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Advancing Healthcare

HOW TO ENSURE **TRUST** IN **ARTIFICIAL INTELLIGENCE** IN HEALTHCARE?

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ARTIFICIAL INTELLIGENCE **IN EU MEDICAL DEVICE LEGISLATION**

SESSION PROGRAMME & SPEAKERS OVERVIEW

Tuesday 11 May 2021

14:00 - 16:00 BRUSSELS TIME (CET)

COCIR, the European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

SESSION PROGRAMME

Although various people may understand the term artificial intelligence differently, it has been a reality in healthcare for decades.

COCIR has identified numerous applications[1] where AI technology has been adopted in medical devices, workflows, and decision-making processes. Rather than replacing the human component of healthcare delivery, artificial intelligence has become a vital tool – a companion - to help improve patient outcomes.

Medical devices are regulated by the new Medical Device Regulation that will apply from May 2021[2]. In addition, a European approach for Artificial Intelligence is targeted for publication on 21 April[3].
It is still unclear how horizontal and sectorial legislation will interact to ensure that high-quality, safe, and performing AI-based healthcare products can be placed on the European market. This webinar is open to anybody involved and interested to learn more about the latest developments in regulation of Artificial Intelligence in healthcare. It is a great opportunity to address questions to experts in the field.

OBJECTIVES

- Learn about the latest legislative trends potentially impacting Artificial Intelligence in healthcare
- Gain insight into the latest regulatory developments for AI-based medical devices
- Exchange views on Artificial Intelligence in healthcare with industry experts, regulators, Notified Bodies, and other stakeholders

1. https://www.cocir.org/activities/digital-health/artificial-intelligence-1.html
2. COCIR analysis on AI in Medical Device Legislation
3. https://ec.europa.eu/digital-single-market/en/news/communication-artificial-intelligence-europe

AGENDA

14:00 - 14:05 WELCOME AND INTRODUCTION **Nicole DENJOY**, *COCIR Secretary General*

14:05 - 14:15 HORIZONTAL DEVELOPMENTS IN AI REGULATION **Salvatore SCALZO**, *Policy and Legal Officer, DG CNECT*

14:15 - 15:05 PART 1 ETHICS & TRUST IN ARTIFICIAL INTELLIGENCE

MODERATOR: **Danny VAN ROIJEN**, *Digital Health Director, COCIR*

View from the EP **Cristian-Silviu BUŞOI**, *Member of the European Parliament*

Healthcare provider perspective **Prof. Elmar KOTTER**, *Chair of ESR eHealth and Informatics SC*

An ethicist's view **Stephen Cory ROBINSON**, *Senior Lecturer Linköping University, Founder Nordic Privacy Center*

Industry perspective **Amied SHADMAAN**, *COCIR member & GE Healthcare*

INTERACTIVE DISCUSSION WITH PARTICIPANTS

15:05 - 15:55 PART 2 CONFORMITY ASSESSMENT OF AI-BASED MEDICAL DEVICES

MODERATOR: **Annika EBERSTEIN**, *Regulations & Research Senior Manager, COCIR*

Overview of medical device software regulation **Nada ALKHAYAT**, *Policy Officer, DG SANTE*

AI and Medical Device Regulation - member state view **Mariana MADUREIRA**, *Coordinator, Regulatory & Projects (Medical Devices) at Health Products Directorate, INFARMED*

Notified body perspective **Andreas PURDE**, *Global Director Functional Safety & Digitisation of Medical Devices, TÜV SÜD*

Industry views on AI under MDR **Koen COBBAERT**, *COCIR MSW Focus Group Chair & Philips*

INTERACTIVE DISCUSSION WITH PARTICIPANTS

15:55 - 16:00 CONCLUDING REMARKS

Nicole DENJOY, *COCIR Secretary General*

SPEAKERS OVERVIEW

Nicole DENJOY

COCIR SECRETARY GENERAL

Nicole Denjoy is the COCIR Secretary General since 2005 and is based in Brussels.
Nicole has gathered more than 35 years of experience in the medical technology industry, working for companies including L'air Liquide, Ohmeda, Boston Scientific and Baxter. Nicole has a Masters in Organisation and Change Management.

Nicole represents COCIR in a variety of influential fora at European Level as well as at international level. Nicole is also Vice-Chair of DITTA, the Global Trade Association representing Medical Imaging, Radiation Therapy and Healthcare IT Industry (www.globalditta.org) and leads the DITTA Industry voice in official relationships with WHO since DITTA was granted a NGO status in 2015 and leads the partnership between DITTA and the World Bank since 2016.

In addition, Nicole is Vice-Chair of the Business at OECD Health Committee representing the private business sector in front of the OECD Health Committee

Salvatore SCALZO

POLICY AND LEGAL OFFICER, DG CNECT

Salvatore Scalzo graduated with a Master's of Science Degree (Italian «Laurea Specialistica») in «European Studies» (with a Law track) at La Sapienza» University in Rome and with a research-oriented Master Programme "Analysing Europe" at Maastricht University in The Netherlands.

He is currently working as a policy and Legal Officer in the field of «Artificial Intelligence» at the European Commission.

Danny VAN ROIJEN

DIGITAL HEALTH DIRECTOR, COCIR

Danny Van Roijen is Digital Health Director at COCIR. Danny holds a Master in Business Engineering and has 15 years of experience as a public affairs professional. Coordinating the association's digital health activities Danny focuses on European policy making, covering topics such as artificial intelligence, blockchain, cybersecurity, data protection, interoperability and mHealth.

Danny represents COCIR in the AI4People initiative and several EU-funded projects.
Danny is also a member of the Stakeholder Cybersecurity Certification Group, established by the European Commission under the EU's Cybersecurity Act. On behalf of COCIR, Danny is chairing the Healthcare working group within the International Association for Trusted Blockchain Application (INATBA).

Cristian-Silviu BUŞOI

MEMBER OF THE EUROPEAN PARLIAMENT

Elmar KOTTER

EUROPEAN SOCIETY OF RADIOLOGY eHEALTH AND INFORMATICS SUBCOMMITTEE CHAIR

Dr Elmar Kotter graduated in medicine from the University of Montpellier, France, and in computer science from the Université René Descartes in Paris, France. He trained in radiology at Freiburg University Medical Center. Dr Kotter is senior consultant and Vice Chair and Head of Imaging Informatics at the Department of Radiology, Freiburg University Medical Center. Since 2008, he is an Associate Professor of Radiology at Freiburg University.

Dr Kotter served as Chair of the «Information Technology» working group of the «Deutsche Röntgengesellschaft» (German Society of Radiology) from 2006 to 2015. He is President of the European Society of Medical Imaging Informatics (EuSoMII) - 2021-2023. He serves the European Society of Radiology as Chair of the eHealth and Informatics Subcommittee - 2019-2022. Dr Kotter has authored or co-authored more than 80 peer-reviewed papers and has given more than 200 invited lectures.

Cory ROBINSON

SENIOR LECTURER LINKÖPING UNIVERSITY, FOUNDER NORDIC PRIVACY CENTER

An Assistant Professor in Communication Design (Docent/Associate Professor in 2021), Cory is the Founder of the Nordic Privacy Center . He is an invited expert in privacy and personal data for AI4People's 2020 «Health and AI» and «Media+Technology» boards, and advises in areas of personal data and privacy. Cory teaches courses in Big Data ethics, privacy in Smart Cities, and topics within communication technology and international marketing.

Focusing on areas of privacy and ethics, his current research investigates disclosure of sensitive personal data, including biometric and health data, in Internet platforms and surveillance technologies, and ethical frameworks for collection of person data in wearables and IoT (Internet of Things). His most recent publication explores the influence of cultural values of trust, transparency, and openness in Nordic national AI policy. The Nordic Privacy Center is a research-based institution inspired by the Nordics' shared cultural values of trust, transparency, and openness, with the intent to inform policy, encourage progressive research in themes related to privacy, including informed, consented use of personal data in AI, IoT, and e-health.

Amied SHADMAAN

COCIR MEMBER & GE HEALTHCARE

In his current role as Director, AI & Clinical Collaborations at GE Healthcare Amied manages AI product development programs with academic and healthcare provider collaborators. The programs under management are centred around taking AI research and discovery projects into new product introductions. These projects span across X-ray, Ultrasound and Nuclear medicine modalities and cover Radiology, Cardiology and Oncology domains. Amied is based in London.

Annika EBERSTEIN

REGULATIONS & RESEARCH SENIOR MANAGER, COCIR

Annika Eberstein is working as Regulations & Research Senior Manager at COCIR. She is responsible for the coordination of all technical and regulatory activities, including the Medical Device Regulation, European and international standardization. She is also responsible for European research & innovation policies, focusing on public funding,

Before joining COCIR, Annika worked on product compliance, standards and R&D&I activities in the ICT and consumer electronics sector. She has a Bachelor's degree in European Studies from Maastricht University and a Research Master in Political Science and Public Administration from the University of Leiden where she also worked as a research and teaching assistant.

Nada ALKHAYAT

POLICY OFFICER, DG SANTE

Nada Alkhayat currently works for the European Commission as Policy Officer in DG SANTE. Previous experience includes a position as Regulations & Industrial Policy Officer at MedTech Europe and a Blue Book traineeship in the European Commission.

She has a degree in Pharmaceutical Law from the Università degli Studi di Parma and a Master's Degree in Advanced European Law & Policies Studies.

Mariana MADUREIRA

COORDINATOR, REGULATORY & PROJECTS (MEDICAL DEVICES) AT HEALTH PRODUCTS DIRECTORATE, INFARMED

Mariana Madureira is responsible for coordinating activities related to European and national projects, within the scope of implementation of new medical devices regulations at Health Products Directorate at the National Authority of Medicines and Health Products (INFARMED), in Portugal. She has also a role of assessor of MD on pre-market and market surveillance activities. Mariana Madureira represents INFARMED at the EU Medical Device Coordination Group (MDCG) and New Technologies WG (MDCG NT WG), where she integrates the co-chairs team. At this national authority, she has more than seventeen years of experience in medical devices, contributing actively for the discussion of its legal framework at national and European level. Mariana is also a member of the European delegations for the subgroups of International Medical Device Regulators Forum (IMDRF) on *Personalized Medical Devices and Artificial Intelligence Medical Devices*.

Andreas PURDE

GLOBAL DIRECTOR FUNCTIONAL SAFETY & DIGITISATION OF MEDICAL DEVICES, TÜV SÜD

Andreas studied electrical engineering and joined TÜV SÜD 16 years ago as auditor and expert for functional safety. He now leads the unit of active medical devices in Germany. The focus team dealing with artificial intelligence belongs to his unit.

Koen COBBAERT

COCIR MEDICAL SOFTWARE FOCUS GROUP CHAIR & PHILIPS

. Koen Cobbaert is chair of COCIR's Medical Software Focus Group. In that role he co-authored the first and second edition of MEDDEV 2.1/6 on the qualification and classification of standalone software and is today co-authoring the software classification guidance for Rule 10 and 11 under the Medical Device Regulation. In that role Koen also co-authored the FAQ on 62304:2006.

In his day to day job Koen works for Philips as Senior Manager - Quality, Standards & Regulations. He has submitted a variety of technical files and 510(k)s for software-only medical devices. Koen has a master's degree in electrical engineering and risk management.

GENERAL INFORMATION ABOUT COCIR

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.

Our focus is to open markets for COCIR members in Europe and beyond. We provide a range of services in the areas of regulatory, technical, market intelligence, environmental, standardisation, international and legal affairs.

COCIR is also a founding member of DITTA, the Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association (www.globalditta.org).

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