AI Champions', who can devote their time and network in order to work upstream on AI-related projects.	Ministry of Health; Healthcare organisations; Fédération Hospitalière de France (FHF)
Provide financial incentives to clinicians and acquire support from their employers, by adjusting their working hours, for example, to advance projects and scientific development.	CHU, Centres Hospitalo-universitaires; Agences Régionales de santé
Establish an open innovation laboratory in each health facility and address the organizational challenges of bringing data sets closer to the "computing business" functions in hospitals.	Healthcare organisations; AP-HP
Integrate physicians/clinicians and representatives of patient/citizen associations into creating an AI solution in a timely and efficient manner.	Ministry of Health; France Assos santé; patient associations
Ensure appropriate use of data between Clinical, Research and Data &IT teams in a translational way and to support the collaboration of the Directory of the Information, Directory of Clinical Research and Innovation with clinicians.	Clinical Training Programmes; academics; Health Data Hub; Fédération Hospitalière de France (FHF)
Build incubating, multidisciplinary teams from the design phase and offer supporting open desks to AI project teams.	Fédération Hospitalière de France (FHF)
Encourage data sharing from the initial stage of AI project development.	Ministry of Health; academia; Ministry of Higher Education, Research & Innovation

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?

Rethink education and skills to invest in new roles and talents.

Physicians should be given the opportunity to work hand-in-hand with data science and AI experts. Many young doctors seek training in data science and AI to ensure that they are on the cutting edge but currently do not have enough access to innovation.

It is necessary to raise awareness of the training opportunities available and to clarify the possible courses choices that integrate the challenges of innovation and data for young doctors and young health professionals. In the future, institutions will need to recruit a critical mass of these new profiles. However, in order to promote and participate in the development of skills and the culture of AI, whether it is data scientists or engineers, requires a cultural change.

More recognition of these topics is also needed, especially from medical school Professors who should encourage rather than question a student's choice to do a Masters' in Data Science. The idea that a subject like data science 'is not really medicine' needs to be rectified. It is also essential to train mature doctors and to integrate these digital tools into their lifelong education.

One option for the training of young doctors, for example, could be the possibility of undertaking a gap year via an experience in an AI start-up.

Generate vocations

It will be valuable to offer dual-degree PhD training in medical informatics and biostatistics and to create PUPH (Professor of University-Hospital Practitioners) academic roles in biostatistics-medical informatics and AI. However, the background necessary to understand AI subjects is not a science reserved for the professional elite. This barrier of access must be as low as possible. Profiles of good data scientists are those who have additional skills.

It is really important for students have a basic foundation and a broad vision of what we can do with AI. These concepts should be introduced from the second year of medicine, pharmacy or health studies as this is the point where vocations are decided.

It is also necessary to educate regulatory authorities about AI and train them because any application of AI intended for use in everyday practice will inevitably come before them for assessment (HAS, CNAM, CEPS, EMA, ANSM).

Train data scientists to understand clinical issues

Data scientists should be encouraged to work with medical students daily. Data scientists should be welcomed into the healthcare sector where they too can put their skills to use for a good cause. They should have the opportunity to use practical skills in real contexts to truly understand the data.

Industry professionals are ready to participate in more training. Classes should be varied and include a diverse range of participants to ensure awareness, ownership and the necessary cultural change.

Clinical application is essential. There needs to be a move from technological proof to clinical proof of AI and a move from experimentation to actual use.

It is important to be vigilant with the cliché of the 'geek doctor' and be very careful not to categorise the clinicians and health professionals who are interested in these projects. Diversity and inclusion matter – including and attracting students of different genders, ethnicities, and socio-economic groups.

Combine technical skills with critical thinking and analytical capabilities

A training framework more general than just AI is essential. It is time to take a step back from technologies in general and a focus on particular medical disciplines, such as radiology. Beyond the toolbox, critical thinking and tangible application of technology are prerequisites for today's emerging medical professionals.

This means creating a culture for physicians that goes beyond just knowing and using IT tools. Training for physicians in statistics is more important than any line of code; it is the doctor's first tool. It is essential to maintain the balance between the medico–technical relationship and the doctor–patient relationship.

What is working well and best practices identified in this domain

Existing successful projects and positive experiences

- In large medical centres, there are often one or two people who emerge as 'AI champions', people from the medical profession who are enthusiastic about AI and who have often worked closely with the data scientists at their institution. These ambassadors can provide training to their teams independently and directly.
- Internal retraining programs for those who want to train in techniques related to AI or data could be offered. Over four months, one day a week, it would then be possible to discover and understand one of these themes.

Best practice examples

- The Institut Pasteur has created a computer centre to prevent laboratories from doing research without subsequently developing publications.
- The NVIDIA Deep Learning Institute (DLI) offers a comprehensive programme of hands-on training in AI, accelerated computing, and accelerated data science. Using the power of GPUs in the cloud, developers, engineers, researchers and students can acquire solid practical knowledge and receive a certificate of competence attesting to their professional development.

Key Points

- Strengthen dual PhD courses in medical computer science/bio-statistics/AI/soft skills and offer reverse mentoring programmes for University Deans.
- Create university positions of Professor of University-Hospital Practitioners in bio-statistics-medical computing and AI.
- To develop in-house training programmes delivered by an 'AI champion' who could 'evangelise' the rest of the healthcare institution.

- Cultivate positive attitude towards AI early on by demystifying AI amongst young talent.
- Promote a 'gap year' or 'validation of the acquired knowledge by experience' in AI start-ups within a curriculum.
- Plan pan-European inter-university courses and support soft skills development within these courses.

Proposed actions and recommendations

Education and skills	
Strengthen dual PhD courses in medical computer science/biostatistics/AI/soft skills and reverse mentoring programmes for University Deans with junior referrals to advance curricula.	Universities; Ministry of Higher Education; innovation and research
Create university positions for PUPH (Professor of University-Hospital Practitioners) bio-statistics-medical computing and professors specialising in AI medical solutions.	Universities; Ministry of Higher Education; innovation and research
Develop in-house training programmes delivered by AI Champions who could 'evangelise' the rest of the institution.	Hospitals
Cultivate a positive attitude towards AI early on by demystifying AI amongst young talent.	Universities
Promote a 'gap year' or a year of 'validation of the acquired knowledge by experience' in AI start-ups within curricula.	Ministry of Health; Universities
Develop pan-European inter-university courses and support soft skills development within these courses.	Universities

3. Regulation and policy making

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

AI solutions should not be assessed differently

Why should different endpoints be used compared with other medical solutions just because a device has an AI component? One of the major challenges is to stop seeing AI as a separate technology, but rather as a healthcare tool like other health technologies. AI needs to undergo clinical and pharmacoeconomic evaluation based on scientific evidence. Therefore, the same criteria must be applied as with other health technologies, namely the clinical benefit/risk ratio based on studies of efficacy and safety.

The standards that have long been applied to drugs or medical devices could be applied to AI. AI-based technology should be considered like any other technology, so it will need to undergo assessment based on data from controlled, randomised trials or pharmacoeconomic criteria, etc.

Depending on the field (radiology, oncology, endocrinology) assessment should be based on clinical studies and use mortality as the primary endpoint. In medical imaging for example, the codes available for post-processing, the possibility for advanced visualisation etc., result in improved productivity and therefore save time at a lower cost. This gain could be subject to an 'incentive' refund.

Using the drug model, a single indicator could be proposed, the relative functional index (IFR): This could use a comparative indicator (so, comparison of practice without AI and/or with the best available algorithm), rating it with respect to the chosen comparator and based on reasoning from scientific evidence of the algorithm, improved clinical efficacy for patient management, clinical utility, and efficacy in the 'real world' setting, resulting in a form of quantification.

Evaluate the real-life impact of AI

Regarding these aspects of clinical evaluation, as for medical devices, it should be possible to demonstrate the actual benefit according to a reference methodology in clinical trials, with a high level of evidence, or even pharmacoeconomic evaluations.

It is also extremely important to continue the 'real life' evaluation of these medical devices outside of clinical studies, through the gradual implementation of health data warehouses which could also potentially support CE marking.

In addition, the correct and appropriate use of medical products a setting where AI could make a big difference for example, to prevent the inappropriate use of antibiotics.

Think beyond proof of concept

Proof of concept of an AI application is not sufficient; it is necessary to think about scalability and deployment within a health system from the very first stage. Without a clear idea of the large-scale market right from the start, it will not be possible to develop an MVP (minimum viable product) with sufficient access to data, interoperability with other tools, and an ability to integrate into health centres. This requires more local funding. Importantly, AI should be considered from the perspective of of productivity gains and/or impact on patient journeys.

Work at the local level

It is extremely important to work locally because within each health system, patient journeys are different. The costs associated with these different stages also vary. This will require each territory to calculate the value that AI brings, not at individual timepoints, but across the entire patient journey.

Looking at AI as a gain in productivity and as a gain in quality and standardisation, goes beyond clinical benefit. Consider the cost over the entire patient journey, taking the example of stroke, to reduce costs by detecting risks very early. Business impact models have been developed for drugs and medical devices.

Develop risk-sharing models that consider the patient journey

A significant financial investment is needed to generate a high level of clinical evidence required to support the adoption of drug or medical device. This evidence must be relevant, statistically significant, demonstrate that the device works well technically, but also whether it provides added value, which is not something that is always measurable in the patient in the immediate short-term.

The question of the continuous evolution of AI applications also arises. A 'Temporary Authorization for Use' (ATU) presents a difficulty in terms of risk relating to AI solutions as the developers feel they are taking all the risks on their own. ATU is well known concept for medicines: ATU can be grated for drugs which are in Phase III clinical development, for example, but which have not yet been granted marketing authorisation. It has shown positive results and could provide access to solutions based on the evolving AI but using an approach closer to the regulatory frameworks of Phase IV clinical trials and post-authorisation evaluation of medical devices to allow the continuous improvement of simulations in a controlled framework.

What is working well and best practices identified in this domain

Existing successful projects and positive experiences

- Provide start-ups with clinical knowledge. In start-ups there is currently a lack of understanding about medical devices, medical research, clinical trials, and the impact on patients.
- Accelerate pilot initiatives. Internal initiatives are faster when integrated with other systems such as CIR, but are often delayed by one year, hence the interest in a fast-track option. Hospitals taking equity in exchange for undertaking pilot studies and evaluations lacks adequate controls and the investment can become complicated.
- Several grant initiatives in France can help speed up evaluation projects in the pilot phase without requiring a full consortium to be established.
- There are also initiatives that provide entrepreneurs and start-ups in the healthcare industry with a one-stop-shop platform to discuss and resolve reimbursement issues. Reimbursement initiatives that calculate patient journey savings are also in place in the United States.
- Landmark digital health law in Germany provides temporary market access and helps catalyse assessment and negotiate realistic reimbursement rates.

Best practice examples

- innovep-xp is a 'borderless' grant that finances evaluation work. On the Ile-de-France plateau, there is innovep-xp, a subsidy of BPI, at a regional level, which allows 50% funding for the entire evaluation work from the moment there is a technological project. It has two or three hospital centres which act as experimental pilot centres, as well as evaluators.
- Grenoble-Alpes University has a technological innovation dimension that supports the development of start-ups. They aim to provide support, assist with technological development, provide advice to help understand the world of health and how to go through the different stages, and introduce concepts, especially with the new European regulation.

Key Points

- Propose some kind of 'Temporary Authorisation for Use' for evolving AIs in a regulatory framework similar to Phase IV trials or post-registration evaluations of medical devices, and review algorithms versus the guidelines from various experts.

- Allow continuous improvement of AI in a controlled 'post-market' framework to avoid the risk of AI drift: promote the idea of a regulatory innovation sandboxes (reference: Villani report on AI).
- What is AI from a regulatory point of view? Confirm what level of evidence and evaluation methods are required to demonstrate the effectiveness and safety of an AI solution based on scientific evidence.
- Define a regulatory framework for AI-based solutions and guidelines at a European level by pathological field/therapy area, considering clinical practices and ethical issues of professional colleges and/or learned societies.
- Define the clinical evidence to be provided according to the principles of randomised clinical trials and without automatically applying the drug or medical device framework (EMA: Medical Service Rendering, impact on the organisation of care and on practices, risk/benefit ratio; reimbursement; added value).

Proposed actions and recommendations

Regulation and policy making	
Action	**Target Stakeholder(s)**
Propose some kind of 'Temporary Authorization for Use for evolutive AI in a regulatory framework for Phase IV trials or post-registration evaluations of medical devices and to conduct a review of various results of algorithms versus guidelines.	Haute autorité de santé; Comité d'évaluation des Produits de santé; EMA; Ministry of Health
Define a regulatory framework on AI solutions and guidelines at a European level by pathological field, which takes into account the clinical practices and ethical issues of professional colleges and/or learned societies and allows the continuous improvement of AI in a controlled 'post-market' framework in order to avoid the risk of AI drift.	Haute autorité de santé; Comité d'évaluation des Produits de santé; EMA; Ministry of Health
Promote the idea of a regulatory sandboxes for innovation (see Villani report on AI).	Haute autorité de santé; Comité d'évaluation des Produits de santé; EMA; Ministry of Health; Regional Agency For Health
Define what AI is from a regulatory point of view, and what level of evidence and evaluation methods are required to demonstrate the efficacy and safety of an AI solution based on the scientific evidence of science.	Haute autorité de santé; Comité d'évaluation des Produits de santé; EMA; Ministry of Health; Regional Agency For Health; professional societies
Define a set of clinical evidence to be provided in advance using the principle of randomised clinical trials and not automatically applying the framework for drugs or medical devices (EMA: Medical Service Rendering, impact on the organisation of care and on practices, risk/benefit ratio; reimbursement; added value).	Haute autorité de santé; Comité d'évaluation des Produits de santé; EMA; Ministry of Health; Regional Agency For Health; professional societies

4. Funding and reimbursement

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

Public funding

Early-stage projects must be publicly funded (collaborative projects), however, it is proposed to restrict allocation of funding to projects that adhere to strict governance and data sharing principles. Other suggested solutions include associating upstream funders with pilot AI testing centres to evaluate real-life AI solutions and accelerate their development.

Reallocate public funding

Public authorities must be involved because it is not a problem of resources but of resource allocation. This cannot be carried by the private sector without generating a risk that is too high.

Involve the state and take advantage of existing legislation

Change is occurring in hospital market access, and therefore the State's commitment. What is realistic at the present time, at the level of remuneration for the technology itself, is based on the existing reimbursement codes. If the reduction or improvement of a parameter significantly improves clinical benefit, the current legislation already says that it is eligible for reimbursement.

Promote the added value AI can bring to healthcare organisations

Beyond pharmacoeconomic arguments, what interests organisations to implement AI solutions is the extent to which the tool will be reimbursed for the technology itself or its use.

The assessment must also include the impact on the organisation and internal process change and/or the business impact and on clinical practices. In these evaluations, it will be necessary to determine the organisational and structural value proposition for the hospital. In the case of administrative, medical or paramedical time savings, this must allow reallocation of resources to other places.

For many of the tools evaluated, there is a strong aspect of security which makes it possible to create legal structures. From a financial perspective, the question that will need to be answered is of procedures within the hospital will cost less if something is optimised with an AI tool. This need to be assessed and provided as evidence alongside the classical clinical and pharmacoeconomic aspects for reimbursement. The medical community and decision-makers will look at both the clinical benefit and the organisation's best interests.

What is working well and best practices identified in this domain

Existing successful projects and positive experiences

> G-nuis is a unique support platform with privileged access developed by the Ministry of Health, in this case the DSIS (Directorate of Health Information Systems). G-nius is only advisory, an aid to understanding or recommendations. The objective of this initiative is to provide entrepreneurs and health start-ups with a unique platform with privileged access, to the NSM, the CNAM, etc., to discuss queries on the reimbursement phase.

Best practice examples

> In France, the CIR aims to improve business innovation and competitiveness. Thanks to this tax credit, companies that incur research and development expenses can be partially reimbursed for these expenses.

Key Points

> Early-stage projects should be publicly funded (collaborative projects), however it is proposed to restrict allocation of funding to projects that adhere to strict governance and data sharing principles.

> Other solutions would be to associate upstream funders with pilot AI testing centres to evaluate real-life AI solutions and accelerate their development.

> Develop models for quantifying the costs/resources consumed at each step of patient care and prospectively measure the impact of the AI solution on previous processes and demonstrate the savings generated.

> As per the new German approach, set up a 'fast track' process for health and digital AI app/solutions allowing entry to the market after 12 months of testing in order to integrate the list of validated solutions with a negotiated refund price 'risk sharing'.

> Plan to reimburse AI solutions that allow better management of a pathology and/or avoid misuse, for example: the misuse of antibiotics is a topic where AI could make a lot of improvements.

Proposed actions and recommendations

Funding and reimbursement	
Actions	**Target Stakeholder(s)**
Develop models for quantifying the costs/resources consumed at each step of patient care and prospectively measure the impact of the AI solution on previous processes, while demonstrating the savings generated.	Sécurité Sociale; fédération hospitalière de France; Ministry of Health
Devise plan to reimburse AI solutions that allow better management of a pathology and/or avoid misuse.	Sécurité Sociale; fédération hospitalière de France; Ministry of Health
Ensure public funding of early-stage projects (collaborative projects), but restrict allocation of funding to projects that adhere to strict governance and data sharing principles.	Agence Régionale de santé; Conseil Régional; Ministry of Health
As per the new German approach, set up a 'fast track' process for health and digital AI app/solutions allowing entry to the market after 12 months of testing in order to integrate the list of validated solutions with a negotiated refund price 'risk sharing'.	Ministry of Health; Sécurité sociale

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

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

Underdeveloped interoperability

France has high-quality medical data sets, but currently lacks the statistical power of the United States. Access to sufficient statistical power and a large shareable dataset is essential to cross certain thresholds. French research institutes always keep their data locally and have ad hoc data hosting systems. However, the interoperability of these systems is essential if we want to use this data to develop AI.

The integration of an open innovation laboratory in each hospital centre or translational institute could guarantee access to a critical mass of data and allow the development of computing capacities by 2030. Benchmarking systems could help to facilitate a secure shared data set.

Today there are supercomputers in France but these still need to be connected to large data sets. The distributed computation could then be done in a distributed fashion. There are several avenues to explore, but the costs can be prohibitive. Opening – while anonymising – data is a major challenge. It is essential for multidisciplinary teams to test their algorithms in other datasets and possibly to aggregate these results. Until then, it remains complex to combine real health data, processing power, efficient algorithms, and real expertise to deliver concrete, out-of-the-box solutions.

Ensure an accurate and verified transfer of datasets

It is recognised that there has been an explosion in the volume of health data in recent years however in order to have a meaningful dataset to work with, data quality and integrity need to be considered. Semantic databases evolve, grow, and are enriched and reworked. The concept of interoperability is also important to allow data transfer and avoid avoid ending up with 'siloed' datasets that are outdate, unrepresentative and therefore no longer valid.

Building up verified and translated anthological databases based on clinical practices, established with doctors, close to their practices and with technicians is also critical, as well as not duplicating the data repeatedly.

Moving from principles to commitment

It needs to be understood that that at the current level of public funding and investment, there are several restrictions on the use and reuse of data, the creation of DNS servers that are interoperable, and developing the technical framework for use.

Fund hospitals first to incentivise them

Hospitals need public funding to build interoperability and to profit from this interoperability. France alone is not sufficient to encourage the relevant actors. Philips Healthcare and the Madrid Hospital as well as several European health authorities have joined the initiative. This funding will be realised via Horizon Europe and recovery plans.

Create a single-entry point for researchers

The Health Data Hub aims to federate the data ecosystem in France and also to be an access point for researchers who aim to carry out research projects of general interest in France, with the SNDS, part of which is the national health insurance data system. All other databases must now be included. On the other hand, there is the health data catalogue but the implementing decree has not yet been voted on.

Indeed, in terms of governance, the fact that there is single point of access for all these data, is a change of perspective. This makes it easier for researchers to access this data, as well as any other actor who can demonstrate that they have a research project of general interest.

Encourage interoperability, not constraint

An economic code for the actors would facilitate interoperability, as the current funding restrictions are complex to implement. Standards have been around for years, developed by many organisations, but there are no longer any real reasons to adopt them; developing incentives seems to be the best solution. The hospital information system is very important but the quality aspects of the data also need to be considered, which represents a barrier to the use of AI, especially for learning aspects.

Create a clear interoperability policy, rules, and standards

Creating guidelines for setting up infrastructures for IT and software providers so they have clear and transparent rules in which to operate seems essential. Another fundamental factor is a clear framework of standards and ontologies, using the principles of Gaia-X. Regarding restrictions, a public–private consensus is also needed in order to avoid protests led by manufacturers on HEC and EPITECH certifications.

Harmonise regulations at European and Member State levels

The question arises of whether it is better to take a 'top down' approach directed from the EU towards all the Member States or whether Member States should be able to develop their own regulations regulations? While there is a desire at for harmonisation at an EU level, in each of the Member States there are different healthcare system and laws. This is a topic that has been highlighted by Gaia-X.

What is working well and best practices identified in this domain

Existing successful projects and positive experiences

- The French Health Data Hub is also in charge of working on the implementation of guidelines and a European Health Data Space providing a single access point for health research with global rules–local governance, and financing of data producers in a high-performance multi-cloud.
- Gaia-X is an initiative of Franco-German origin initiated a little over a year ago and led by Peter Altmaier, Minister of Industry in Germany, and Bruno Lemaire, Minister of the Economy, Finance and relaunch in France. Gaia-X aims to solve interoperability issues and emphasises transparency in clouds and protection of European digital assets. There are set policies, rules, codes of conduct and standard frameworks; the idea is to create a trusted European health data space.

Best practice examples

> At the end of October, a joint action by 26 countries, including France with INSERM, on rare diseases and semantic interoperability, the Hospices Civils de Lyon and Aix Marseille University was submitted to the European Commission as part of the work package.

Key Points

> Data standards have been around for years, but there are no longer any real reasons to adopt them if there are no incentives or restrictions; developing incentives seems to be the best solution: governance, data sharing and interoperability of data could be required in exchange for public funding.

> Semantic interoperability is a very important issue, it does not call into question the consensus on DSMs but requires the development of a common pan-European ontology validated by learned societies and clinicians.

> It is important to 'secure' health data in a safe infrastructure close to its place of production without replicating it. It was proposed to build on Gaia-X, a Franco-German initiative that aims to make a European data infrastructure available, in the form of a governance entity that will enact broad principles of data security, interoperability and portability. Then, several companies will be able to offer their service compatible with Gaia-X which is a de-centralised meta-cloud.

> It is important to involve citizens and patient associations by drawing on the work of the Health Data Hub, via the European Health Data Space.

> The French Health Data Hub is in charge of working on the implementation of guidelines and a European Health Data Space, through data catalogue, a single access point for health research with global rules–local governance and financing of data producers in high-performance multi-cloud.

Proposed actions and recommendations

Strengthening data quality, governance, security, and interoperability	
Action	**Target Stakeholder(s)**
Develop a common, pan-European ontology validated by professional societies and clinicians.	Professional societies and hospitals; software providers
Governance, data sharing and interoperability of data could be required in exchange for public funding.	Health Data Hub
Build on Gaia-X, a Franco-German initiative that aims to make a European data infrastructure available.	Institut Mines Telecom
Involve citizens and patient associations by drawing on the work of the Health Data Hub, via the European Health Data Space.	Health Data Hub
The French Health Data Hub is working on the implementation of guidelines and a European Health Data Space, through data catalogue, a single access point for health research with global rules–local governance and financing of data producers in high-performance multi-cloud.	Health Data Hub; SNDS

6. Liability and managing risk

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

Calling on the responsibility of physicians

Health professionals and institutions already bear a great deal of responsibility, so it is necessary to consider the human actors and their way of functioning. In traditional medical culture, the clinical and scientific decision is independent of the AI algorithm. The health professional may consider that the recommendations of the AI tool go against their judgement or what is usually done in his specialty or the specific case which brings up questions of consequences and responsibility.

Should healthcare professionals or manufacturers have the final say?

When we consider responsibility, those who develop the solutions, the manufacturers, also need to be considered. How much responsibility do medical device suppliers or manufacturers have for technical failures, independent of AI? Each device or solution will have a Marketing Authorisation and a specific indication for use, and if it is used use is outside this framework, that must be justified by the doctor. They are professionals who act within an ethical, organisational, and legal framework for the benefit of the patient.

Measure and validate the impact

In the phase of commercialisation of AI, documented studies were undertaken on the interest of using these AI systems; today we are clearly in a phase of observation of measuring the impact of

these solutions and have quantitative data and qualitative analyses on the impact of these new technologies.

Differentiate between problems caused by AI or other components

How should the problem of risk and assignment of responsibility for an error be resolved? Existing legislation or regulations that could be built on probably exist.

Medicines are assessed on a balance of risk (side effects) versus benefit (clinical efficacy). As with Phase IV and post-registration trials, once the drug is introduced, safety and efficacy are monitored to reassure all stakeholders and users of this product. Importantly, the benefit/risk balance should always be on the benefit side.

On the issue of liability in AI, the parallel with medicines is extremely limited. For example, the issue of potential misuse of AI on target populations that are not suitable for the initial prescription of AI.

Establish good manufacturing practices for AI tools

The good manufacturing practices (GMPs) for pharmaceuticals, and initiatives such as post-registration Phase IV trials, could be adapted for AI tools to build confidence in these products and perhaps mitigate risks and mismanagement. For evolving AI tools, GMPs should be put in place, including managing data sets, and ensuring fairness and balance between population parameters. It is important that there is good documentation and mechanisms for controlling for the types of patients and populations to which these tools will be applied to ensure that they are representative and therefore produce meaningful results.

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

Existing successful projects and positive experiences

> Look at what has been done in other sectors where these questions have arisen, such as in the financial sector where the consequences were dramatic during the 2008 financial crisis.

Best practice examples

> The provisions for the protection of personal data in the EU after the implementation of the General Data Protection Regulation (GDPR) ensure a high level of data protection.

Key Points

> The health care professional is not supposed to ignore the law. The doctor following recommendation of an AI system is no more at risk than when prescribing an ineffective drug for a patient or one that would induce significant, or even fatal, adverse effects (reference: Price's article, JAMA 2019).

> The benefit/risk approach used in the field of the medicines is probably the way to go.

> The autonomous car sector may be useful to study as a benchmark.

> Although the use of AI is risky, this does not call into question the skills of health professionals using these AI solutions.

> Long-term monitoring of medical devices and AI-related technologies should enable the

assessment of the benefit/risk balance and post-marketing monitoring process.

- A 'gold standard' of data is needed to compare AI in a use case to test risk.

Proposed actions and recommendations

Liability and managing risk	
Action	**Target Stakeholder(s)**
Develop processes for the long-term monitoring of medical devices and AI-related technologies to enable the assessment of the benefit/risk balance and post-marketing monitoring process.	Ministry of Health
Implement good practices for manufacturing AI tools, managing data sets, fairness, balance between women and men, etc.	

Appendix 1: Round Table Meeting participants

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

Name	Organisation
Advisers	
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Emmanuel Bacry	Chief Scientific Officer, Health Data Hub
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4. Platform G-nius to stimulate innovation in Digital health Accueil G_NIUS | G_NIUS (esante.gouv.fr)
5. European Health Data Space European Health Data Space (europa.eu)
6. Nvidia programme Clés d'un futur plus intelligent : l'IA pour la Santé | NVIDIA
7. AI For Health Home (aiforhealth.fr)
8. National system of Health data Accueil | SNDS
9. Partnership AP-HP and Owkin L'AP-HP et Owkin lancent une série de projets de recherche sur données qui s'appuieront sur le machine learning | APHP
10. Pasteur institute's community platform on AI Intelligence artificielle : une nouvelle plateforme pour la communauté biomédicale (pasteur.fr)
11. European Joint Programme on Rare Diseases led by Inserm on Semantic Interoperability EJP RD – European Joint Programme on Rare Diseases (ejprarediseases.org)