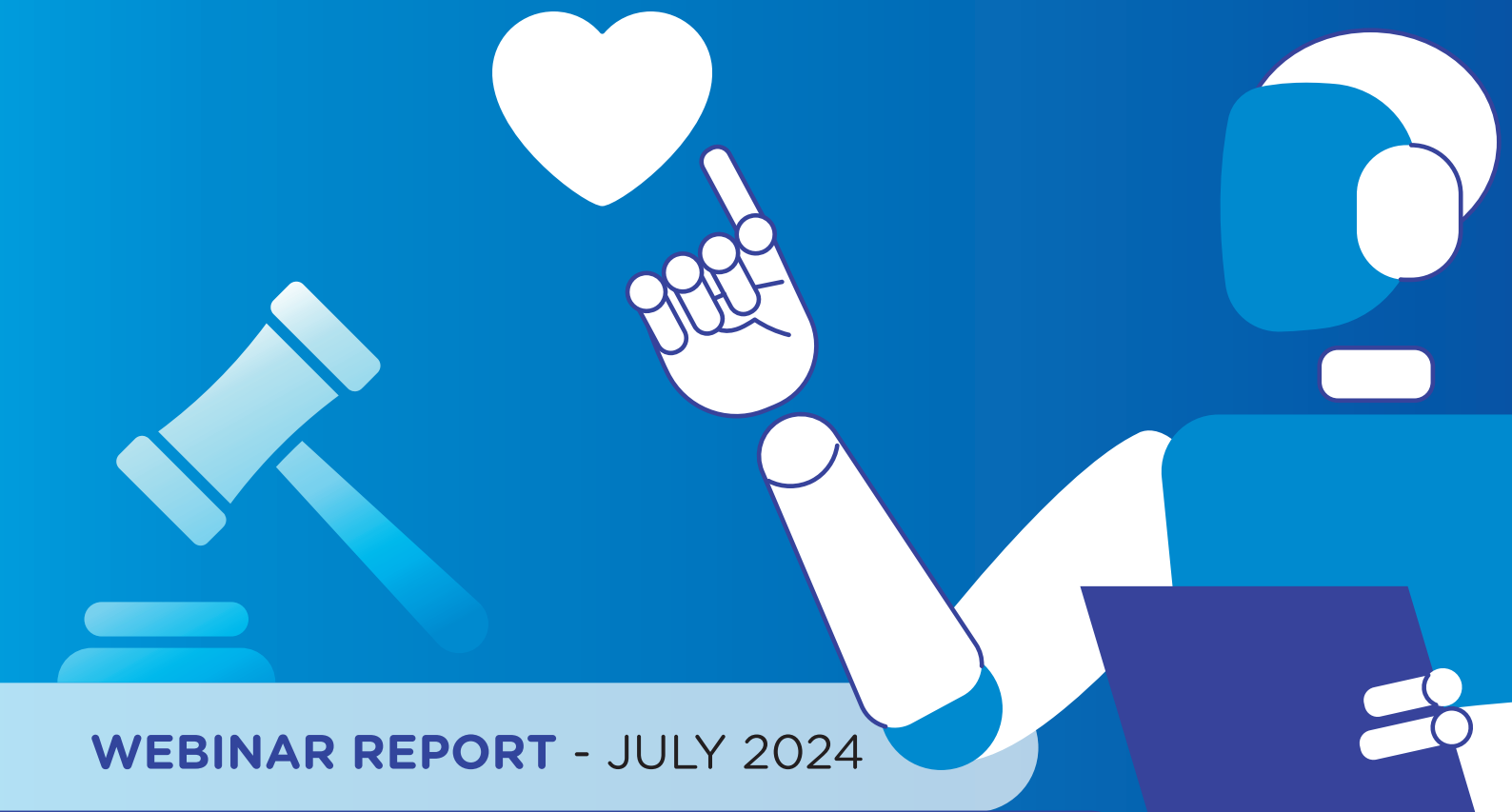
Smart CHANGE | DataTools4Heart | AI4HF

AI in Healthcare:
The AI Act and other Regulatory Issues



WEBINAR REPORT - JULY 2024

Funded by the European Union

The three projects are funded by the European Union under the Horizon Europe research and innovation programm.

Introduction

The extraordinary developments in **artificial intelligence** in recent years hold the promise of facilitating advances in many different fields, and **healthcare** is no exception.

The three projects presented in this webinar (SmartCHANGE together with AI4HF and DataTools4Heart) have all been funded by the EU to carry out exciting research in the use of AI in areas ranging from chronic heart failure to lifestyle improvement in youth.

However, the approval of the Artificial Intelligence Act (the final text of the Regulation 2024/1689 published in the Official Journal of the European Union is available here) on 13 March 2024 by the European Parliament reminds us that healthcare - surely the most human-centric sector of all - needs regulation in order to ensure our ***safety***, ***privacy***, and general ***well-being***.

The AI Act introduces a risk-based approach that tries to strike a balance between necessary regulation and innovation. In addition, it interacts with existing legislation such as the European Medical Device Regulation, which has governed the certification of digital health instruments for several years.

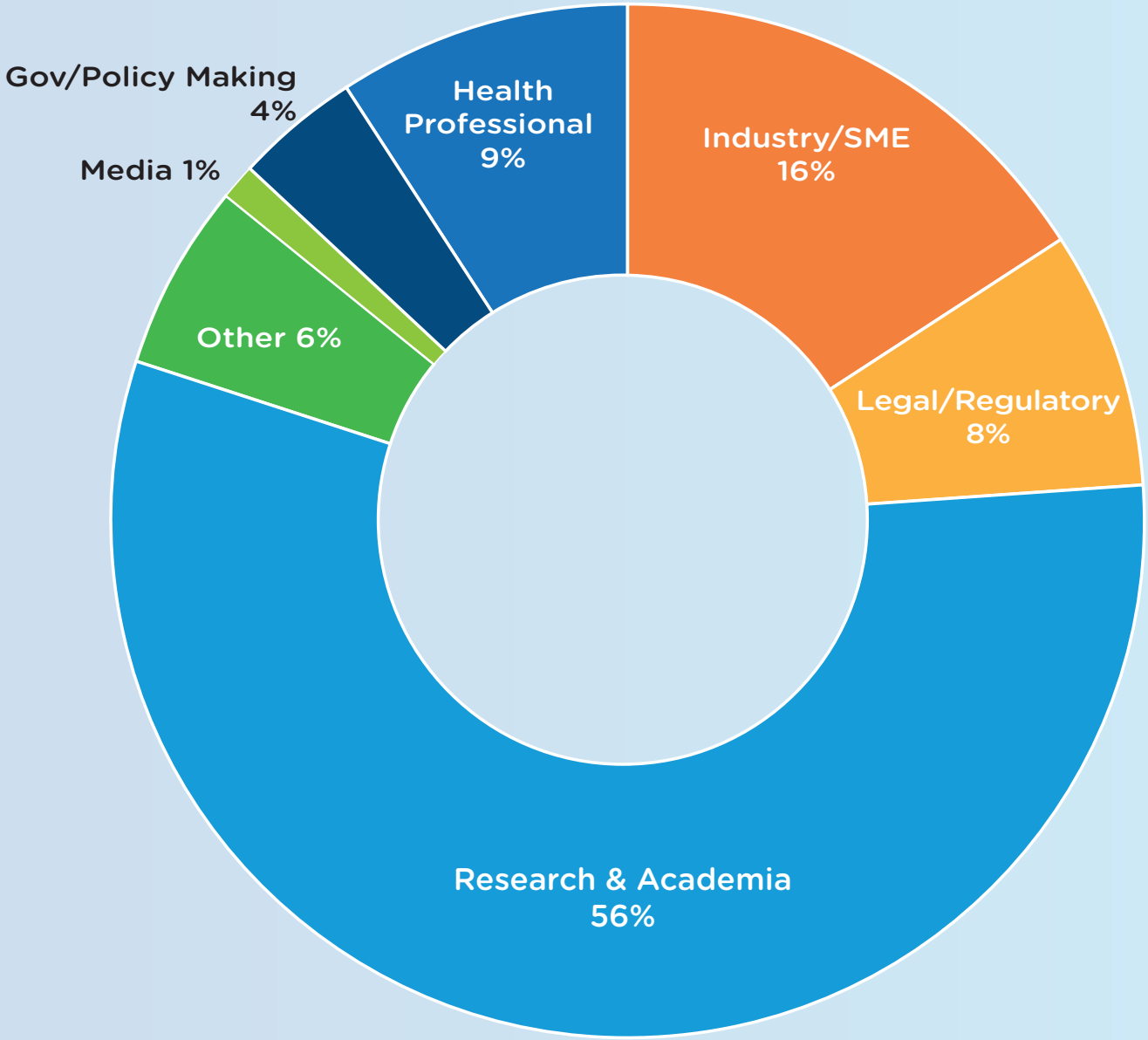
In this first webinar, of the SmartCHANGE's series, our experts provided information and insights from several **different perspectives** resulting from their work in untangling the many new concerns and uncertainties arising from these recent regulatory developments. This post-webinar report summarises insights emerging during the webinar as well as recommendations from our expert speakers.

The complete speaker presentations, together with a video recording of the full session, is available here at the SmartCHANGE website.

Webinar Participation by Sector

The webinar gathered over 130 registrations, with a significant segment of the audience being research and academia – that is, peer professionals who are confronting the same kinds of issues addressed during the webinar. There was also significant representation from industry and SMEs, as well as a sizeable group of health and legal professionals, resulting in a mix of participants that raised several interesting questions over the duration of the webinar.

Webinar registrants: AI in Healthcare - 11 July 2024



Moderator and Speakers

John Favaro, Moderator - Senior Research Analyst at Trust-IT, SmartCHANGE Communications and Dissemination Team

John Favaro is a Senior Research Analyst at Trust-IT, where he is responsible for tracking cutting-edge technologies and trends. He has industrial experience in numerous sectors, and is currently also a Department Editor of *IEEE Software Magazine* and a member of its Advisory Board. John has degrees in computer science from Yale University and the University of California at Berkeley.

Speakers

Paul Quinn – Vrije Universiteit Brussel, Research Group on Law, Science, Technology & Society (LSTS), SmartCHANGE Legal Issues Expert

Prof. Paul Quinn is active in pursuing a number of his research interests as a research professor at LSTS. This includes in areas such as data protection, privacy issues and problems related to stigmatization and discrimination. He is part of the Health and Aging Unit at LSTS where he co-ordinates research on such issues. Paul has developed considerable experience in privacy and data protection issues in the area of health care delivery and scientific research. He has been successful in securing participation for LSTS and the VUB in a large number of research projects as an expert on legal and ethical issues related to privacy and data protection issues. Paul is also a member of the University's Ethics Board for Research in the Social Sciences. He holds degrees in European and International Law (LLM, Institute of European Studies, Brussels), Law (MA, University Sheffield) and Biochemistry, (University of Sheffield).

Achim Mayer - Regulatory Affairs Expert at CE Plus, AI4HF Compliance Lead

Dr. Achim Mayer is a regulatory affairs expert with a focus on software as a medical device and Artificial Intelligence at CE Plus– ceplus.eu. Achim is a Medical Software Engineer by training and received a PhD from Heidelberg University on 3D visualization of medical image data. As a development manager he has gathered more than two decades of experience in the successful development and market authorisation of medical device software products. As a consultant he is now using that knowledge to support numerous companies in CE marking of their products in Europe. In AI4HF he is supporting the team to prepare the developed AI to be compliant with current and future regulatory requirements to facilitate it becoming a certified medical device software.

Renato Sabbadini – Doctoral Researcher, Vrije Universiteit Brussel, Research Group LSTS, SmartCHANGE Legal Issues Expert

Renato Sabbadini is a doctoral researcher at the Law, Science, Technology and Society (LSTS) research group at the Vrije Universiteit of Brussels (VUB) and a member of the Health and Aging Law Lab (HALL). His interests gravitate around the impact of modern technologies, especially AI, on rights and freedoms, in particular the right to privacy and freedom of speech. His experience includes a political career as a municipal council member and an advisory capacity at the European Parliament, as well as several executive positions. He graduated summa cum laude in 1995 in linguistics at the University of Bergamo (Italy). He is currently completing his PhD at VUB.

Lorenzo Cristofaro – Panetta Consulting Group, DataTools4Heart Legal Coordinator

Lawyer, DPO and Partner at Panetta Consulting Group, CIPP/E and CIPM, Lorenzo has been assisting domestic companies and multinational groups for more than 15 years in the fields of Data Protection, Artificial Intelligence, Data Economy, New Technologies, Digital Health and Digital Transformation. He was Legal Coordinator for EU Horizon2020-funded projects MyHealthMyData and currently holds this role for DataTools4Heart and EDITH-CSA. Lorenzo is Senior Consultant at Strand Advisory and Lynkeus and was included among global '40 under 40' by Global Data Review and Data Privacy. For four years in a row, Lorenzo has been recognized as Privacy and Data Protection 'New Generation Partner' in the global ranking of Legal 500.

Questions and Answers

During the webinar and subsequent panel, a number of questions arose, both during the presentations and during the panel session, which were addressed by the speakers. Here we present a representative selection.

Question: Anonymisation is also an act of processing; and so, on what legal basis should data be anonymised by a research institute and be made available to a company for AI product development?

Answer (Paul Quinn, SmartCHANGE): This is a very interesting question, because there is even variation in Member State law about whether anonymisation itself is an act of processing – and so, the answer depends on where in Europe you are. Even with the GDPR, this is not clear-cut across Europe. If you look at the Article 29 Working Party Opinion, I agree that it would suggest that anonymisation is an act of processing. In that case, the anonymiser needs a legal basis to process, and discerning whether that would apply in a particular circumstance is quite contextual.

Question: We are hearing a lot about Generative Artificial Intelligence (GAI). How is it being treated by the AI act?

Answer (Lorenzo Cristofaro, DataTools4Heart): There are a number of obligations in the AI Act that apply to General Purpose AI (GPAI) systems that include GAI. It is fair to say that all of these obligations are in one way or another related to the concept of **transparency** – that is, clarity about the fact that the user is interacting with an artificial intelligence system or model. So, for example, deep fake, synthetic audio, images or video or any kind of AI-driven content produced online will have to display a disclaimer, a privacy notice and AI policy that makes very clear that you are interacting with an artificial intelligence system. Furthermore, in some cases, which are clearly identified by the AI Act, whenever a **systemic risk** – meaning high-risk (for example, concerning public health, individual rights, public policy, environment, and so forth) – can be triggered by these kinds of AI systems, other additional obligations can apply. And further to what Paul said earlier concerning context in the processing of data, in this case it will also be absolutely necessary and crucial to have strict cooperation between legal and ethical experts on the one hand and technical experts on the other hand. And by the way, I'd like to mention that the AI Act has introduced for the very first time in European legislation the concept of **synthetic data** – which (in my humble opinion) are generally treated in the Act more as a type of *anonymous* data than in the context of *pseudonymous* data. Suffice it to say that there is a debate going on right now about the exact nature of synthetic data in this context.

Question: Given the amount of effort (in terms of both work and expense) that can be involved in certification, what are the pros and cons of pursuing certification of a medical device versus "merely" doing research (which enjoys an exemption from certification) in the area of interest?

Answer (Achim Mayer, AI4HF): I believe that it would be a shame if research were to stay research "forever". And if you want to at least retain the chance to move research into a product – either yourself or by a different company – there are certain things you need to prepare for, and data management is probably the most important one of those. Many other things can be retrofitted: you can do risk management later on; you can think about human oversight later on (and hopefully you will find ways to implement a User Interface that will fulfil those requirements). If you don't keep the

actual data, you quite clearly won't be able to use them later to train the model – but this is something that researchers might not be thinking about. For example, you might need specific consent from the patient to even keep that data in order to reuse it to build a certified medical product. That consent must cover the long term, not just a limited period of time for research. To make sure that you are able to review the data for possible bias, you also need to take note of metadata together with the data, so that you can properly review whether your data is sound, or later on if you were to hit a potential problem, you could go back and try to see where the problem is coming from (for example, is there an imbalance over the data? Is more data needed for different age groups, or different regions?). But if you haven't taken note of those characteristics from the very start, then it will simply be gone.

Remark (Paul Quinn, SmartCHANGE): I'd like to add this thought: we all know that in the past there has been a problem with EU projects producing tangible products that go to market. This is something that the Commission might want to consider in the future while designing the calls, tailoring them in such a way as promote concrete, pragmatic results, and to avoid a focus on "just getting through the project", rather than considering medical device certification.

Question: Is there a middle ground between full medical device certification and pure research with no certification whatsoever? What about, for example, products in the so-called "wellness" category?

Answer (Renato Sabbadini, SmartCHANGE): The issue in the case of SmartCHANGE is that it starts by putting together two things that in the real world are not normally considered medical devices: on the one hand a risk calculator, and on the other hand a kind of wellness application used within the family for children and teens. The fact is that here, in terms at least of the research necessary to produce SmartCHANGE as a self-standing tool without the need of a healthcare professional in the long-term future, there will be years of research needed and validation of the results before that can happen. So the question is: while you have these two separate components that in reality are not medical devices but when you put them *together* and the healthcare professional becomes a central figure to interpret the data produced by the tool in order to formulate advice and a risk-minimizing strategy for the family, has it become a medical device? The answer is probably Yes. In general, this is a problem because the GDPR, Medical Device Regulation, and the AI Act are all relatively recent pieces of legislation. For the GDPR you already have consistent case law with many gaps filled in; currently less so with the other pieces of legislation, although the same thing is expected to happen eventually. And so, this puts everybody in an uncertain position as to which interpretation will eventually establish itself.

Looking Toward the Future

Given the uncertainty around the evolution of regulation affecting AI in Healthcare, the speakers were asked for their thoughts on how they see the near future unfolding: what are their hopes and concerns around the regulatory landscape, and its impact on researchers, developers, and all of us as end users of these new and powerful technologies?

Achim Mayer, AI4HF

I believe that by now I have exposed myself as somebody who mostly *welcomes* what is described in the AI Act (I realise not everybody will enjoy hearing me say this). I think that the majority of what is described there is actually best practice that we should all be following. While acknowledging the fact that formal certification is costly and time-consuming, generally speaking I'm quite happy from a medical device point of view with the principles described in the AI Act. There two things I have pointed out already which I think are going to cause a lot of discussion, which I hope they will find a compromise on. The first is **sandboxes**, which should be a way to "go live" without being certified under the supervision of your local competent authorities – which, if done correctly, should help especially smaller companies to move into the market without first having to overcome the huge burden and lengthy procedure of certification first. That is something I'm looking forward to, if done correctly. The second issue is **adaptability**. This is something that people involved in the Medical Device Regulation still shy away from: you build something, you freeze the design, validate it, and then put it into the market. Having this adapt *while it is in the market* makes classical MDR people "freak out" – but it is certainly something which is a necessity in a fast-moving world which AI is part of now. In fact, this shouldn't be limited to AI only, but *anything* which should adapt quickly to the environment that it is deployed into. In summary, the future is going to be interesting!

Lorenzo Cristofaro, DataTools4Heart

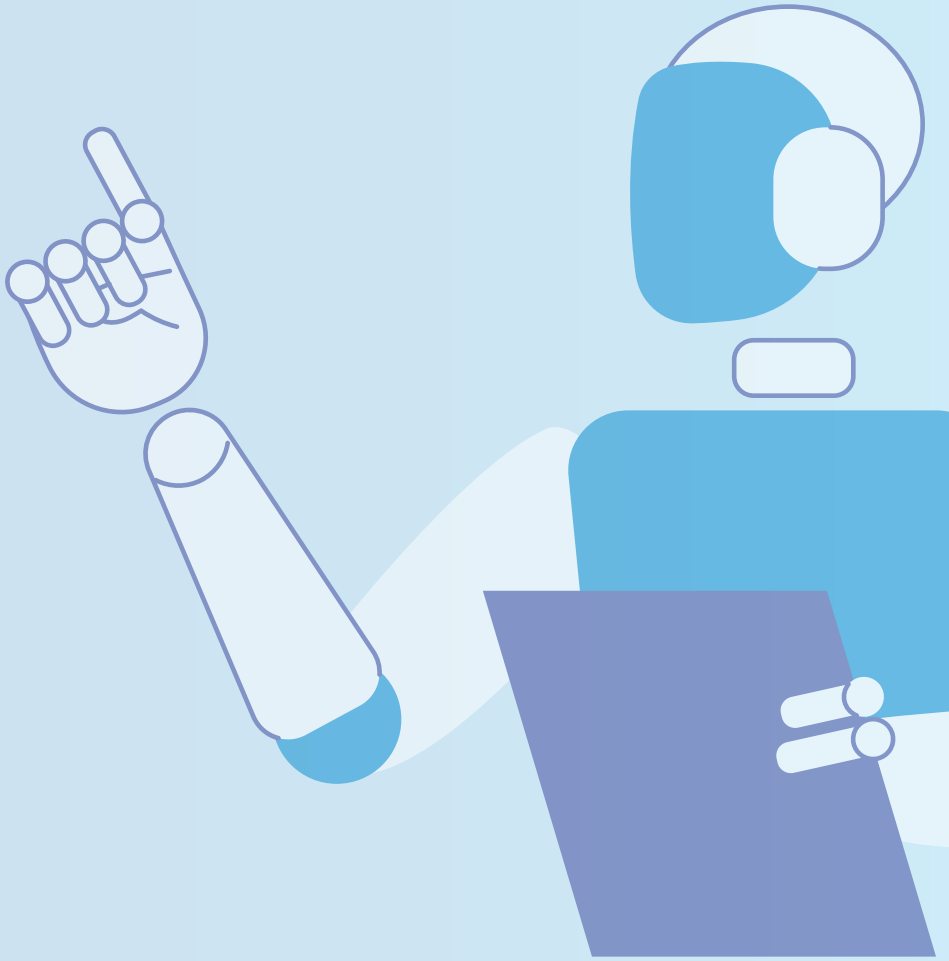
From my perspective, it will be absolutely crucial that all of us, and especially market players, take a very strict **ethics** approach. In the AI Act, it is absolutely evident that the distinction between legal and ethical issues is very blurred. There are many obligations that can be considered as *both* coming from an ethical perspective and from a typical legal scenario: transparency, non-discrimination, clarity, human-in-the-loop, and so forth. I would say that ninety-nine percent of the obligations can be considered as having both a regulatory and ethical nature. It will be necessary that this kind of ethics approach be concretely implemented by developers of AI systems (and especially *models*), to protect children, to protect minorities, and to protect all of us in general – because it is not always easy to understand the outputs of an AI system: What is real? What is fake, generated by AI? And so, considering that our high-risk systems cannot possibly foresee everything that will happen in the future, an ethics-based approach will be absolutely necessary in order to ensure that human rights are safeguarded. Otherwise, I see a scenario that may trigger problems in the future.

Renato Sabbadini, SmartCHANGE

We live in very interesting times indeed, because the legislature has now produced some very important pieces of legislation on technology that is probably already central, but is probably going to become even more central to our lives in the future. But, because of this, I suspect that it will likely be a bumpy road before we get to clarity for anyone who researches and then produces AI related systems and products.

Paul Quinn, SmartCHANGE

There are simply too many issues to address, of course, so I'll restrict myself to saying a few words about the data protection topics I was discussing earlier. I hope and believe that in the coming years we will see more cases at the highest level in Europe that will sensibly narrow the notion of **personal data** to make it more intuitive and to allow further innovation



About the Projects

Obesity and a lack of physical fitness are risk factors for various non-communicable diseases (NCDs). Many NCDs have early precursors that manifest at a young age, and unhealthy lifestyles are prevalent during this period. SmartCHANGE aims to develop long-term risk prediction models for cardiovascular and metabolic diseases in individuals aged 5 to 19. Machine-learning methods enable accurate risk prediction, while federated learning techniques ensure data privacy. These methods are being leveraged to design two applications (one for health professionals and another for citizens).

Cardiovascular disease (CVD) remains the main cause of mortality worldwide, accounting for about a third of annual deaths. Re-use of both structured and unstructured data has the potential for major health benefits for the population suffering from CVD. Healthcare data re-use in Europe faces privacy and fragmentation issues, a high diversity in data formats and languages, and a lack of technical and clinical interoperability. DataTools4Heart (DT4H) is tackling such challenges and developing a comprehensive, federated, privacy-preserving cardiology data toolbox.

Cardiovascular diseases continue to claim countless lives worldwide, with heart failure (HF) at the forefront of this health crisis. HF's intricate web of causes, symptoms and unpredictable courses presents an urgent need for tailored care. In this context, the EU-funded AI4HF project will reshape the landscape of HF management. By harnessing the power of advanced AI, this project aims to develop a reliable and personalised approach to assessing and addressing HF risks. Its robust testing across diverse clinical centres and adherence to ethical AI development guidelines make it a beacon of hope for HF patients worldwide. AI4HF envisions a future where HF is met with precisely tailored, cutting-edge solutions.

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Access the complete speaker presentations and unlock valuable insights from our recent event.

https://tinyurl.com/3xv58ra2