SIEMENS Healthineers

Siemens Healthineers – contribution to the public consultation on Artificial Intelligence – A European Approach to excellence and trust

Siemens Healthineers welcomes the European Commission White Paper on Artificial Intelligence, and in the particular the focus on the intention to unleash the potential of big data and AI in the healthcare sector, which we believe will help further accelerate the transformation of healthcare systems across Europe, spur innovation, and ultimately benefit European citizens, patients, and healthcare professionals.

We are strongly convinced that the use of AI in healthcare can be an invaluable aid to help doctors interpret symptoms accurately and make correct diagnosis at an earlier stage. AI is already used in healthcare in diagnosis of cancers or lung disease for instance[1], and also to support clinicians on COVID-19[2], as Chest Computed Tomography (CT)[3] is used to evaluate the disease and assess its severity and progression. An AI-powered analysis of radiological images has the potential to reduce the growing burden on radiologists, speed up their reading time and accuracy.

SHS is glad to have the opportunity to contribute to the work of the Commission and provide input. We have gathered below additional feedback to the questions in the public consultation, where we felt additional details or explanations were needed.

[1] Researches show how AI can help doctors. For example, a research from the Catholic University of Leuven (KU Leuven) showe of the doctors were able to correctly diagnose the primary disease in 45% of cases (with a range of 24-62%) while the AI gave a correct diagnosis in 82% of cases https://www.sciencedaily.com/releases/2018/09/180918180501.htm. Also on cancer the deployment of AI has had great results: this study from Cornell University (https://arxiv.org/abs/1606.05718) computational systems obtained an area under the receiver operating curve (AUC) of 0.925 for the task of whole slide image classification and a score of 0.7051 for the tumor localization task. A pathologist independently reviewed the same images, obtaining a whole slide image classification AUC of 0.966 and a tumor localization score of 0.733. Combining our deep learning system's predictions with the human pathologist's diagnoses increased the pathologist's AUC to 0.995, representing an approximately 85 percent reduction in human error rate.

[2] Siemens Healthineers CT https://www.siemens-healthineers.com/medical-imaging/diagnostic-imaging/ai-covid-19-algorithm. The primary features seen on a lung affected by COVID-19 are peripheral focal or multi-focal ground glass opacities, consolidations and crazy-paving patterns. Non-contrast chest CT has been useful not only to detect, quantify severity, and assess the progression of the disease, but also to evaluate the potential response to therapy alternatives. Similar results can be achieved with chest X-rays, e.g., for tracking the disease progression and follow-ups. The inclusion of radiological findings in confirming the COVID-19 diagnosis of a patient has significantly increased the workload of radiologists. An AI-powered analysis of radiological images has the potential to reduce this growing burden on radiologists, speed up their reading time and accuracy.

[3] https://arxiv.org/ftp/arxiv/papers/2004/2004.01279.pdf

Siemens Healthcare GmbH
Management: Bernhard Montag, Chairman;
Jochen Schmitz, Michael Reitermann

Karlheinz-Kaske-Str. 2
91052 Erlangen
Germany

Tel.: +49 (9131) 84 0
siemens.com/healthcare

Chairman of the Supervisory Board: Michael Sen
Registered office: Munich, Germany; Commercial Registry: Munich, HRB 213821
WEEE-Reg.-No. DE 64872105

Section 1 – An ecosystem of excellence additional comments

Consider the existing framework and legislation

As the White Paper highlights, before introducing new legislation specific to AI, existing horizontal and sectorial regulations should be taken into account (for example regulatory frameworks on Software as a Medical Device; both sector-specific and horizontal).

- Software with a medical scope is already subject to **strict existing regulations**. Whether an artificial intelligence (AI) solution is embedded in a medical device or is a self-standing medical device software, it would be covered by the principal medical technologies sectoral regulations: the In-Vitro Diagnostics and Medical Device Regulations (IVDR/MDR). Therefore, these trigger considerably stricter legal requirements and liabilities than software, without a medical scope, as the manufacturer must thoroughly substantiate that the software is safe, performs as intended, and delivers a clinical benefit.
- We believe that existing laws and regulations cover AI in a sufficient manner. Therefore, we would advise caution when considering introducing new AI specific legislation, in particular in view of the risk of creating conflicts between the various AI-relevant regulations, and of the need to avoid creating additional barriers for the development of AI-supported medical devices in Europe.
- Furthermore many of the issues raised in the consultation **are not specific for AI**. Cybersecurity, risks related to the loss of connectivity, and changes to the concept of safety are not limited to AI, but rather apply to digital solutions/ICT in general.

Data as enabler of AI

Healthcare generates vast amounts of data, but it often does not meet the needs of AI which requires access to high quality, representative, structured health data. Much of the existing data does not meet the required standards for clinical evidence, faces additional technical/interoperability constraints, or is shielded by data protection. For the development of a European Health Data Space as envisaged in the European Data Strategy the **availability of high-quality, standardised, structured data** will be key.

Section 2 – An ecosystem of trust

We are concerned that the discussion has been focused on risks rather than the potentials of using AI. We believe we should rather focus on the benefits of using AI compared to not using it. The assertions in the question need to be contextualized.

- “Discriminatory”: it pertains to of how data have been collected in the past, we should focus on the chance to change things.
- "Not always accurate" is not inherent to AI but depends strongly on the application where AI is used, on the used data set and on the input order of data.
- “Explainability” will always be difficult for complex, deep learning algorithms, and we are focusing on providing more accurate results and recommendations.

It has to be underlined that AI in the medical devices is used to support – not to replace – the physician.

Clear liability and safety rules

As the Commission concluded itself in its fifth report (COM/2018/246 final) on the Application of the Product Liability Directive, we believe that on the whole, the Directive ensures satisfactorily liability for defective medical devices products. The Directive contributes to a reasonable balance between protecting those who suffer injury and ensuring fair competition. It seeks and achieves a "fair apportionment of the risks inherent in modern technological production".

While we support a status quo of the current Product Liability Directive, we see value in developing guidance to clarify certain issues under the Directive (e.g. case studies), based on practical cases.

- The German Ministry of Justice – *report Lämder-working group "Digital Restart" - Robotic Law, Blockchain, copyright on data*[4] - recently examined whether potential gaps in current liability law with respect to medical devices and its finding are quite revealing.

The experts concluded that **manufacturing and distribution of an autonomous system into the healthcare market is not deemed a particular risk per se**. In addition, that there is no need to change the rule that the manufacturer is not liable according to product liability law if it can prove that state of technical knowledge at the time of putting the product on the market made it impossible to discover the defect.

Also, **the report found that there is generally no need for strict liability** for the operator if the persons being in contact with the autonomous system have been sufficiently informed about the risks and if the autonomous system has been subject to a regulatory clearance.

It has to be underlined that AI is not used for "final" autonomous decision making in healthcare (not comparable with autonomous cars or drones), AI is used to support (not replace) the physician and for ethical reasons the physician will always have the "last word". **Accordingly, AI used in the afore-described manner does not increase but mitigate the risk of personal injury resulting from faulty diagnosis.**

The medtech sector is already regulated through a system which has its foundations in the identification of risk profiles and the management of risk, and which also builds on the PLD's liability regime. Many aspects of AI are included in MDR/IVDR (i.e. ensuring the safety and the performance of a medical device (and so also those with AI) and as such subject to severe processes, evidence collections, risk/benefit assessment. It is therefore important that any new proposal takes in due consideration existing liability rules applicable for medtech manufactures (i.e. manufacturing defects; design defects; warning defects) and therefore considers to provide exception for the medtech sector.

[4] https://www.justiz.nrw.de/JM/schwerpunkte/digitaler_neustart/zt_fortsetzung_arbeitsgruppe_teil_2/2019-06-06-JuMiKo---Beschluss.pdf