COCIR
Advancing Healthcare

ARTIFICIAL INTELLIGENCE IN HEALTHCARE

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Executive Summary

Artificial Intelligence in Healthcare is already a reality. Healthcare providers have embedded the technology into their workflows and the decision-making process.

The introduction of Artificial Intelligence in healthcare has brought improvements for patients, providers, payers and other healthcare stakeholders as well as society at large.

However we will only get the full benefits of Artificial Intelligence in Healthcare if we appropriately identify and address the key challenges we currently face in the field of:

- Access to data
- Go-To-Market
- Regulatory and technical matters
- Legal matters
- Ethical framework

Rather than replacing the human component of healthcare we instead see Artificial Intelligence in Healthcare as an essential tool – a companion - for physicians to help them improve patient outcomes.

To make that happen we need a broad dialogue between healthcare providers and physicians, patients, payers, industry, policy makers and other relevant stakeholders to overcome any barriers that withhold broad adoption of Artificial Intelligence in Healthcare.

Based on the actual discussion and adoption of Artificial Intelligence in Healthcare, we can extract from our experience the following recommendations:

1. **Access to data** needs to be promoted in a fair, transparent and non-discriminatory way.

2. **Standards and definitions** need to be endorsed on the European level. Sector-specific standards should only be developed where strictly necessary.

3. There is a need to clarify how existing **legislative frameworks** can be made more inclusive so that all forms and applications of Artificial Intelligence in Healthcare benefit from the same legal clarity and certainty. A more thorough evaluation and an evolution of the understanding of industry's responsibility should be required prior to assessing any new or additional policy options.

4. The **Ethics Guidelines for Trustworthy AI** [1] should encourage voluntary commitment and allow for self-regulating processes on an industry sector level.

[1] https://ec.europa.eu/futurium/en/ai-alliance-consultation/guidelines

1. Artificial Intelligence in Healthcare – Building Awareness

The foundational concepts of Artificial Intelligence were laid more than fifty years ago. However, it was only relatively recently that the twin effects of an exponential increase in computational power coupled with the omnipresence of data made Artificial Intelligence (AI) a powerful, practical reality. There is a sense that we are at the beginning of a new era as Artificial Intelligence becomes more and more widely available and affordable. Artificial Intelligence now plays an important role in almost every economic sector.

Despite its long history there are still many different understandings and definitions of what constitutes Artificial Intelligence.

The EU Commission defines Artificial Intelligence as follows[2]:

> *Artificial Intelligence (AI) refers to systems that display intelligent behavior by analyzing their environment and taking actions – with some degree of autonomy – to achieve specific goals.*

Based upon this definition we can distinguish between two different types of AI implementations in daily practice:

1. A software that has been trained before placing on the market (e.g. machine learning algorithm); or
2. A software that is continuously adapting and optimizing device performance in real-time to continuously improve outcomes

The outline to AI made in this White Paper are based on point 1.

Artificial Intelligence in Healthcare is already a reality[3]. Healthcare providers have embedded AI enabled applications into their workflows and caregivers use it as part of a decision-making process.

The introduction of Artificial Intelligence to healthcare has brought improvements at various levels, for example:

- On the **patient** level, Artificial Intelligence in healthcare allows for more accurate and/or rapid detection, diagnosis and treatment, resulting in improved outcomes for patients.

  As Artificial Intelligence solutions and platforms become increasingly more common and affordable, and improve continuously, it is essential to ensure that patients will have easy access to these type of specialised and personalised healthcare delivery.

[2] Artificial Intelligence for Europe {COM(2018)237 final}

[3] COCIR is building a library of use cases which will be published on the COCIR website, http://www.cocir.org/

- On the level of **healthcare providers and professionals**, there is a clear benefit from Artificial Intelligence to support the decision-making. Not only can it increase the accuracy of diagnosis and efficacy of treatment, but also improve efficiency of their workflows by having information readily and quickly available, reducing greatly the throughput and lead times.

- On the **societal** level there will be also significant increase in the overall level of health and well-being with reduced costs of care.

Based on current use cases it is very clear that Artificial Intelligence in Healthcare has already opened up diagnosis and treatment opportunities that were previously not possible, for instance in detecting suspicious lesions that may have been overlooked.

We foresee that further advancements in technology will contribute even more to the uptake of Artificial Intelligence in Healthcare, resulting in a better healthcare delivery to the benefit of us all.

2. Access to Data

The efficacy of Artificial Intelligence applications relies heavily on access to datasets on which the system has been trained. The higher the quality of data that goes into the system, the better the outcome of the AI specific task. Without unhindered access to high quality of data at scale the huge potential of AI will not be realized in healthcare.

On the one hand it is a matter of quantity: the more data that is available to the system, the larger the datapool and by this the considered patient population on which the system can train and detect patterns. On the other hand, and even more importantly, there is a need for high quality data. Even though data is all around us, it can be challenging to get access to high qualitative data.

Data that is available may require additional curation before it can be put to good use, for instance by cleaning or labeling the data or linking the several data repositoriues together along a single patient. Furthermore it is important to identify whether the available data sets may create or strengthen any bias to the outcome of the AI system, whether or not this is desirable for the intended purpose of the system.

To ensure a level playing field and spur innovation, it is vital that access to high quality data is fair, transparent and non-discriminatory:

- Access to data should be publically available, particularly in those cases where the data was collected through public sector initiatives and/or funding

- Entrance costs to acquire access to data should be avoided where possible. If this is not possible, then access to data should be offered at a minimum reasonable cost to cover genuine costs associated with access since

    - Higher costs will hinder AI solutions coming to market

- Higher costs will create barriers for smaller market players
- Higher access costs will make it more likely that AI technologies are not developed in Europe, to the detriment of patients, clinicians and businesses in Europe.
- The value of high quality data is highly dependent on the purpose and outcome of the AI system the datasets are being used in

- Data should be made available in a non-discriminatory way, with market players having equal opportunities to access data and no exclusivity can be claimed by or awarded to selective market players.

3. Go-To-Market

The number of possible AI applications, methodologies, use cases etc. that are already on the market today or will be coming to the market in the future may have different Go-To-Market scenarios in mind. The section below is therefore not intended to be conclusive as it outlines a couple of the most reasonable scenarios in an non-exhaustive list

Healthcare providers are interested in supportive tools to improve their decision-making for diagnostic and therapeutic procedures or any clinical decision at the point of care.

While for medical image interpretation there are already useful stand-alone AI algorithms in clinical use, the broader implementation of AI in daily healthcare requires versatile platforms that are there to support the procedures and decision-making in a streamlined way, so that all relevant AI applications necessary to perform complex tasks can be easily integrated into existing workflows and IT infrastructure, ensuring everyday healthcare routines can be performed in a more effective and efficient way.

Traditionally AI algorithms are developed to solve a well-defined clinical problem. However in reality healthcare is much more complex (e.g. reading a Chest CT scan and detecting Lung nodes, Emphysema, Coronary Arteries, the Aorta, the vertebrae etc.) so that multiple algorithms need to work together to best support decision making, like detecting suspicious lesions.

The Go-To-Market and deployment scenarios, and by extension the adoption of Artificial Intelligence in Healthcare, will - already today - not so much depend on the question of whether or not using AI, but more on the question of how to integrate different AI applications into existing infrastructures and physician workflows.

Examples of such scenarios might be to offer AI solutions embedded in a PACS reading workstation or to deploy AI applications through some form of App store where healthcare providers have access to a wide collection of applications and algorithms.

Each vendor will need to carefully consider the best way of deployment to fulfill the clinical needs of any healthcare providers. Many different scenarios can apply, ranging from smaller vendors focusing on single-use applications to bigger vendors offering AI platforms, a wide range of companions, assistance-like systems or online marketplaces.

In this respect it is also crucial to consider the appropriate business model. Current reimbursement systems do not provide premium imbursements where AI solutions are being applied, additionally to the existing reimbursement codes.

Traditionally the main business model within the software industry is to still sell licenses and support-services. However, shifting deployment scenarios more and more from on-premise to cloud, other business model scenarios are being explored and introduced. One of the most prominent business models being introduced in several industries are Subscription or volume-based SaaS (Software-as-a- Service) models. These models are also increasingly used for AI applications.

While these business models run as “transactional models” and can be performed between all market participants (providers, payers, vendors and others), it is mission-critical for adoption of such models, that there is a transparent and robust “order to cash” process, which can also be audited and prove accuracy of billing of the transactional volume.

4. Regulatory and Technical Matters

To a large extent Artificial Intelligence may be simply considered as a specific type of software, and in that respect current classification models established by the Medical Device Regulation[4] (MDR) and IVD Regulation[5] (IVDR) are applicable and suitable. The general safety and performance requirements are generic principles which do not necessarily require adaptation to a new technology. Hence existing regulations should be applied.

[4] Medical Device Regulation EU 2017/745
[5] In-Vitro Diagnostic Medical Devices Regulation EU 2017/746

As different AI approaches such as machine learning and deep learning may be applied by different industries, current standardisation work ongoing within various standardization bodies aims to establish e.g. good "machine learning practices". Such standards should be endorsed to create a reliable pathway to market for manufacturers, notified bodies and regulators alike.

Common standards and definitions on AI should be endorsed on the European level. New standards in development may be independent of the sector where AI is applied. Sector-specific standards should only be introduced where strictly needed.

While Artificial Intelligence today already makes use of compatible regulatory frameworks to access markets, not all AI models and technologies are supported. For example, certain continuous learning approaches are not compatible with existing frameworks and require a more thorough evaluation and an evolution of the understanding of the manufacturer's responsibility.

An AI system which changes its performance and safety characteristics during its use and without explicit manufacturer involvement is currently not compatible with EU medical devices regulatory frameworks and requires further development of guidance. This next step in AI will not be possible without appropriately addressing the following non-exhaustive list of questions:

- How would one determine and manage a change, either significant or non-significant to an AI system?
- Can we distinguish (non-)significance of changes to the system in terms of the performance of the AI system, particularly if this would result in different decisions made by the AI?
- How would changes to AI systems affect regulatory obligations related to for instance labelling and registration?
- Who would be considered the manufacturer and to what extent can the manufacturer exercise control?

5. Legal Matters

Artificial Intelligence does not operate in a vacuum. Any deployment in the field will trigger a number of legal obligations under existing frameworks and might furthermore raise a number of critical questions.

There is for instance the matter of **liability**. In this respect we can make a distinction between applications that support decision-making and applications that can make autonomous decisions (e.g. autonomous driving).

Today in healthcare the industry is offering AI applications in support of clinical decision making, for instance by highlighting suspicious regions in an image. However, the physician is performing any downstream decision to further manage this patient and therefore the liability lies with the user/physician.

Liability needs to be considered in various scenarios, such as unforeseen use, off-label use, user errors, inadequate training, lack of maintenance or a defective product.

The General Data Protection Regulation[6] (GDPR) introduced a more strict framework for the **data protection** of natural persons within Europe. There might also be design constraints for AI systems in terms of data access, transparency (both to healthcare providers as patients) and interpretability of AI algorithms. Furthermore, lack of consistency in data protection laws across Member States might hamper the development and deployment of AI applications on a European scale.

There is a need to feed high quality data into AI systems to properly train the algorithms. Whereas this input can be based directly on patient data, in many cases additional work may be required to optimize the data sets, by curating or cleaning the data sets or by annotating or labeling the data.

The development of AI may also raise a number of questions regarding **Intellectual Property Rights** (IPR)**.** Specifically in cases where AI algorithms are being built in close collaboration with clinical partners, questions referring to IPR need to be addressed in advance.

6. Ethical Framework

On 25 April 2018 the European Commission announced its Strategy on Artificial Intelligence[7], which was followed in December 2018 by a communication on a Coordinated Action Plan on AI[8].

One of the main pillars of the Strategy is the need to ensure an appropriate ethical and legal framework. Whereas much power has been attributed to Artificial Intelligence, the algorithms that run these systems are developed by humans. Consequently any bias or ethical considerations that consciously or unconsciously are programmed into the system will determine the output of these AI systems.

There has been a plethora of initiatives focusing on the ethical aspects of Artificial Intelligence. Pre-dating the Commission's initiative COCIR partnered with AI4People.

[6] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32016R0679
[7] http://ec.europa.eu/newsroom/dae/document.cfm?doc_id=51625
[8] https://ec.europa.eu/digital-single-market/en/news/coordinated-plan-artificial-intelligence

AI4People is a multi-stakeholder forum, bringing together all actors interested in shaping the impact of new applications of AI, including the European Commission, the European Parliament, civil society organisations, industry and the media.

In November 2018 AI4People presented its "Ethical Framework for a Good AI Society"[9].

The AI4People Ethical Framework builds upon 5 main principles:

- Beneficence ("do good")
- Non-maleficence ("do no harm")
- Autonomy ("preserve human agency")
- Justice ("be fair")
- Explicability ("operate transparently")

Upon mandate of the Commission a High-Level Expert Group on Artificial Intelligence has been created and tasked to create an ethical guidelines framework.

The Ethics Guidelines for Trustworthy AI[10] have been published by the European Commission on 8 April 2019. The Ethics Guidelines list seven key requirements that AI systems should meet in order to be trustworthy:

1. Human agency and oversight
2. Technical robustness and safety
3. Privacy and data governance
4. Transparency
5. Diversity, non-discrimination and fairness
6. Societal and environmental well-being
7. Accountability

The Guidelines present an assessment list that offers guidance on each requirement's practical implementation. This assessment list will undergo a piloting process in order to gather feedback for its improvement.

COCIR members will be involved in testing the assessment framework to ensure it can be coherently integrated into the design principles of Artificial Intelligence in Healthcare.

[9] http://www.eismd.eu/wp-content/uploads/2019/02/Ethical-Framework-for-a-Good-AI-Society.pdf
[10] https://ec.europa.eu/futurium/en/ai-alliance-consultation/guidelines#Top

7. Conclusions and recommendations

It is clear that Artificial Intelligence in Healthcare has great potential and that we should create the best possible conditions to enable further growth and expansion into uncharted healthcare territories, bringing benefits to patients, physicians, healthcare providers as well as society at large.

Based on the actual discussion and adoption of Artificial Intelligence in Healthcare, we can extract from our experience the following recommendations:

1. **Access to data** needs to be promoted in a fair, transparent and non-discriminatory way.

2. **Standards and definitions** need to be endorsed on the European level. Sector-specific standards should only be developed where strictly necessary

3. There is a need to clarify how existing **legislative frameworks** can be made more inclusive so that all forms and applications of Artificial Intelligence in Healthcare benefit from the same legal clarity and certainty. A more thorough evaluation and an evolution of the understanding of the industry's responsibility should be required prior to assessing any new or additional policy options.

4. The **Ethics Guidelines for Trustworthy AI** should encourage voluntary commitment and allow for self-regulating processes on an industry sector level.