



COCIR CONTRIBUTION TO THE 10 JULY 2019 HIGH LEVEL HEALTH TECH ROUNDTABLE

COCIR Secretary General was invited by the European Commission to a high-level roundtable on 10 July together with other industry senior representatives and wider stakeholders' representatives.

The purpose of this roundtable was to gather inputs on various subject matters, similar to what was done last 25 Oct. 2018. This roundtable was under the leadership of Commissioner Gabriel and Director General Roberto Viola and included other representatives of DG CNECT, DG SANTE, the Chair of the European Data Protection Board and ENISA.

COCIR is happy to continue to contribute to the identified topics as we consider those are important elements towards digital transformation and integrated care.

COCIR also released recently our expectations for the next 5 years towards:

- Better healthcare systems
- Vibrant medical and digital technology sectors

Hereafter are the COCIR responses to the questions received prior to the meeting.

1. How can your organisation support the uptake and evolution of the European EHR exchange format and of the tech specs in the Recommendation?

While COCIR supported this recommendation at time of publication earlier this year, at the same time we urged the European Commission and the Member States to allocate sufficient funds and resources in order to accelerate implementation and uptake, thus delivering an effective tool for interoperability.

We referred to the continuing slow deployment of interoperable digital health solutions in Member States remaining a barrier for scaling up integrated care and bringing its benefits to citizens. Member States need to deploy this recommendation at national and regional levels, to allow healthcare professionals and citizens to securely access and use relevant health data, including in cross-border exchange.

The Digital Europe programme should be used as an effective Instrument to raise digital skills and support those transformative processes that embed Interoperability by design.

COCIR noted the ongoing work on further elaborating the European EHR exchange format through a joint coordination process but we believe industry should be more associated to such process as well as IHE and other stakeholders.

To increase the uptake of interoperability accelerated stronger actions are needed at the demand-side, to have a clear and determined choice in supporting interoperability through national eHealth strategies, prioritising ways to connect platforms through APIs and international standards. In this respect it may be interesting to learn from similar initiatives in other geographies, like In Switzerland ([eHealthSuisse](#)) or in the United States on image exchange ([Carequality](#)), image share proposal, implementation guide, as well as carequality's existing EHR exchange.

COCIR has been supporting the case of interoperability for many years. We have a dedicated focus group working on interoperability and our members are involved in developing interoperability standards. Next to that, COCIR has been a contributing partner to the Horizon 2020 project [EURO-CAS](#), working on the development of an eHealth

Interoperability Conformity Assessment Scheme for Europe which now needs to be truly deployed with EC financial support at the beginning.

In conclusion, COCIR can continue to support MSs and EC once sufficient funding has been allocated at regional, national and European level to support mandatory use and reference of standards and IHE profiles in public procurement. Deployment of the conformity assessment plan developed by EUROCAS and more training on interoperability is required. We are ready to actively participate under MS leadership in multi-stakeholder initiatives to support local deployment as our industries are present in all EU countries. We should also ensure the critical role of the eHealth Network and the eHealth Competence centres to accelerate effective deployment and scaling-up at national and regional level. Alternatively, we would be ready to coordinate with IHE Europe a dedicated Task Force to work with competence centres on Lab, Imaging, Discharge Use cases and Specifications.

Three suggestions are as follows:

- to continue to drive the impact of the recommendation to make the EHRxF recommendation **a prerequisite** to receive funding for digital health related projects. This shall be true for all funding pillars (Horizon2020/structural funds and from 2021 also Digital Europe).
- To integrate EHRxF **into public procurement** processes
- To educate the eHealth solutions purchasers to address the lack of deeper knowledge on interoperability at regional and local decision makers (procurers) and healthcare providers (e. g. hospitals). This reflects the aim of pillar three "literacy" of the Communication on Digital Health (2018) and aims to overcome the currently very fragmented EHR market which is partly due to the lack of expertise of the people in charge on the local level.

2. **What would your organisation see as priorities to support the emergence of a European Health data space?**

We need to unlock the vast amount of health data that is already existing today, but still hidden or holed up in private or proprietary registries. There should be a clear framework to validate and curate that data to make it fit for purpose. Access to qualitative data should be warranted in a fair, transparent and non-discriminatory way with a sensible discussion on the financing and incentive mechanisms.

There is a key role for a European Health Data Institute to govern and coordinate such activities as it has been recommended by the EU Health Coalition, to which COCIR is a partner.

Clear governance would be needed to allow the re-use of data for secondary purposes while respecting individual rights and freedoms regarding data protection. Adequate operational and technical measures should be put into place to ensure secure data management.

Given the breadth and complexity it is necessary to have a clear roadmap towards the creation of a European Health Data Space. Such project will face a variety of challenges touching upon topics like interoperability, data protection, cybersecurity, big data analytics and artificial intelligence.

COCIR and its members have vast experience and expertise to offer in these policy areas and can make valuable contributions to the planning, development and implementing stages of a European Health Data Space.

The Coordinated Plan on AI (Dec. 2018) already announced the implementation of an EU Data Space for Imaging (initially focusing on cancer). **We congratulate the EC for the publication of such [call](#) recently.** COCIR is also happy to share the recently publicly

available [report on Breast Cancer](#) Science Business released which is covering the value-add of medical technologies.

We also know that the Commission aims to publish two H2020 calls “this summer” to drive the implementation of this Data Space. Our industry will be happy to contribute and to address the challenges that are rightly mentioned and bring to the table our vast experiences. If the European Commission aims to keep AI algorithm research and development competitive in Europe, these Data Spaces need to be available asap.

Beyond this, there should be ambitious plans to target other topics (like “EU Data Space for Lab”) and also try a non-silo approach: e. g. there could be a “EU Hospital Data Space” that does not integrate disease specific data, but patient specific data horizontally.

In summary, to support the emergence of a European Health data space, COCIR see as priorities:

- To learn from existing experience (refer to USA – patient health data are already accessible)
- The allocation of a dedicated funding at European level (part of Digital Europe) to support the establishment of a multistakeholder group to reflect in setting-up a European Health Data Institute

3. Where investments are most urgently needed to achieve the ambitions for data driven, digitally transformed, health and care systems to the benefit of society?

COCIR believes that investments are urgently needed on the following matters:

At EU level investments are urgently needed for the following:

- Centralizing patient data, de-silo various existing registries (ref PARENT) and ensure secure access by patients and HCPs but also allow fair and transparent access by health tech industries so that it can contribute to better health outcomes through machine learning and building the right analytics
- Reforming training of HCPs to include education on digital tools and their value and developing eSkills mechanism(s)
- Developing new education schemes and professions such as data scientist
- Allocation of funding from Research and innovation to support the European industries in ensuring secured solutions are available to efficiently share patient data

At National level investments are urgently needed for the following:

- Reform the national and regional health systems to ensure better access through digital tools
- Educating purchasers at hospital level to better understand value of interoperable solutions and better use of existing standards and profiles

4. With regard to electronic identification - from your perspective, what needs to happen / how can you support to see this integrated into the emerging citizen centric common health data space.

COCIR developed a paper on eID in partnership with SIA, the Secure Identity Alliance.

It is critical to ensure at country level a unique eID not only for the patients but also for healthcare providers (HCPs). Progress at country level is heterogenous for the time being and unless this is part of the country strategy it won't happen.

There should be a thorough review of identity management within the healthcare environment. For the Patient ID system, a trusted identity management system should

provide for a secure data platform that empowers patients to manage their health data transversally, throughout their entire lifetime. Such framework would facilitate the basic structure for an integrated care approach and furthermore accommodate cross-border exchange of health data.

COCIR considers the following needs to happen:

- Strong support from EC accompanied by funding and the emergence of a European Data Institute (as recommended by the EU health Coalition)
- Strong commitment by national public authorities and a concrete national digital strategy driven by the Member States(s) integrating eID for patients and HCPs
- Clear and transparent governance at the EU and national level
- Stronger role required for the eHealth Network to ensure they have a meaningful impact on the decision making to realise the necessary changes within their country
- Need to remove reluctance in sharing data (also learning from other regions, like in the United States)

5. What is your view on technologies such as block-chain, AI in healthcare?

Healthcare is a highly innovative sector that continuously works to improve the health outcome. New technologies are therefore being introduced almost every day. We notice however that these technologies face difficulties in reaching a large-scale deployment.

On the one hand, more efforts are needed from public authorities to put in place mechanisms that efficiently assess and use those technologies and the need to put processes in place to create appropriate frameworks for procurement and reimbursement. On the other hand, more awareness and education are required to address lack of knowledge and skills.

Regulatory sandboxing should be further promoted to test new technologies under favourable conditions that might include relaxing of existing legal requirements.

Adequate resources should be made available to train and educate the current and future workforce on the use, development and deployment of these new technologies.

With regard to blockchain, development within the healthcare sector is still rather premature. Nevertheless, there is a growing sense that there are valid use cases for healthcare, for instance to empower patients to manage their consent or to ensure adequate data protection when creating AI algorithms.

COCIR has therefore been one of the founding members of the [International Association for Trusted Blockchain Applications](#) (INATBA) and part of a dedicated working group on Blockchain In Healthcare.

COCIR recommends targeted funding and financial initiatives to support these emerging ecosystems. Next to that it encourages Member States to run regulatory sandboxes, where new technologies can be tested under controlled conditions.

With regard to Artificial Intelligence, the technology is already here as we also recently demonstrated in our [General Assembly Open Session](#) and articulated through our White Paper.

As COCIR we have identified 7 different areas where more work should be done to fully unleash the potential of AI in healthcare: building awareness, access to data, go-to market, use cases, legal matters, technical and regulatory matters and ethical framework.

COCIR is actively engaging on these topics. For instance, with regard to the ethical framework, COCIR has been member of the European AI Alliance and will pilot the Ethics Guidelines for Trustworthy AI. Next to that, COCIR is also a partner of AI4People. Since 2017.

On the matter of AI, COCIR recommends that:

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 AI 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 should encourage voluntary commitment and allow for self-regulating processes on an industry sector level

6. How can research pilots be encouraged to scale up? What does each actor need to do?

COCIR has said at many occasions that we need to stop doing pilots, including in research, if those are not followed by true and efficient deployment mechanisms and ensuring funding is supporting MSs at their national and regional levels. We have seen too much of such pilots.

Crucial role of industry in ensuring that pilots funded by the European Union are relevant for the market. Early collaboration with systems, HCPs and carers is important to ensure the uptake by users.

Our proposed public-private partnership under Horizon Europe brings together the European Commission and six industry associations, in consultation with member states and other stakeholders (payers, academia, patients, HCPs etc.).

Current proposal for Strategic Research Agenda suggests funding in five areas actions, including to:

- Develop patient-centric, integrated care solutions along the entire healthcare continuum
- Combine Big Data with advanced analytics/artificial intelligence to enable the new integrated healthcare approach

There is a need to ensure synergies between Horizon Europe (funding for R&D&I including pilots, prototypes, demos) and Digital Europe (investment in infrastructure and support for deployment of IT solutions). This alignment should already take place now during the strategic planning process.

The European Regional Development Fund (part of the cohesion policy) also supports the deployment of digital solutions, especially in less-developed regions. The European Commission should encourage and incentivise EU Member States to cooperate with each other in order to meet the challenges in the healthcare sector. Such cross-border initiatives could provide positive synergies between different systems and settings.

Interoperability and the use of international standards are the prerequisites to scale up eHealth solutions. Health authorities have a determining role in incentivising good practice through the demand side. All actors across the care continuum have a duty to incorporate best practices regarding interoperability to ensure data cannot be siloed up.



General Recommendation:

COCIR recommends:

- establishing permanently a High-Level Group by DG CNECT as Chef de File with associated services like SANTE, GROW, RTD, etc...encompassing relevant stakeholders
- and organize joint meetings of eHealth Network with eHealth Stakeholders.



ANNEX 1

On Artificial Intelligence

COCIR White Paper - [Artificial Intelligence in Healthcare](#) (April 2019)

On Big Data

COCIR White Paper – [Making Sense of Big Data Through Analytics](#) (December 2016)

On Blockchain

INATBA Press Release – [105 Organisations Announce New International Association of Trusted Blockchain Applications](#) (3 April 2019)

COCIR White Paper - [Beyond the Hype of Blockchain in Healthcare](#) (June 2017)

On Electronic Identification

COCIR Press Release – [Secure patient identity management is an essential component in advancing integrated care](#) (29 May 2018)

Joint White Paper COCIR, SIA – [Identity in Healthcare – A key enabler to Integrated Care](#) (May 2018)

On Interoperability

COCIR Press Release – [European Commission’s adoption of the recommendation on a European EHR exchange format is welcome](#) (6 February 2019)

Joint White Paper COCIR, IHE Europe, PCHAlliance - [We Are All in This Together: Advancing eHealth Interoperability](#) (May 2017)

On scaling and deployment of digital solutions

Joint statement - [Beyond innovation – supporting large-scale digital health deployment in Europe](#)

COCIR Position Paper - [COCIR Contribution to the EC Cohesion and Values Proposals \(ERDF & CFI and ESF+2\)](#)

Other references:

EU Health Coalition - [Recommendations for a healthier Europe](#)







The EU Health Coalition is a multi-stakeholder Initiative composed of patient organisations, EU research-oriented medical societies, industry representatives and other relevant stakeholders that share a common vision for health.

Integrated Care Alliance - [Multi-stakeholder Digital Health Roadmap to Support Integrated Care](#)

The [Integrated Care Alliance](#) is a multi-stakeholder group of experts committed to working together to develop sustainable health and social care systems that meet the holistic needs of citizens, patients and carers, especially those with complex and long-term health and social care needs.

ANNEX 2

COCIR White Paper - [Digital Health Roadmap to Support Integrated Care](#) (May 2017)

	1	2	3	4	5	6
	CAPTURE	AGGREGATE & SHARE	COLLABORATE	COORDINATE	SMART CARE	POPULATION HEALTH
PHASES						
FUNCTIONS	All stakeholders in the care continuum capture all necessary data	All stakeholders in the care continuum may access, share, aggregate and visualise meaningful data on a daily basis	Multidisciplinary teams, including the patient, formal and informal caregivers and processes for collaboration are set-up	Delivery of integrated care may begin, based on agreed care pathways across health and care settings, covering first medical care but evolving to wellness and social care	Smart applications routinely support caregivers and patients, taking into account the changing medical, social and operational context. Quality management processes are in place	The acquired experience and insights trickles down to health care experts and health policy makers, enabling them to further focus on outcomes and adopt a VBHC approach
	POLICY		INCENTIVES		SKILLS	

	INTEROPERABILITY	DATA PROTECTION	HEALTH TECHNOLOGY ASSESSMENT	
TECHNOLOGIES	<ol style="list-style-type: none"> Usability of EMRs, data capture and navigation tools Non-traditional data capture: medical devices, wearables, social media, -omics, Patient Reported Outcomes Cloud and Mobile-ready tools 	<ol style="list-style-type: none"> Semantic Interoperability for data and workflows Standards Natural Language Processing Identity management and patient consent Visual integration of external data sources Data sharing platforms 	<ol style="list-style-type: none"> IT support for the establishment of teams and collaboration between team members Bi-directional instantaneous communication between team members 	<ol style="list-style-type: none"> Distributed and dynamic workflows and associated tools Patient-specific care plans Visual integration in daily used IT tools and apps Gamification to engage citizens and patients Telehealth
	<ol style="list-style-type: none"> Big Data Lakes (from diverse data sources) Deep Machine Learning (bottom up) Rule based decision support (top down) Knowledge sharing platforms Big data analytics, including risk stratification tools Impact assessment tools 			