

COCIR preliminary input to the eHealth Stakeholder Group's priorities and work programme

COCIR commends the European Commission for renewing the mandate of the eHealth Stakeholder Group. Now more than ever, the eHealth Stakeholder Group should play an important role in advising and supporting the European Commission, the EU Member States and the eHealth Network in their vision of a digital transformation of health and care, especially as health has taken a central role in our daily lives. We do hope the eHealth Stakeholder Group will have regular interactions with the eHealth Network to ensure necessary dialogue is established between the eHealth Stakeholder Group and the Policymakers in charge of the Digital Health programme.

The current COVID-19 pandemic crisis revealed the need for a call for action on the importance of, and the urgent need to accelerate the use of digital health technologies including telehealth in order to provide the best care and protection to patients.

COCIR remains committed in positively and pragmatically contributing to the topics that will be chosen by the eHealth Stakeholder Group.

Considerations for the eHealth Stakeholder Group

It is important that the eHSG works in a coordinated and effective way to ensure its activities lead to practical and tangible outcomes that will help the European Commission, the Member States and other relevant stakeholders realising the full potential of the digital transformation of health and care.

It is paramount that the work of the eHSG closely aligns with other activities and projects driven by the Commission and the Member States. The eHSG should create impact beyond Brussels and be able to interact on a regular basis with the eHealth network and national policy decision makers.

COCIR fully endorses the Commission's ambitions on establishing a European Health Data Space. Strategic views should take due consideration of the roadblocks and enablers in order to realise this: a trusted data governance framework respecting data protection and privacy rules, taking into account data quality and interoperability aspects, and underpinned by a solid and secure technical infrastructure. Capacity building is also necessary, providing technical resources like high-performance computing, and targeted policy actions for a future-proof digitally skilled workforce.

COCIR proposed top 3 priorities for the first year

In light of the discussions during the eHSG's kick-off meeting of 13 July 2020, COCIR recommends that the activities of the eHealth Stakeholder Group should consider the following three key topics for the first year which are fundamental for the trust in digital health and the success of the European Health Data Space:

1. Artificial Intelligence

Artificial Intelligence in health has been recognised as a promising and valuable tool in addressing the current and future health challenges we face as a society. To ensure we can make full use of its power, we need to find the right approach to determine how to develop and deploy trustworthy AI, for example in the area of diagnosis, early detection, treatment and after care.

In April 2019 COCIR published its paper "[Artificial Intelligence in Healthcare](#)", followed this year by the [publication of 10 AI use cases](#) from our membership, building awareness on how AI is already being used today. COCIR is actively engaged on AI, including on a [regulatory approach](#), conformity assessment, liability and ethics. COCIR has also been providing input to the work of Medical Device Coordination Group on New Technologies as well as to the High-Level Expert Group on AI. COCIR is a member of the [European AI Alliance](#) and a partner of the [AI4People](#) multi-stakeholder platform. At the international level COCIR has been working through DITTA on AI, which is now being considered as a new work item by IMDRF.

COCIR would expect to see a concerted effort between the eHSG and EU institutions with strong support and involvement of the eHealth network to build trust in the value of AI in healthcare and to ensure a fit-for-purpose approach on AI tailored to the healthcare sector.

2. Cybersecurity

The rapid digital transformation of health and care and the increase in connectivity have drastically changed the threat landscape. As an essential service to society healthcare services are increasingly under pressure to be secure and resilient. The complexity of the healthcare ecosystem requires a coordinated and joint response from a broad range of stakeholders to address the lack of cybersecurity-related skills, measures and investments.

In March 2019 COCIR called for the need of a [comprehensive approach](#) on cybersecurity in healthcare. COCIR has been organising cybersecurity workshops and seminars, further engaging with healthcare providers to promote awareness on the shared responsibility of cybersecurity. COCIR recently provided its [initial views](#) on the revision of the NIS Directive. COCIR is a member of the [Stakeholder Cybersecurity Certification Group](#) as established this year by the Cybersecurity Act, and also represented in ENISA's eHealth Security Expert Group. At the international level COCIR is active through DITTA in response to the activities on cybersecurity by the IMDRF.

COCIR would expect to see an opportunity to increase awareness on the regulatory framework and the development of international standards. It is also crucial to have a joint effort to articulate more clearly the shared responsibility and the critical role of governments, industry, healthcare providers, healthcare professionals and others in addressing cyber risks.

3. Interoperability

Interoperability is a prerequisite to build the digital future of healthcare. Without it there is no way to meaningfully share data with patients, between healthcare providers and professionals, or to unlock it for scientific and other research.

For many years COCIR has been actively working and publishing recommendations on interoperability matters, inter alia coordinating the eHSG interoperability report in 2014¹. COCIR has been a partner to the [EURO-CAS](#) project that looked into establishing a European conformity assessment scheme for interoperability. Recently COCIR published its paper [mHealth: COCIR recommendations for an effective deployment](#)

COCIR would expect to see how to effectively deploy interoperability with top-down support from EU Member States, incentivizing the uptake through procurement and tender processes.

COCIR supporting the work of the eHSG

In view of the above priorities COCIR would volunteer to take the lead on the priorities of Artificial Intelligence and cybersecurity and support the work on interoperability. Although we were requested to limit ourselves to list 3 top priorities, COCIR is supportive of many other topics where we have competencies and happy to support the eHSG activities, such as data protection / codes of conduct, telehealth, mHealth and economic models.

COCIR participation on EEHRxF

COCIR [welcomed](#) the Commission's recommendation on a European Electronic Health Record exchange format at the time of adoption. Having been the longstanding industry voice on interoperability, COCIR has been vocal on the slow and unequal uptake of electronic health data formats (including patient summaries and ePrescriptions), that has not been used in an optimal way for patients.

COCIR would like to play an active role in driving the uptake of and exchange of electronic health data in and across borders. There is a need to speed up the current level of implementation and prepare the work on the imaging, lab and discharge reports.

¹ https://ec.europa.eu/newsroom/dae/document.cfm?doc_id=5168



ANNEX

COCIR is the European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries.

Founded in 1959, COCIR is a non-profit association headquartered in Brussels (Belgium) with a China Desk based in Beijing since 2007. COCIR is unique as it brings together the healthcare, IT and telecommunications industries. www.cocir.org

COCIR has been an active member of the eHealth Stakeholder Group since its inception in 2010.

COCIR has dedicated groups of experts, focusing on digital health, including on artificial intelligence, cybersecurity, data protection, integrated care and mHealth.

COCIR has been a Blue Print champion (EIP on AHA) and is partner to several Horizon 2020 funded projects focusing on the digital transformation of health and care, such as [Digital Health Europe](#) and [UNICOM](#).

COCIR has been extensively working with other stakeholders, for instance through the [Integrated Care Alliance](#) since 2016, or through the [EU Health Coalition](#) where COCIR is chairing the Health Data and Digital Health working group. Furthermore COCIR is a member of the [International Association of Trusted Blockchain Applications](#), co-chairing the healthcare working group.

COCIR is one of the main industry stakeholders working on an [institutionalised public-private partnership on health innovation](#) with the European Commission.

At the international level COCIR is representing the medical industry through [DITTA](#) at the IMDRF level. COCIR is also represented on the WHO Digital Health roster of experts.

COCIR Responses to recent public consultations

[COCIR response on the revision of the NIS Directive \(IIA\)](#) (August 2020)

[COCIR response on the data governance framework of common European data spaces](#) (July 2020)

[COCIR response to the AI White Paper](#) (June 2020)

[COCIR input on the European Strategy for Data](#) (May 2020)

[COCIR response on the application of the General Data Protection Regulation](#) (April 2020)

COCIR Publications

[mHealth: COCIR recommendations for an effective deployment](#) (June 2020)

[European Health Data Space: Towards a better patient outcome](#) (November 2019)

[Artificial Intelligence in Healthcare](#) (April 2019)

[Advancing Cybersecurity of Health and Digital Technologies](#) (March 2019)

[Identity in Healthcare – A key enabler to Integrated Care](#) (May 2018)

[Beyond the hype of blockchain in Healthcare](#) (December 2017)

[Digital Health Roadmap to support Integrated Care](#) (May 2017)

[We're all in this together: Advancing eHealth Interoperability](#) (May 2017)

COCIR eHealth Toolkit [2015](#) [2014](#) [2013](#) [2012](#) [2011](#)

Other COCIR references

[Artificial Intelligence in Healthcare – COCIR adds 4 new AI use cases](#) (June 2020)

[The vital role of Artificial Intelligence in a time of COVID-19](#) (June 2020)

[Artificial Intelligence in Healthcare – First publication of COCIR AI use cases](#) (January 2020)