# SPECIAL COMMITTEE ON ARTIFICIAL INTELLIGENCE

# IN A DIGITAL AGE (AIDA)

# HEARING ON AI AND HEALTH

**Panel I: AI Governance in the Health Sector**

Kyriakos Pierrakakis, *Minister of Digital Governance, Greece*

Vicky Lefevre, *Head of Unit Public Health Functions, European Centre for Disease Prevention and Control*

Claire Bury, *Deputy Director-General of the European Commission, Food and feed safety - innovation, Health and food audits*

Prof. Laura Palazzini, *Professor of the Philosophy of Law at the LUMSA University in Rome*

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**Panel II: Exchange of views with representative of the Industry, Civil Society and Academia**

Prof. Frank Noe, *Professor for Artificial Intelligence in the Sciences, Freie Universität Berlin*

Doctor Markus Lingman, *Senior consulting cardiologist and Chief Strategy Officer, Board member at Halland Hospital Group*

Prof. Andrew Hopkins, *Chief executive officer of EXSCIENTIA, Chair of Medicinal Informatics and SULSA Research Professor of Translational Biology*

Jelena Malinina, *Digital Health Policy Officer at the European Consumer Organisation*

**BRUSSELS**

**WEDNESDAY 2 DECEMBER 2020**

1-002-0000

**IN THE CHAIR: DRAGOŞ TUDORACHE**

*Chair of the Special Committee on Artificial Intelligence in a Digital Age*

*(The hearing opened at 9.05)*

# 1. Opening remarks

1-004-0000

**Chair.** – Thank you very much and good morning to everyone. Welcome to this new hearing of the Special Committee on Artificial Intelligence in a Digital Age (AIDA). Let's hope that technology will work with us throughout this important hearing, important discussion that we have scheduled for today and that everything will work smoothly.

I have two points of order and a very brief Chair's announcement to make before we move on to the substance of the hearing. The two points of order relate to the adoption of the minutes of our last meeting of 9 November and also the adoption of a calendar for the hearings of 2021 – a calendar that for now only consists of the dates, not yet the topics, for these hearings. We have tried in this calendar, which was also endorsed by the coordinators, to accommodate as much as possible most of the Members of our committee who are mostly sitting either in the Committee on the Internal Market and Consumer Protection (IMCO) or in the Committee on Industry, Research and Energy (ITRE) in a way that the meetings of AIDA will not overlap again to the extent possible with the ITRE and the IMCO hearings over 2021, and I believe we have tried to do that in the best possible way. So if there are no objections, we would be adopting both the minutes of the last meeting as well as the dates for 2021.

In terms of the Chair's announcements, I will only take notes, and I'm sure that you know that on 25 November last week, the Commission adopted its proposal on the Data Governance Act: of course a very important first piece in the puzzle related to the overall data strategy of the EU. There will be two new proposals, and again I'm sure you know that on 9 December next week on the Digital Markets Act and the Digital Services Act, two other very, very important pieces of legislation, all of which will, of course, be part of the analysis and the reports that this committee, under the lead of our rapporteur, Mr Axel Voss, will be part of our assessment in the final report of AIDA.

It is important to state the goals of the proposal of last week. According to the Commission, this proposal is meant to facilitate data sharing across the EU and between sectors, with the overall objectives of creating wealth for society, increase control and trust of both citizens and companies regarding their data, and offer an alternative European model to data handling practices of major tech platforms. Again, I am hoping that somewhere in 2021 we will also be able to schedule some hearing that will look into the governance of data in the EU, the way we use industrial data, personal data and how it all benefits to artificial intelligence and to the objectives that we set for the Union in this regard.

With that, I'm done with the formal part of the opening of this hearing and we can move on to the substance. We have an important topic today and that is AI in health: how AI contributes to the health sector. I think it's no surprise why we have chosen health as the first thematic section of the first thematic hearing of our committee. It was a consensus at the level of the coordinators of all the political groups that we should start with this theme because of its importance also for our citizens, and I think that if we ask citizens in the street, as well as politicians, they would all say that one of the first benefits that comes to mind when we speak of technology and

artificial intelligence is its contribution to the health sector, and again, that reflects into the priority that we have decided to give ourselves to this topic.

I will go through the housekeeping rules for this section, how it is structured, how we go about discussing, interacting, having the conversation that we wanted to have on this topic. We have structured today's hearing into two panels, in two parts. We will start with a first introductory remark coming from our colleagues in the Committee on the Environment, Public Health and Food Safety (ENVI) Standing Committee, which we have asked, given their competence on health policies, to address a few words at the beginning. Mr Adam Jarubas, who is also the rapporteur of the ENVI Committee on the opinion on a framework on ethical aspects of artificial intelligence, robotics and related technologies, to give those opening remarks. He will have five minutes right at the start to present the position and the views of ENVI on these important topics.

Afterwards, we will start with the first panel and then the second panel, each of them with the same structure. Each panel is broken down in three parts. The first part would be an opening remark from our guests. We have four guests for the first panel and four other guests for the second panel. Then the second part of each panel will be a brief, moderated interaction of the panellists, orchestrated by Mr Wolfgang Hiller, for the Directorate for Impact Assessment on European Added Value in our own Parliament's EPRS services. That will be slotted for 20 minutes. Afterwards, in each of the panels, we will open for interaction with our Members. Each Member will have a five-minute window to interact with the panel, where ideally the first two minutes would be reserved for the question. I would kindly ask that we stick to these time slots so that we can all be fitting into the time that we have. So, two minutes for the Members to ask their question, to pose the concerns, the observations that they have and also address those questions and observations to one of the panellists or to two of the panellists. The idea is to stick to the five-minute window and then, right after the question, without me intervening so that we can save time, the respective panellist to whom the question is addressed will have an extra two minutes to respond.

At the end it was the first panel, we will also have an intervention from the Chair of Science and Technology Options Assessment (STOA), Ms Eva Kaili, related to the topic of the first panel, which is governance in the health sector, and then immediately afterwards we will start with the second panel, which will follow the same structure. And at the very end and we have slotted some concluding remarks were Mr Axel Voss, our rapporteur, will also present his views on the topic of today and will close, together with myself, the session.

So without further ado, I will now start our hearings on AI and health and I will give the floor to Mr Adam Jarubas, representative of the ENVI Standing Committee, for five minutes to give us the views of ENVI on this topic.

1-005-0000

**Adam Jarubas (PPE),** *Member of the Committee on the Environment, Public Health and Food Safety***.** – In view of the limited time, allow me to focus on a few points from the ENVI opinion. According to the European Commission estimation, every year more than 400 000 people in the EU die prematurely due to the consequences of air pollution. AI supports transport decarbonisation and energy efficiency. This means also smog reduction, better air quality impacting health. On the other hand, we have to be aware that AI development is highly energy consuming. The EU's strategy, as stated in the AI white paper, should therefore be pursuing advantage in energy-efficient computing and progressing the Green Deal, energy, just transition. And the opinion stresses that AI solutions may reduce the use of pesticides, fertilizers, supporting Precision Farming 2.0, marking effective production with higher environmental standards and better utilisation of resources. Apart from improving food safety,

this will contribute to health in rural areas, and the opinion stresses that AI can be applied to almost any field in medicine.
During last week's plenary presentation of the Pharmaceutical Strategy for Europe by Commissioner Stella Kyriakides, a lack of new antibiotics and rising antimicrobial resistance was emphasised. AI can offer solutions in biomedical research as exemplified by the AI-discovered new antibiotic halicin in 2019. And the position explores AI benefits and challenges to many areas, from cancer early diagnosis, personalised therapies, via medical education, revolutionising robotic prostheses, telemedicine, to overall efficiency and interoperability of the health system, diminishing costs and increasing accessibility.

Special attention should be pitched to AI potential for transmissible disease control. A Canadian start-up using AI analysis of big data from formal state reports to internet social media chatter predicted and warned about the COVID-19 pandemic nine days before the WHO. The ENVI opinion and the position adopted in plenary urged the Commission to equip the European Centre for Disease Prevention and Control (ECDC) with the legal framework and resources, including such AI tools. With satisfaction, I note that the recent Commission communication on building a European health union proposes such solutions.

AI in medicine has tremendous capacity to threaten patient safety, preferences, data security and privacy. Regulations addressing those will require review, including a new legal framework on data protection and privacy. The Union must undertake all necessary steps to guarantee that its ethical values expressing the acquis apply effectively to all AI areas. The risk-based approach methodology proposed by the Commission recognises healthcare as an AI high-risk sector by default and introduces requirements beyond existing Union rules. ENVI strongly supported the Commission in establishing a common Union AI ethical framework. We must prevent AI double standard across Member States for AI developed in the Union and beyond. We should not lose economies of scale offered by common EU market. AI needs data; health research needs AI data analysis.

One of the flag initiatives of the Pharmaceutical Strategy for Europe debated during last week's plenary is European data space in the field of health, to be initiated in 2021. By 2025 the space is *(inaudible)* the cross-border use of information. Working in European Parliament's Committee on Beating Cancer, I found it crucial. I cooperate, among others, with the Polish Oncological Society and its oncological network. Their experience shows that IT solutions – big data artificial intelligence analysis – can bring substantial progress in research, but also in overall optimisation and accessibility of oncological healthcare. Further support is needed to progress oncology based on big data. Oncology is a unique area where synergies between Horizon Europe, Cancer Mission, EU4Health and European health union could bring revolution by applying AI analysis to big data in transnational data space. Disease and health may depend on DNA code, but health must not depend on postal code. We need equal opportunities EU-wide but also between highly- and less-urbanised areas, and AI in health can assist with this.

1-006-0000
**Chair.** – Thank you very much Mr Jarubas for the words brought from the Committee on the Environment, Public Health and Food Safety (ENVI), of course very important work that they do also on your side, and clearly there's room to further engage, interact between ENVI and the Special Committee on Artificial Intelligence in a Digital Age (AIDA) in the future.

## 2. Panel I: AI Governance in the Health Sector

1-008-0000
**Chair. –** We will now start with the first panel, and I will very briefly present the four speakers for this panel, of course thanking them very much for the availability to interact with us today. The first speaker is Mr Kyriakos Pierrakakis, the Minister of Digital Governance in Greece.

The second speaker is Ms Vicky Lefevre, Head of Unit, Public Health Functions in the European Centre for Disease and Prevention and Control. The third speaker is Ms Claire Bury, Deputy Director-General of the European Commission Food and Safety, Innovation, Health and Food Audits; and the fourth speaker is Professor Laura Palazzini, Professor of Philosophy of Law at the LUMSA University in Rome. For all the speakers, try please to stick to the five minutes for your initial interventions and then Mr Wolfgang Hiller will take over for the second part of a moderated discussion before we open the panel for interventions from our Members.

1-009-0000

**Kyriakos Pierrakakis,** *Minister of Digital Governance, Greece***.** – Mr Chair, dear colleagues, thank you for today's invitation and for the organisation of this virtual meeting. For the Greek Government, digital transformation is a priority. It's one of the key policy areas on which we have been greatly focusing since 2019. COVID-19 has acted as a digital accelerator on all fronts, making tackling outstanding issues, in our case, an absolute necessity.

We believe that, first of all, prior to speaking about A.I. and about Fourth Industrial Revolution technologies, one needs to have concluded all outstanding ... *(interruption for technical reasons)*

So, as I said at the beginning, thank you for today's meeting. Digital transformation has been at the forefront of the Greek Government's policy ever since 2019. A.I. and all Fourth Industrial Revolution technologies of course have been at the forefront of our policy design since this new government came to power. But we understand very well that one needs to have concluded outstanding issues with Third Industrial Revolution technologies in order to better proceed.

So, the interoperability of systems, the development of ICT systems in the health sector and elsewhere, something as simple as the digitisation of files, of paper and rendering paper files into data, into information, is a necessity in order to be able to move forward, because the necessary ingredient of artificial intelligence is the capability to have big data. It is the capability to feed algorithms with data. Thus, what we're currently doing and will be announcing as a government is our digital bible – our national digital strategy – this week. We presented it in Cabinet. Putting down a series of 400 projects for the next four years is actually to fill this gap analysis, to have a very clear idea of all the different systems that we need in order to be able to take the next step in A.I.

To give you an example, in the area of health, we currently have a digital prescription system which we have actually used a lot during the COVID-19 lockdown, having augmented it to allow citizens to receive prescriptions from their doctors via SMS or by e-mail. But we still lack electronic patient records and this is because we still need to put systems in place in more private and public hospitals in Greece that will be interoperable and that will have the capability to 'feed' such a system centrally.
Also, we understand that this transition from paper to data, from paper information, is also a necessity, and we will be making good use of the RRF funds (Recovery and Resilience Facility) and the funds of the next programming period of EU structural funds in order to be able to upgrade ourselves on our digital technologies.

Now, on A.I. per se, obviously there is a big regulatory issue at hand and a big data privacy issue at hand. The GDPR (General Data Protection Regulation) is obviously a compass for us, first of all, to begin with. But we understand that, moving forward, this regulatory framework needs to be further augmented and it's our view that it should be augmented both at European and national level. But, generally speaking, we need to make a next step as a Union on how to regulate algorithms and how to move forward with the necessary requirements for algorithmic transparency, for instance, which for us would also be a necessity for A.I. algorithms moving forward.

Now, infrastructure investments are necessary in any policy area. We are speaking about health, but on taxation, for instance, which is also a policy priority for us and how to use A.I. algorithms in taxation will also be a key ingredient of policy moving forward.

Thus, we believe that there are challenges ahead. The biggest challenge for us had traditionally been to outline a strategy. We have a very clear strategy right now and a very clear action plan for the years ahead.

Financing capabilities were previously a challenge but the RRF will provide us with the opportunity to cover those financing acts together with the next EU programming period.

We recently passed a law on open data, on the transposition of EU communications code(s) and a series of other measures, which collectively – our digital law – gives us, I would say, the legal software to be able to take the next steps.

Thus, most of the policies so far have been uncovering the gaps of the past.

Nonetheless, we have started implementing A.I. algorithms, step by step, in our daily interactions with policy. One such example has been the usage of a PLF form (Passenger Locator Form) for citizens who wanted to visit Greece. We integrated an A.I. algorithm by researchers, developed within the PLF, to optimise target testing for those who wanted to visit Greece in the summer. But our plan overall is to start integrating A.I. algorithms on all facets of policy.

The overall idea is that as we will be achieving interoperability, as we will be pooling big data analytics and big datasets within the next couple of years, we will also *(inaudible)* test *(inaudible)* products on every *(inaudible)* area in A.I. in order to better see how this can feed our policy design and how it can further stimulate and educate the way we make decisions.

Obviously, transparency is a given in all of those policy decisions and, obviously, we understand that collaboration is also a necessity with our EU partners and other EU Member States.

Bearing all this in mind, to conclude, the way forward is to adopt a national strategy of gentle, gradual integration of artificial intelligence into the systems of public administration, starting with pilot applications in specific policy areas, and health will be one of them.

Therefore, we encourage the introduction of systems that are ‘trained’ in open paid public datasets, rule-based A.I. systems or systems that enforce human supervision as a last step in our decision-making.

1-010-0000

**Vicky Lefevre,** *Head of Unit Public Health Functions ECDC* **.**– First of all, I would like to thank you very much for giving the European Centre for Disease Prevention and Control (ECDC) the opportunity to bring our perspective on digitalisation and artificial intelligence (AI) for EU surveillance of communicable diseases. In the last years we’ve made quite some progress in the area of process automation and digitalisation of our systems through the ongoing surveillance systems re-engineering programme.

So you may think, what is surveillance? Now the ECDC collects epidemiological data on 58 infectious diseases across Europe. The bulk of the data is actively submitted by the Member States on a weekly, monthly or annual basis, depending on the disease, through the ECDC surveillance system. For example, for COVID-19 this data submission is weekly.

The system currently already allows machine-to-machine data transmission and it includes automated verification, validation, analysis, reporting and visualisation steps, which reduces the burden on the Member States and also on the ECDC surveillance experts who are the users of the system. The system still needs to be improved in terms of capacity and technology, and we are launching an upgraded system next year which will be called EPIPULSE and this system will be further expanded in 2022.

We also must be realistic. The transmission of the data from the place where it is generated, be it the general practitioner, the hospital, the lab, through the local, regional and national authorities until it reaches the EU level still requires a lot of human intervention. It means putting the data in the right format and it sometimes even still includes paper notification steps at the sub-national level in some Member States, which means that this is time-consuming and resource-intensive. Also this machine-to-machine transmission requires adaptation of the systems on the Member States' side. So this is where the major investments are needed in the future on infrastructure and improved technology.

We are currently exploring the use of electronic health records for EU surveillance purposes. This is what we call secondary use. These health records contain the patient's medical history and, as was said before, this is still at an early stage and it heavily depends on the Member States, the progress that has been made. We are launching a proof-of-concept study on the use of electronic health records for severe acute respiratory *(inaudible)* COVID next year. In the future such data from electronic health records would be obtained through the European health data space to which the ECDC would connect in the future with EPIPULSE, but currently the health data space is still rather at the conceptual stage, with a very limited number of Member States connected.

Because of issues with the timeliness of Member States' data reporting, the ECDC also does internet-based epidemic intelligence screening for global monitoring of infectious diseases. For instance, for COVID, the information on the number of cases and the number of deaths is collected on a daily basis by the ECDC through web-scraping techniques. This is done at country level for the world and at subnational level for the EU, EA and the UK. In this area, an agreement at EU level on the data formats and semantics used for the publication of those data on national websites – and this has been proposed by the e-Health Network – would facilitate this process enormously.

Also through the epidemic intelligence on a daily basis, the ECDC screens webpages for the detection of public health threats worldwide and this is done through web aggregators, such as GPHIN, EIOS, MEDISYS, HealthMap and other automated tools for signal detection. So AI is certainly the present and the future for epidemic intelligence, allowing automation of the processes, but also improving the timeliness and the sensitivity in detecting signals.

Another such example is epitweetr, which is a free, open source, R-based tool that has been recently developed by the ECDC and that supports automatic monitoring of Twitter messages for detection of public health threats.

In addition, epidemiological modelling and forecasting techniques have been widely used by the ECDC, and also in the Member States, to provide the short and also longer-term projections on the COVID-19 pandemic and they have also been used to assess the effectiveness of the measures that have been put in place, what we call the non-pharmaceutical interventions.

To conclude, staying abreast with the latest scientific developments has been one of the major tasks of the ECDC during this pandemic. With thousands of *(inaudible)* posts published on a weekly basis. So this is a very resource-intensive work and also in this area of systematic

literature reviews, the ECDC is exploring the potential of artificial intelligence, in collaboration with the European Food Safety Authority, which is leading on this project.

Concerning the application of artificial intelligence techniques, we are still at an early stage with some applications already in use on a daily basis, but others still very much under development.

1-011-0000

**Claire Bury,** *Deputy Director-General of the European Commission, Food and feed safety – innovation, Health and food audits***.** – I'm very pleased and honoured to participate in this panel. Thank you very much for inviting the Commission along. As several of the speakers have already said, we observe very rapid developments on artificial intelligence in health at the moment, thanks to the availability of more health data and unprecedented advancements in AI, and these advancements from the Commission's perspective offer a very promising potential to revolutionise healthcare.

I think we see this in many facets of health care from prevention, epidemiology, public health, to diagnosis, imaging technologies and to treatments, drug discovery. Every week there seems to be some kind of new discovery. For example, this week the remarkable discovery of how to predict what 3D shape a protein may take, which might help find drugs for incurable diseases. But there are still some important challenges to overcome, and I'd like to just talk briefly about the challenges and what the Commission is doing to try and overcome those challenges for the moment.

So first of all, at the outset, for AI to provide tangible benefits it requires vast amounts of health training data – much more than is currently available. So this means that different types of health data should be collected and electronic healthcare records should be created. Ms Lefevre mentioned how important this is in terms of delivering benefits in practice.

In order to achieve this, it's essential that the Member States and healthcare providers set up the appropriate infrastructure, and this requires expertise and it also requires financial resources. It's essential that the health data which is collected is of good quality and, of course, free of biases. Additionally, health data and electronic health records should be interoperable and easily transferable between the Member States and within the Member States, of course, as well.

Another substantial concern for healthcare professionals and providers are the rules on privacy. As the Minister mentioned, the fragmented implementation of the data protection legislation in different Member States, which the Commission has seen in a series of workshops that we ran with the German Presidency at the beginning of this year, makes it very difficult to collect and transfer health data between healthcare providers in the EU. The deployment of AI in real healthcare settings also encompasses its own challenges, because there are uncertainties related to safety and liability in AI in health care, which might create further mistrust and concerns over the use of AI in health.

Another pressure on health care systems is, of course, capacity-building and the development of digital skills. So what is the Commission doing to address these challenges? The Commission is trying to work to address these challenges through different actions and instruments. These range from legislative initiatives facilitating cooperation, exchanges of best practice and supporting the Member States actions and specific projects through various funding instruments.

On the legislative front, the Commission is now working intensely towards the creation of the European Health Data Space, which Ms Lefevre also mentioned and its relevance to the work of the ECDC (European Centre for Disease Prevention and Control). The Commission aims for

the adoption of a legislative proposal on the European Health Data Space in 2021 so that we can move from what is now indeed a conceptual phase into reality.

This proposal will have three main objectives. First of all, to put in place a clear framework for health data, including issues of governance, privacy, quality of health data and rules concerning infrastructure and interoperability, and in this respect it will be complementary to the Data Governance Act, which was adopted last week. Secondly, removing obstacles to the free movement of digital health services and products in the internal market. And thirdly, establishing clear rules for digital health, including artificial intelligence in health.

Regarding funding for actions concerning health data, digital health and AI in health, the Commission provides support through a series of different instruments: at national level through the European Social Fund, InvestEU and especially the Recovery and Resilience Facility, which the Minister also mentioned that Greece would be using in respect of their digital health systems, but also projects at European level, especially via the EU4Health Programme, the Digital Europe Programme and Horizon Europe.

So to conclude, the Commission hopes that, by combining these different tools and instruments, we can address the obstacles to a successful development and deployment of digital technologies in AI in the health sector and to make Europe one of the world leaders in this area.

1-012-0000

**Laura Palazzini,** *Professor of the Philosophy of Law, LUMSA Rome***.** –Thank you very much for inviting me. It is an honour to take part in this hearing. I would like to say that it's not very easy to outline in a few minutes the ethical framework of a debate of AI applied to medicine.

I should say that we have very different ethical frameworks, because we have very different AI application in medicine. We have also a heterogeneity and pluralism in ethics, ranging from a technophilic attitude, that is open to technology's application of AI in medicine, and technophobic, that's against application of AI.

There are in Europe and on international level a lot of committees of bioethics just discussing in interdisciplinary and pluralistic way these questions of AI. I would like to quote, for example, a working group in UNESCO – International Bioethics Committee (IBC) – and also in WHO (World Health Organization). In Europe, I am a member of the European Group of Ethics in Science and New Technologies at the European Commission. We issued a statement on exactly this question of ethics of AI in 2018. Also at the national level, as a member and Vice-Chair of the Italian Committee for Bioethics, we issued opinions.

And there are opinions from UK, Sweden, so we have a lot of documents about this idea – to have a prudent approach to the application of AI, using AI, because it opens new opportunities, but on the other hand, to have careful attention on the risks of AI. In these documents, you may find something very common on ethical point of view.

I want just to mention some ethical requirements for the regulations of AI applied to medicine. Starting from the idea that, because of the rapid acceleration of technological progress, above all, in AI applications, we cannot just rely on thinking about ethics and thinking about regulation after the application, but we need to anticipate ethics. The anticipatory ethics is now really a very innovative approach to this technology.

The idea is that we need to focus on ethical requirements and to include these ethical requirements from the beginning – that is, by design, in design, for designers of the technologies of AI. Which are these requirements?

The first one is the so-called 'meaningful human control'. This was an expression that was used in the military setting, above all, in robotic weapons. But it's very important also in AI applied to medicine, because of the possibility to have a sort of replacement of the machine to the physician. Think about software that can stratify patients and data, and using these in order to diagnose, to prognose, and to give therapies to patients without the intervention of the physician. There is a big worry in ethics about the replacement of physicians, and so we need to have a control, that is a human oversight on the process of application of AI in medicine. This is very important to raise the question of complementarity between humans and machines.

The second point is safety. As we have safety protocols, clinical trials in pharmaceuticals, we need clinical trials of software. We cannot apply AI in medicine without safety rules – that is, a validation of software. So we need ideas about that.

The third point is transparency against capacity, so we need to trace back the steps of the decision that AI applies to the patient. And so we need more transparent design in AI. The fourth point is equality. We need to overcome bias, and we need a very inclusive approach. So all the patients need to be represented in the clinical data in order not to exclude them because of age, gender, or ethnicity.

And the last point is the responsibility and liability of physicians, and liability of all the subjects involved in the application of AI in medicine, also the owner of AI, the designer of AI, the vendor of AI, and also physicians. So we need to clarify also the responsibility.

1-013-0000

**Chair.** – Thank you very much, Professor, for this view on the ethics of AI in health – very much valid for almost any other sector, but I'm sure we'll dive more into these issues of ethics as well in the questions coming from our Members.

Now will move on to the second part, which I would kindly ask Mr Wolfgang Hiller to try to compact a little bit, maybe into 15 minutes rather than 20 as was initially planned, so that we catch up a bit. We are a bit behind schedule.

The idea for this intermediary discussion, this moderated panel discussion, was to pave the way, to prepare a bit the questions that may come from our Members and maybe open new avenues for our conversation.

Director Hiller, you have the floor to try to make it into 15 minutes.

1-014-0000

**Wolfgang Hiller,** *Director EPRS.* – Thank you very much Chair and hello to everyone, particularly to panellists and members in the room and at home. As you have said, we are a bit late, so I will try to do my best to concentrate this panel discussion in 15 minutes and base our conversation on the very interesting contributions which we have already heard. I am planning to start the discussion by putting my own first question to each of the panellists, but the panellists are also invited to react to what they have just heard so that a real discussion can start and can go on in the limits of this online setting.

My first question is to Minister Pierrakakis, who has already told us about the plans and the ambitions of the Greek Government in providing and pushing forward the digital transformation in its public and private health sectors and the use of artificial intelligence (AI). I would like to ask you to tell us a bit more about the practical challenges that you are facing. Are these more an issue of budget, of regulation, problems in implementation or timing? What are the actual limitations of implementing your strategy in case? Over to you Minister, please.

1-015-0000
**Vicky Lefevre,** *Head of Unit, Public Health Functions, ECDC***.** – Yes, Mr Hiller, indeed, the new legislative package on the health union with the new ECDC mandate and the new regulation on cross-border threats certainly provides the legal basis for the further digitalisation of EU integrated surveillance systems with additional funding, both on the ECDC side and on the Member States side. It also provides for ECDC access to the data in the future European Health Data Space and also for us to act as a known data provider.

In addition, it also provides the legal basis for more harmonisation, more standardisation of EU surveillance than we're actually doing with the same surveillance objectives and looking at the same standards, which would also provide not only more data, but also better quality data, which is actually a prerequisite.

In addition, there would also be the role for ECDC to support Member States with the implementation of this and also monitor how our Member States are doing – monitor their surveillance systems.

1-016-0000
**Wolfgang Hiller,** *Director, EPRS***.** – Thank you. I am now addressing myself to Ms Bury from DG SANTE. It is obvious that the digitalisation in the health sector is providing a lot of potential, but what is the Commission doing in order for these benefits to really be distributed equally? Digitalisation is not something which is equally accessible to everyone and so if we have a European health data space, is this going to be really beneficial for all patients in Europe?

1-017-0000
**Claire Bury,** *Deputy Director-General of the European Commission, Food and feed safety – innovation, Health and food audits***.** – Thank you very much Mr Hiller for the question. Of course, as you say, the potential is huge and I think that the potential is really to revolutionise the way that healthcare is distributed. When we do that, it's very much a priority for the Commission that everybody can benefit from this, that this is really an inclusive agenda and not something which means that some will benefit and benefit more and that others will lose out altogether. So, I think the AI could alleviate pressures on healthcare systems and that would benefit regions with less advanced medical structures.

Secondly, of course it may mean that people in remote areas or older people or people with mobility problems can gain access to healthcare through tele-medicine, through tele-monitoring and also through technology-based supply of healthcare.

I think for everybody to benefit in the way that we would like it to happen, then we need clear rules on privacy – I mentioned that already. We need clear rules on liability and safety – Professor Palazzini mentioned that as well – we need to be clear about what the rules are. We need interoperability, we need capacity-building and we need digital skills. The Commission is also focusing very much on digital skills, both for health professionals but also for basic literacy skills for citizens, because we hope indeed that this will be a revolution that will benefit all and ensure that healthcare and good quality healthcare is made available to all in the community.

1-018-0000
**Wolfgang Hiller,** *Director EPRS***.** – Thank you, Ms Bury. My next question is to Professor Palazzini, who has already told us about the ethical requirements for the use of artificial intelligence in that area. Linked to that, of course, is the issue of privacy in data-sharing. I wonder if you could tell us a bit more about how privacy really needs to be protected in this field of using artificial intelligence when sharing health data. I think this is sensitive to many people who are subject to that issue. Over to you, Professor Palazzini.

1-019-0000
**Laura Palazzini,** *Professor of the Philosophy of Law, LUMSA Rome***.** – This is one of the main questions from both an ethical and legal point of view, as sometimes there is mention of the so-

called end of privacy and the evaporation of privacy because of the massively huge amount of data.

We need clinical data for research and that is the most important. That's why, in ethics, you always see a reference to data-sharing. We need to share data.

Thinking about the situation now with pandemics, we need to share clinical data and that's a big improvement for research.

We need new regulation, new awareness about this question. We need rules that could protect privacy, above all in the use of data, in the abuse of data. I mean when data are used in the workplace or by health insurance or in a commercial setting. We need to use data only for research. That's the best protection. In that way, I think that citizens would be willing to donate their data. Now there's also mention of the donation of data, to share data. Which is really something important for our research.

We need a sort of literacy of people, of citizens, to better understand the importance and the relevance of data for research.

1-020-0000

**Wolfgang Hiller,** *Director EPRS***.** – Thank you. We have tried to connect with the Minister but we have not been successful yet, so I'm coming back with a question to Ms Lefevre and Ms Bury. Do you think that the current crisis is making it a lot easier, basically, to implement your plans, and what are your predictions in that context?

1-021-0000

**Vicky Lefevre,** *Head of Unit Public Health Functions, ECDC* **.**– Thank you very much for your question. Yes, I think the current crisis has opened our eyes, certainly on the EU harmonised approach, and it's already visible that there are changes under way. There are new legislative proposals, as you see, and there's a proposal on the health data space. It has made it very clear what the gaps and the weaknesses in our systems are, like for COVID-19. What is the surveillance strategy that Member States have applied? It was not always the same. Who do you test? Member States have applied very different testing strategies, from testing only severe cases to population-wide screening, so how do you compare this type of data? Also, who do you count as a case? There have been differences in Member States and in reporting those cases which have made the data very difficult to compare. I think all these gaps that have been shown will certainly speed up the changes in the coming years.

1-022-0000

**Claire Bury,** *Deputy Director-General of the European Commission, Food and feed safety – innovation, Health and food audits***.** – That's a very good question. I think I would agree with what Ms Lefevre has just said. I think there's been a growing awareness amongst the population of obviously health issues, but also of the relevance of data to health issues and of artificial intelligence and the need and the potential use that can be made of health data.

I wanted to give one example as well, which was that we've been working for the last six months on the mobile tracing apps and actually connecting up those apps through a European federated gateway. And when you think about the developments that this has entailed over the last six months – we had I think 80 meetings of the eHealth Network to be able to put the system into operation. We now have, I think we're going up to 12 Member States that are involved and hopefully by Christmas, we should have around 15 or 16 Member States that are involved in being able to exchange data through these mobile tracing apps, which is really a big help to the contact-tracing that has to go on in the current situation. And as I say, I think to achieve what has been achieved in six months was remarkable. So I think that shows how much, once the pressure is on and people realise the potential, we can act more quickly and we can deliver the benefits on the ground.

1-023-0000
**Wolfgang Hiller,** *Director EPRS* **.**– As time is moving fast, we are now also moving to our last question to Professor Palazzini. I would like to ask you what does all this mean for the training and the education of our doctors for the future?

1-024-0000
**Laura Palazzini,** *Professor of the Philosophy of Law, LUMSA Rome***.** – We need to change education for our physicians, above all to guarantee the continued education of physicians to update on new AI technologies, and also to rethink the education of physicians, because we need the convergence of all the traditional disciplines for the training of a physician with mathematics, informatics, computer scientists.

On the other hand, we also need the ethical education of engineers and informatics experts and data scientists because they are the ones that design the new AI technologies.

We also need a very general education and debate in our society. There's mention of a recent document of the Council of Europe committee for bio-ethics, the one on public engagement. So we need to train physicians, we need to train informatics, but also to educate people. AI literacy, it was mentioned before, is really very important because people need to be included in these new opportunities of emerging technologies.

1-025-0000
**Chair.** – Thank you very much Mr Hiller and thanks to all the panellists for already laying the ground for the questions that will come and for the exchange with our members. Without further ado, I will now start the sequence. I would remind our colleagues that they have a five-minute slot for each intervention and if you manage to compact your questions maybe into one minute you can also address two of the panellists if you would like to do that. As long as you stick to the five minutes that are reserved for each political group then you could also have two or maybe even three questions if you are fast. So we'll start with Edina Tóth for the PPE Group.

1-026-0000
**Edina Tóth (PPE).** – Thank you very much Chair, and thank you very much to the panellists for their very interesting presentation.

In the second wave of the COVID-19 pandemic, it has become more pressing than ever to discuss more about how AI can contribute to healthcare. We heard that the aim of the European Commission is to remove obstacles from the free movement of digital health services and products in the internal market. However, I believe the use of AI applications in the healthcare sector is more than just a problem of the fragmentation of the EU single market. While there are now many AI applications that have been deployed in high-income settings, its use in the context of relatively resource-poor countries remains lower. At the same time, high-income countries are likely to have more capacities and resources to invest in AI technologies in the healthcare sector, and we all see that this gap between the countries is widening. I would like to address my first question to Claire Bury from the Commission. How do you intend to ensure that countries lacking resources can have good access to AI technologies?

With my second question, I would like to focus on a more human-centric thought. Deep learning has already made several remarkable achievements in the area of medicine, and a number of major steps have been taken with regard to the changes AI can bring about in the area of healthcare. With respect to AI applications in health, a major concern for the public is the risk of the erosion of human interaction caused by AI technologies, or that they could in some way degrade the patient's healthcare professional relationship, because some believe that the warm and comforting tone of the doctor can have positive effects on the patient's treatment. Professor Laura Palazzini, from a human-centric point of view, do you think the use of AI applications will improve patient's healthcare professional relationships because doctors will be able to spend more time communicating with patients?

Thank you very much for your attention. I look forward to your replies.

1-027-0000

**Claire Bury,** *Deputy Director-General of the European Commission, Food and feed safety - innovation, Health and food audits***.** – Thank you for your question Ms Tóth.

I think there are three things that I would highlight. First of all, we know from indexes like the Digital Economy and Society Index that there are indeed as you say big differences in terms of digitisation between different countries. So I think we have to use that index. We have to see where the weaknesses are in terms of those countries because it gives five different indicators in different areas from connectivity to digital skills, etc. I think we need to work closely with the concerned countries to build up on where there are weaknesses.

Secondly, I think I mentioned in my intervention, as well, of course there will be funding for A.I. and there will be funding for digital health in a number of the programmes. We're looking with the Member States on the RRF, there is a recovery fund. I think the Minister also mentioned that that was an area that Greece was looking into for digitisation. There will be help at EU level through EU4Health and the Digital Europe Programme.

And thirdly, there are actions that we do to promote best practices between Member States so that they can learn from each other. And we have to promote the mobility of students and others and healthcare professionals into other countries so that they can, where necessary, learn and then take their learning and the enhanced technological capacity that they have back to their own countries.

But, as I said in response to Mr Hiller's question, for the Commission, this is very much an inclusive agenda and we will do our best to make sure that all Member States can benefit from the healthcare revolution that may take place through AI.

1-028-0000

**Laura Palazzini,** *Professor of the Philosophy of Law, LUMSA Rome***.** – Thank you very much for the question. It gives the possibility to better explain the difficulties of the relationship between physician and patient. First of all, we wouldn't like to think from an ethical point of view of artificial intelligence substituting a physician, so that there's only a relationship between AI and patients, so patients received diagnosis, prognosis, therapies by AI without the presence of physicians, so, as you mentioned, the human touch, the empathy and the clinical evaluation that isn't present.

The best way is just to think about AI as a complementary, as an assistance and the support of the actions, of the decisions of a physician. But there is one risk, the risk of the de-skilling of the physicians. That's from an ethical point of view very important and so the idea that if the physicians can use AI, it is very supportive and very important for physician to have a lot of data to analyse, to be analysed and all the scientific literature, and also algorithms giving correlations between data, that's absolutely very important. But the real problem is that sometimes physicians can rely on technology, that is a sort of technological delegation. There was a mention of a human loop in a certain way the man can be captured by machines and that's a real risk from on ethical point of view, to lose some kinds of capacity in the relationship and also in the competence of the physician. So we need also training for physicians in order to interact in a very fruitful and productive way with AI and also, on the other hand, information from the side of the patients in the application of AI. The patients need to be reassured about the opportunities and risks, and also to take the decision to receive the application of AI in a very balanced way.

1-029-0000
**Adriana Maldonado López (S&D).** – It is clear that artificial intelligence is changing our consumption habits in all areas, the way we interact with one another. This is bound to continue in the health systems a result of the serious pandemic we are now experiencing.

The COVID-19 crisis has accelerated this process of digital change, including within national health systems. For example, in Spain, the government set up the General Secretariat for Digital Health, Information and Innovation of the National Health System in August this year with the aim of overhauling and modernising the Spanish healthcare system.

The various autonomous regional governments are also increasing funding for the digitalisation and modernisation of their public health systems. For example, the Navarre Regional Government has been working to develop a unique social anamnesis by digitising patients' data so as to ensure far smarter management of operating theatres, based on AI and in full interconnection with the Internet of Things. Ultimately, this will help doctors take better on-the-spot decisions as regards patients, waiting lists and even the hospital equipment and facilities to be used.

My question is a very practical one, and is for Ms Lefevre, I believe that Europe needs a better-integrated healthcare system. We need to harmonise research procedures for the use of shared data that facilitate disease research, diagnostics and potential treatments throughout the European Union. I would like to ask what concrete measures the EU institutions can take. In other words, how can we better legislate, under an EU mandate, in this parliamentary term, to achieve greater interoperability between national healthcare systems?

The EU institutions are themselves working on various texts. How can we incorporate these concrete measures into this EU legislation?

Finally, as regard the data we use, I would like to ask Ms Palazzini what factors we should take into account, when harnessing the unique social anamneses on which some European regions are working, to enable the public and hospital staff to make the best use, in IT terms, of this data?

1-030-0000
**Vicky Lefevre,** *Head of Unit Public Health Functions ECDC* – I think there is a need for further harmonisation of new surveillance systems, in terms of harmonisation of the type of data we collect – standardisation. The role of the ECDC here is actually to come up with a blueprint for the future of EU surveillance using potential new technologies, but also building on existing technology. We should do a map from the 'as is' towards the 'to be', and I think the use of electronic health records, once this is sufficiently developed, could be a great source of information.

Now we're also looking into the potential use of contact-tracing apps which is very valid for COVID-19, but we do not know if this will still be valid for other diseases.

A second point, and this has been mentioned before, is that there should be sufficient support to Member States to actually build those interoperable systems; there's the EU4Health programme, but there are also other funding sources.
The role of ECDC is to come up with a plan and to advocate for this implementation and to ensure that the funding goes to the right projects, to the Member States that need it the most.

1-031-0000
**Laura Palazzini,** *Professor of the Philosophy of Law, LUMSA Rome***.** – Yes, for sure, the pandemic has accelerated this sort of digitalisation of data and use of data for research or clinical data. There are a lot of initiatives in Europe and also at international level of having an open

register of data where all the clinical data of all the patients and all the results of research data can be gathered and that's a very important step towards research.

Pandemic means global, so we need some kind of initiatives, harmonisation, not only in Europe but also outside Europe, on a global level. And of course we need to protect patients because of privacy, as I said before, and this protection can be really done with a sort of implementation of regulation trying to balance privacy-protection on the one hand and on the other hand also the sharing of data – open data – because it's really necessary for research. That's very important. Patients also need to be aware about that; there should be informed consent. They need to give their consent to the sharing of data – open data – for research.

1-032-0000

**Dita Charanzová (Renew).** – I will just follow up one issue which is about privacy.

Further development of anonymisation and pseudonymisation to better exploit data while protecting patients' privacy is often mentioned as a way forward.

Anonymisation has been championed more as a solution, however, since pseudonymisation data can be traced back to an individual. As I understand, it's not always a practical solution. For example, for anonymisation you cannot do follow-up on patients, which can be problematic in healthcare. There is no silver bullet.

Has any work been done among health authorities and privacy regulators on how to tackle this?

When it comes to the conformity assessments to be put in place for high-risk health technologies, we need to ensure this is done in a measured manner. We need to ensure the high standards of these *[inaudible]* and technologies on our market and at the same time avoiding the creation of unnecessary red tape and burdensome obstacles in establishing these procedures, which could cause delays and potentially stifle innovation if too strict.

This isn't just about competitiveness in the sector, but about enabling life-saving technologies. How do you think we should strike this balance, and what can be learned from other AI leaders globally?

1-033-0000

**Claire Bury,** *Deputy Director-General of the European Commission, Food and feed safety - innovation, Health and food audits***.** – I guess the Commission is always the preferred victim if no one else is identified – that's part of our job.

On the point about data protection, anonymisation and pseudonymisation – indeed these are two techniques which can be useful, but not always 100% useful. I think, as you said, anonymisation is probably the one which is more championed in terms of being used, but your question was specifically the work between health authority and privacy regulators. I think I mentioned in my intervention that the Commission organised, with the German Presidency, at the beginning of the year some workshops which involved health practitioners and, obviously, privacy experts as well to look at what was actually happening in practice. What we discovered was that there is quite a bit of fragmentation between how the privacy rules are being applied in different Member States. I think this leads us to the conclusion that this is an area which we need to certainly study in more detail, doing it in the way that you suggest, with both the health authorities and the privacy regulators, and that is one of the areas that we probably need to clarify a bit further for us to be able to put in place the European health data space. I think you identify very good points, and we will be following up on that.

1-034-0000

**Chair.** – Thank you very much and maybe for the question relating to the balancing act between privacy and what our industry needs, I will go to Professor Palazzini.

1-035-0000
**Laura Palazzini,** *Professor of the Philosophy of Law, LUMSA Rome***.** – Yes, of course we need a balance between the two because we cannot hinder the market. We all know that the market has a specific aim, which is profit. But on the other hand, when the market has to do with health, there is a social responsibility, which we can see nowadays with the pandemic. Of course, pharmaceutical companies need to make a profit, but they also have a social responsibility towards the health of all the population.

So we need to balance this. The role of ethics really is to underline this ethical responsibility. Otherwise profit overcomes the dignity of the human being. The dignity of the human being needs to always remain at the centre of our discussions, because we need to also remember that the EU Charter of Fundamental Human Rights stresses the dignity of the human being. We cannot use humans as a means, but rather as an end in themselves. So we need to protect, first of all, the patients.

1-036-0000
**Kim Van Sparrentak (Verts/ALE).** – I have a question about data bias in health care and in AI.

Our healthcare systems often use the average white male as a yardstick. From the early research stages of illness or medicines right up until the medical test trials, men's bodies are used as a standard. But women's bodies can react differently to those of men, and women are subject to different health risks than men are. In practice, this means women are repeatedly misdiagnosed and mistreated. And not only women but also people of colour are not represented in data sets in health care.

The COVID-19 pandemic has made painfully clear that the spread of the virus based on physical factors can ultimately be traced to backgrounds and opportunities – a context AI would probably not have recognised based on anonymised health data.

Using biased AI in health could be a matter of life and death. We have to build in safeguards to make sure AI can help save all lives.

So my question to Ms Lefevre is: what is the ECDC doing to provide safeguards for this problem? Because we know that AI will not create this bias but it might exaggerate it.

And my question to Ms Palazzini is: what kind of legal safeguards do you see or do you think that we can build into AI legislation to try to tackle this problem?

1-037-0000
**Vicky Lefevre,** *Head of Unit Public Health Functions, ECDC***.** – To make it very clear, the data we receive and analyse have been verified, validated and submitted by the Member States – so these are validated, case-based data with information on patients.

The technologies we use for the analysis of these data are based on statistical techniques, including spatial modelling and mathematical modelling. But of course, there is always the human verification step to see if what we get through the analysis of those techniques is actually valid. The same also goes for the web data that we scrape, or that we analyse through different techniques, or where we pick up signals, there is always a final step of human verification if the information is valid. I hope that answers your question.

1-038-0000
**Laura Palazzini,** *Professor of the Philosophy of Law, LUMSA Rome***.** – I completely agree with this question of the quality against bias, because above all today with precision medicine in genomics it is exactly the trend to personalise, to tailor, the medical approach to the single patient regardless of age, sex gender, ethnicity and so on.

All research should include everyone, and also AI design should be very inclusive. That's an ethical point and it's very important because of the principle of non-discrimination.

How to translate it into legislation? Just asking for and regulating a design in AI that is very inclusive as an ethical requirement means that it is representative of all the populations without any distinction of gender, age and ethnicity.

1-039-0000

**Alessandra Basso (ID).** – Chair, colleagues, we have already heard it said that man and machine need to be complement one another, and we know that artificial intelligence can serve to provide accurate diagnoses by analysing data provided by patients themselves, or by physicians after examining them. Thanks to artificial intelligence, we can also run the process in reverse, which is to say take a homogeneous set of data and then in a variety of ways simulate diseases on which students can work, thus limiting physical interaction with patients until – theoretically – this is necessary. This is without doubt an efficient way of doing things, both in terms of costs and in terms of standardising teaching models.

However, the data on which AI works is always historical data, so I would like to ask Dr Palazzini whether there is a risk, if we become over-reliant on these teaching methods based on analysing a host of retrospective information, of physicians becoming unaccustomed to tackling situations they have never encountered before or about which they are uncertain? I say this specifically because of the way that many scientists have been caught completely off-guard by the COVID pandemic.

To what extent do you feel, Dr Palazzini, that using AI for case studies should also be accompanied by human beings using their intuition and capacity for innovation?

1-040-0000

**Laura Palazzini,** *Professor of the Philosophy of Law, LUMSA Rome***.** – I would just say that the question raised on education, mutual education, is something very promising, but on the other hand it gives a sort of distance from real cases, and we all know that physicians have to deal with real cases.

On the other hand, there is the question of retrospective studies that are going to increase in this period, above all in trials. I'm not really very worried about that because retrospective studies are very useful because of the gathering of a lot of data and correlations about the data that can give new ideas for future therapies and technologies for future patients. It is like going back *(inaudible)* to analyse something for the future.

On the other hand, I think in the relationship between a machine and a physician, the point is that the machine maybe performs better than human beings in gathering data, but innovation is up to the physician, to the human being. And in this sense, we need to avoid technological delegation as I said before, and try to train physicians to use in a very productive way technologies avoiding this failing.

1-041-0000

**Chair.** – Thank you very much. Adam Bielan for the ECR has informed us that he is not available. So we now move on to Pernando Barrena Arza for the GUE/NGL Group.

1-042-0000

**Pernando Barrena Arza (GUE/NGL).** – Many studies underline the massive impact on jobs and markets due to the transformation and development of artificial intelligence along with upgrading the skills of workers. We are concerned that automation may give society the option to cut the number of hours worked, *(inaudible)* on workers' living conditions and health. This will require to search sector by sector an average amount of job losses across Europe and evaluate the reduction of working time necessary to keep the workforce working.

The increased use of robotics and artificial intelligence should also be an opportunity to reduce human exposure to harmful and hazardous conditions. Do you think that this will help create more equality, more quality and decent jobs before improving *[inaudible]*? Is this a correct approach as regards to the Commission?

Furthermore, I would like to raise awareness of the potential impact of artificial intelligence on mental health. Increasing interactions with non-humans can and will have an impact on people's mental health. I'd like to know about any awareness on this issue by the European Commission.

Additionally and finally, the development of artificial intelligence might lead to the crucial transition of economies to carbon neutral, also in the field of health. We have cases of this *(inaudible)* experiences in the Basque Country where start-ups like *(inaudible)* have worked tirelessly to develop advanced technology in rehabilitation systems through artificial intelligence applications.

1-043-0000

**Claire Bury,** *Deputy Director-General of the European Commission, Food and feed safety - innovation, Health and food audits***.** – I'll take, first of all, the question of the awareness of digitisation. I think you talked about it quite generally: digitisation on mental health.

This is an issue that the Commission is studying. It does give rise to concern in all its manifestations, so we are looking into it and we will feed into the policy work that we do the results of those studies.

Secondly, you asked about jobs and the kind of jobs that may be created. I think, indeed, we can hope that, as you mentioned, better jobs created by AI could reduce human exposure to hazardous conditions. I think we've seen that in previous industrial revolutions, normally the conditions in which humans work has been improved by the changes which have been brought about.

On the question of loss of jobs through automation and through artificial intelligence, there are some studies that have been done on this, and there are probably still more studies to be done, in terms of trying to project much more clearly what the impact will be, but I think the one thing that we can say is that when we weigh those things in the balance, we see that artificial intelligence should create many new jobs and probably create as many new jobs as are changed by this.

I think that we, obviously, have to be very careful. We have to look, we have to study what we think the impact is going to be of artificial intelligence, and we have to accompany the transition. I think that's probably one of the things that we have to learn from previous industrial revolutions: that we need to accompany the transition and that needs to be done in a very astute way to make sure that those who need to be changed from their current jobs can be changed into new ones.

1-044-0000

**Sabrina Pignedoli (NI).** – Chair, colleagues, artificial intelligence can make a telling contribution to improving various aspects of health care, such as preventive medicine, predicting the demand for health care, and on line diagnosis and treatment. However, technology can never be 100% error free, so we need human oversight of the data.

These systems need to be continually monitored and updated. Are we placing sufficient emphasis on the bias factor when developing algorithms? Health and healthcare data and systems are open to attack, sabotage and theft by cyber criminals. Are we doing enough to

prevent the risks arising from cybercrime against AI systems in healthcare facilities and hence against people's health?

1-045-0000
**Laura Palazzini,** *Professor of the Philosophy of Law, LUMSA Rome***.** – I completely agree on the necessity to guarantee the human check, the human control, the human oversight on the reliability of the application of AI in medicine, and of course there is a big question on cyber security, on cyber safety of data above all in this huge amount of data that we use in AI. So I think we need implementation.

1-046-0000
**Chair.** – Thank you very much. The first question I would put to Professor Palazzini, since it is also related to ethics. Maybe the Commission could answer the second question on the risk of cyber-theft and cyber security in general, and when it comes to AI in health.

1-047-0000
**Laura Palazzini,** *Professor of the Philosophy of Law, LUMSA Rome***.** – Yes, thank you for the question. I completely agree on the necessity to guarantee the human check, the human control, the human oversight, on the reliability of the application of AI in medicine, and of course there's a big question regarding cyber security and on cyber safety above all in this huge amount of data that we use in AI.

So I think we need implementation of sanctions for abuse, because abuse can develop a lot, and so we need also to develop technologies in order to protect data and the quality of data.

So we need to try to implement legislation and technology in order to avoid cyber crimes, above all in the health field.

1-048-0000
**Chair.** – Thank you. Thank you also for addressing the second question, but I would still go to the Commission, which has announced it is preparing a proposal on the European health data space. Are you factoring in the issue of security of data as well in your proposal?

1-049-0000
**Claire Bury,** *Deputy Director-General of the European Commission, Food and feed safety - innovation, Health and food audits***.** – Thank you for the question. Yes, of course, I mean all digital uses, as we know, run a risk and that's why we have pieces of legislation like the Network Security Directive which the Commission is in the process of upgrading and will make a proposal on in the coming weeks, but obviously the risk in the health area is a particular risk and therefore that is one of the things that we will need to factor into our European health data space to make sure that all those electronic records, all the data which is being exchanged is properly protected. We recognise that this is really very, very sensitive data which may require special measures.

1-050-0000
**Chair.** – Thank you very much. Since Eva Kaili, the Chair of STOA, has just informed us that she is unable to connect to contribute to this panel, that means that we can conclude Panel One on AI governance in the health sector. I would like to thank again all the panellists for their very valuable and very lively contributions and interactions, both in the debate with Mr Hiller, as well as with the members of our committee. We will of course invite you again in the coming year if we will come back to the issue of health. Thank you very much.

# 3. Panel II: Exchange of views with representative of the Industry, Civil Society and Academia

1-052-0000
**Chair.** – And with that I will move on to Panel Two, which is meant to be an exchange of views with representatives of industry, of civil society, of academia, and to try to broaden a bit the

perspectives that we take in this conversation, bringing in the other stakeholders relevant for the discussion that we have today.

We will follow the same sequence, the same order of business, for the second panel, so I will give the floor first for five minutes to each of the four guest speakers that we have:
Professor Frank Noé, Professor for Artificial Intelligence in the Sciences at the Freie University in Berlin. The second speaker is Doctor Markus Lingman, Senior Consulting Cardiologist and Chief Strategy Officer, Board member at Halland Hospital Group. The third speaker is Professor Andrew Hopkins, Chief executive officer of EXSCIENTIA, Chair of Medicinal Informatics and SULSA Research Professor of Translational Biology. And the fourth speaker is Ms Jelena Malinina, Digital Health Policy Officer at the European Consumer Organisation (BEUC).

Again, five minutes for each of the speakers, then followed by the panel discussion with Mr Wolfgang Hiller, and then the interventions and the interactions with our members.

So without further ado, I would kindly ask the first speaker, Professor Frank Noé, who as far as I understood also has a presentation, to give us his first five-minute introductory remarks.

1-053-0000
**Frank Noé,** *Professor for Artificial Intelligence in the Sciences, Freie Universität Berlin***.** – I will speak about AI for the sciences and especially health sciences of course.

I will start with an example. This is the coronavirus SARS-CoV-2 (*referring to a visual presentation*), and on the surface of it, you see these so-called spike proteins, and they are used by the virus to attach to human cells and to enter it.

Here's a human airway cell with receptors on the surface, and this is where the virus attaches, and as the cells replicate, it infects the host. So if we want to develop therapeutics – drugs – to prevent this from happening, then a good strategy is to attack at this point, to prevent – to block – the interaction between the virus and the cell, and this is what is happening right now.

The first problem we need to solve when we do this is to understand the structure, the 3-dimensional structure of the proteins, of the receptors involved, in order to be able to find medication – drugs – that can block them.

This is a basic science problem: it's the so called protein-folding and protein simulation problem. These are problems that are 50, 60, 70 years old, and now machine learning and artificial intelligence is making massive strides in order to speed up these problems and help solving these problems.

With classical simulation techniques, these are problems where we would need to simulate something like a year or even 100 years on an entire supercomputer to solve this problem once, but now with new machine learning techniques we can speed this up to practical amounts of time, and this is happening at an extreme pace.

On the other hand, we are using machine learning and AI to search through large databases of chemical compounds which can serve as drugs and to compress the information so that it becomes practical. We are also using machine learning in order to match the tools to find drug molecules that bind to proteins. And this is not only happening in the computer, this also involves laboratory experiments where we test our drugs. This is involving experiments where we investigate whether cells can indeed be protected against intrusion of the coronavirus, animal models, etc.

Now the first result of these strategies, which were mainly identifying drugs that we already have on the markets, that were admitted and could be useful against COVID, are in clinical trials and we are essentially developing the next generation of better drugs that will still be needed, even if we have a vaccine, because people will keep getting sick and will need treatment, even if we have vaccination. Hopefully in much lower numbers, of course.

This is one example where AI is making revolutionary changes in the fundamental sciences, in the basic sciences: sciences such as quantum mechanics, protein structure prediction and design, statistical mechanics – the study of how these proteins move and what their function is – and these are important scientific problems that have been around between 50 and 100 years with relatively gradual, steady but little progress at a time. Now with AI this has been really speeded up incredibly.

This is important because all of these basic science problems are fundamental to solve technological problems like developing vaccines, drugs, but also non-health applications, such as developing enzymes to break down ocean plastics, chemical processes to take $CO_2$ out of the atmosphere, solar cells, better materials, etc.

This is happening, and this connection of basic sciences in AI is actually something that Europe is pretty good at. There are a lot of leading scientists in the EU, and in Europe, that do this.

But then of course we need the second stage in order to bring these new developments to market. And let me just give one example here: BioNtech. That's a company that you all know by now, I think, developing perhaps what will be the first vaccine and bringing it to the market with Pfizer. BioNtech is a company which has been developing an important technique, the mRNA technique, for 20 years. It used to be a university start-up, and it needed a pandemic – COVID – to infuse it with the hundreds of millions it needs to scale to a level where it can now actually bring a vaccine to a market and impact hundreds of millions of people.

I believe we need a mechanism in Europe to do this, even if we don't have a pandemic and to scale these early tech companies that have important ideas more rapidly.

1-054-0000

**Chair.** – Thank you very much, Professor, for the very interesting information. I'm sure that our Members will have lots of questions related to that. We now move to the second speaker, Dr Markus Lingman: you have the floor.

1-055-0000

**Markus Lingman,** *Senior consultant cardiologist and Chief Strategy Officer, Board member at Halland Hospital Group***.** – *(inaudible passage)* sure and healthcare leader, I'm blessed to be working in a healthcare environment where we have succeeded in building the necessary ecosystem of competences to translate data into value for patients. This ecosystem in Halland, Sweden includes clinicians, managers, computer scientists, a legal team as well as researchers and contributors from the life science industry.

My message today is that the use of AI in the fact-based, information driven, *(inaudible)* and healthcare system brings hope when many of us conclude that the current way of providing care will not be sustainable in the long term due to increasing demand and novel treatments. Five years ago, we set out to structure all of our clinical and resource data to cover the entire care chain from all necessary perspectives simultaneously, and to deploy cutting-edge analytics on that data. By increasing precision in care delivery, and by tailoring diagnostics and treatments on the level of the individual, both efficiency and safety can be improved beyond the reach of manual work. You can identify the risk of adverse events before they happen and initiate preventive measures based on that information before needs escalate. You can see important patterns in the holistic complexity of a person's health situation that were not visible in the pre-

AI era. On the system's level, AI can be used to direct resources to wherever it can be most beneficial, such as in actions against mental illness or a pandemic.

However, both use and development of unbiased, fair, ethical and safe AI tools requires large amounts of data that in healthcare are often sensitive, fragmented and stored locally in silos. Today, access to the necessary data is the most limiting factor in the unleashing of the power of AI for good in healthcare.

While protecting privacy and integrity, it might even be unethical to refrain from enabling the translation from data in a society with shared risk into health and longevity. For that, better regulatory guidance on secondary use of data for good is required, preferably under the supervision of trusted parties in line with internal review boards, as already exists in medical research.

We need clarity on when a decision supporting an AI tool is ready to be implemented in a clinical setting. It is sometimes challenging to reconcile with the fact that what might be the most powerful technology of our time is used to influence our behaviour as consumers but thus far rarely to improve our health or prolong our lifespans.

Today, data is an indispensable component when developing the much-needed solutions of tomorrow. If we want to leverage the value of AI and other information-handling technologies, Europe needs to offer cloud capacity on a par with regulations, safeguarding privacy and avoiding exploiting citizens without holding back scientific research or development that will make healthcare better and sustainable. This is not an issue for IT departments, but an issue for society and the healthcare sector. Thank you.

1-056-0000

**Andrew Hopkins,** *Chief executive officer of EXSCIENTIA, Chair of Medicinal Informatics and SULSA Research Professor of Translational Biology***.** – Thank you all very much today for the opportunity to talk to you about the advances we are making in artificial intelligence (AI) to directly impact health, we believe, by the creation of new medicines using AI. I'm the CEO and founder of a company called Exscientia. The name derives from the Latin phrase meaning 'from knowledge', and that's the fundamental philosophy of the company – how to create new medicines from knowledge. Exscientia is what we call a pharmatech. It's a technology company which discovers drugs, and we are the originators of the first truly AI-designed molecule now to enter into clinical trials, which we announced in January this year, and we will be announcing further drugs designed entirely using AI entering into clinical trials in the next few weeks and months.

What we have now is what we call a full stack AI drug discovery platform, from identifying new drug targets to the design and optimisation of novel drug candidates. So we can go from originating an idea all the way to putting a drug into clinical trials now.

The company was founded in 2012 as a spin-out company from the University of Dundee in Scotland, based on the original automated drug design algorithms we published in the scientific journal Nature. We now have headquarters in Oxford in the UK, with offices in the USA and Japan. We employ about 100 people, and that is split equally between technologists and drug discovery scientists. Fundamentally, the combination of disciplines at Exscientia between technologies and drug hunters enables a dialogue to understand the problems we're trying to solve and develop the appropriate technology to try to solve those problems. I would say, actually, for any areas where one wishes to apply AI successfully into a new domain, it does require that equal combination of talents from two different domains to come together.

I'm proud to say that we've now used our AI algorithms to develop new drugs to enter into Phase 1 and preclinical toxicology testing for at least five drugs now on that stage, so therefore we're confident to say that now the design of drugs using AI is established and validated as a new approach to creating new experimental medicines. A motivation behind all of this has been, we believe, patients have waited far too long for new ideas that arise from investments in basic science that we make and publish in academia to become new drug products developed by the pharma industry. There's a huge moral urgency and an impetus to develop new medicines quicker, and the global pandemic that we are all suffering from has really put us sharp in focus, and the need to accelerate new developments needs to go beyond just vaccines for Covid.

I want to give you some background about how we use AI to design drugs. A drug is a precision engineered piece of technology, at a scale where every atom and how it connects determines the future success or failure of that compound as a new medicine. Therefore, to design a specific drug, it's down to potentially billions of different design decisions we could make about how then we design the molecules. It's a huge, vast search space we're trying to efficiently explore. Conventionally this has been done in the pharma industry by, firstly, screening hundreds of thousands or even millions of compounds in biological assays, and secondly, the human and drug designer looks at that data makes hypotheses about which molecules, which atoms to change in the design of that molecule. And this iterative testing and making process, this optimisation process, actually can take up to four and a half years and test and make at least two and a half thousand compounds per project. That's even before we begin to enter clinical trials.

This is a problem Exscientia is dedicated to try to solve: and how do you design drugs more efficiently than is conventionally the case? When we start off to design a drug for AI, we need to define the objectives: what do we want the drug to do? And with that then we can use a combination of algorithms from deep-learning, active learning algorithms to actually then generate novel compounds in silico, explore virtual search space far more efficiently than we could ever do in a laboratory. And if we can use the wealth of data we have from public sources like patents and literature, from protein structures, as well as from proprietary sources, from screens done by pharma companies to build machine-learning models, predict the properties of those molecules.

However, it isn't just a case of selecting the best model and selecting the fittest compounds. The drug discovery is both a big data problem and also a small data problem. There's a wealth of biological data. A lot of it is supported by public sources, which we can use to build machine-learning models. However, for the vast majority of new proteins in the human body we've identified, we want to get new drugs to, it's actually a small data problem or a sparseness problem. We actually know very little about many of the proteins in the human body. That's why we use a set of algorithms called active learning, transfer learning, to help us learn as quickly as possible through these small data challenging projects.

Human biology is incredibly complex, and do not think for a minute that we are even close to beginning to predict all the possible ways that a drug may attract to a body using AI. That's many, many years off. However, what we can do is potentially move drugs forward based on evidence and to learn faster and use AI to help us learn faster. It's a process optimisation and learning process where AI is really making the difference now – how then we could create those hypotheses by AI and help us select which hypotheses to test. Basically, learning faster is a way we can optimise more quickly conventionally the case.

What are the benefits, then, of using AI in this kind of drug discovery? There are five assets we have now brought forward. We found that actually rather than four and a half years, that discovery phase is averaging about twelve months. This is a reduction down to 20% compared to the conventional way of running drug discovery. We're making only a fifth of the number of

compounds we normally have to make and running projects far, far quicker. We believe and this really is the start, when you begin to understand the potential of AI to speed up pharmaceutical innovation. Add these cost savings together and we believe, actually, there is a real potential of AI actually to speed up and enhance pharmaceutical innovation.

To finish off, what we would say that at the start of 2020 we saw the first drugs designed by AI enter into human clinical trials, and I would predict that by the end of this decade I expect all drugs entering into a clinic will effectively be designed through AI.

1-057-0000

**Jelena Malinina,** *Digital Health Policy Officer at the European Consumer Organisation (BEUC)***.** – I hope you can hear and see me. I want to present the consumer view on the uses of artificial intelligence in health care and probably beyond, because artificial intelligence is mostly linked with data. It's fuelled by data and it needs data to function. But also, health data is specifically not defined anywhere because health data can be nearly anything. It doesn't have to come from health records. It doesn't have to come from clinical trials. It can also be our shopping habits; it can also be how many steps we make per day. It always depends on the context we're using.

So to ensure that artificial intelligence is not only developed and produced and being deployed in the Member States and in the EU but also used by people, one of the most important openings is ensuring user trust. And in order to ensure that trust, we need to speak about legal rights. We need to speak about enforceable rules on artificial intelligence, and today I want to speak about five of the main ones, which apply both to the healthcare sector and beyond.

First of all, it's the right to transparency, explanation and objection. Whenever we speak about any health care setting, if we go to the doctor we can always ask for our doctor to explain how the diagnosis was made. So the same must apply to AI. We must have a route to see on which basis the diagnosis was made. What was the process? And it is also closely linked with the right to check a diagnosis or seek a second opinion, for instance.

The second right is the right to accountability and control. It's extremely important in the context of health care that any AI-based tools are going through a thorough assessment, not only before they are allowed but throughout the product lifecycle. Their performance must be monitored and assessed by the deployers and dedicated alternatives on a regular basis, and right now, we do have the Medical Devices Regulation, which is coming into force next year. But what is important in the context of the Medical Devices Regulation is that for now it contains all the provisions for so-called simple algorithms, but there are no rules for the moment on how to assess self-learning algorithms both premarket and post market, because whenever it's on the market, it's an entirely different product from before.

Thirdly, right to fairness and non-discrimination. It was already mentioned that it's of huge importance that algorithms are programmed and made in such a way that we avoid potential bias in decision-making and also due to the fact that our health data is highly sensitive, there is a need for independent and additional monitoring to prevent any discrimination and deepening of health inequalities between different populations.

Fourth, right to safety and security. There were many mentions in the Panel One discussions on the need for data protection and privacy. This is very, very important. We also fully support the fact that AI-based tools must be private and secure by design, and of course we do have the General Data Protection Regulation as our data protection bible. But what is important also is to ensure appropriate enforcement of the GDPR, because as we have seen throughout the review process, national data protection authorities often do not have financial and human resources to thoroughly ensure implementation of this regulation. And for security, it's super important to

consider this, because despite certain measures like the NIS Directive, which has been in Europe for some time already, the amount of healthcare cyber-attacks is rising every year, and this is something to work on, for sure.

And last but not least is the right to access to justice. So, it's very important from the point of the consumer to have the right to redress and public enforcement in case of any damage occurring through AI, and it's very important to ensure both in the context of services and products. And here we will face a lot of debate, probably due to the difference of the competences between the Member States and health care in the EU.

If, for the products, we have the Liability Directive and overall rules, then comes the services, and it becomes more complicated because healthcare professions are regulated by the Member States and it's up to them to ensure how it would work. So we need to speak about all these things and more, in order to ensure trustworthy AI, which will be used by European consumers.

1-058-0000
**Chair.** –That concludes the first part of the panel. I will now hand over the floor to Wolfgang Hiller for him to moderate, and again I would kindly ask that you try to compact it to 50 minutes, so that we have enough time for the interaction with our members. Wolfgang, you can take over please.

1-059-0000
**Wolfgang Hiller,** *Director, EPRS***.** – Thank you, Chair. We are definitely aware of the timing. I will proceed as I did in the first panel discussion: I will start with one question to all of the panellists. But I would like to encourage the panellists to also use this opportunity to comment on what they have heard if they feel the need to add a comment or something which they think would be appropriate to add.

I will start with Mr Noé, who in his fascinating presentation on signs making revolutionary changes has already shown us what can be done. And he ended his presentation by mentioning and hinting that there is a need for a second phase in all this, and this is bringing scientific revolutions to the market. I would like to ask you what needs to be done? What can we do in order to help these scientific revolutions be successfully implemented on the European market? Over to you, Mr Noé, and please do not forget to press the button again.

1-060-0000
**Frank Noé,** *Professor for Artificial Intelligence in the Sciences, Freie Universität Berlin***.** – Hello, and thank you for the question. That's a very good question, of course. I think Andrew gave this very nice talk and I think Exscientia is a good example of where it worked quite well, and they raised quite a substantial amount of money.

In general, I feel that in Europe we have relatively little investment capital for risky start-ups, and that is becoming a problem because AI is developing so fast. In all the examples that I have given, essentially four years ago almost nobody used machine learning AI to do any of this, with very few exceptions and with very preliminary methods, but now it's almost unthinkable not to use it.

I believe that, essentially, if we don't want all companies to be in the US or in Asia, but successfully do this ourselves, I think we somehow need much more funding that can be invested in promising start-ups and for risk-taking. And I don't know how to do that because*a chiedere, in tutte le opportune sedi a livello europeo* in the US, and also probably in some places in Asia, there are a lot of private investors, while here in Europe we unfortunately have far fewer people who do that. So perhaps we need to do a little bit more on the political level. And if you see the billions that are spent on essentially maintaining our infrastructure during COVID, I think it's not unthinkable to have something like a 'vision fund' in Europe, which would be like a $100 billion fund for things like this, and this is one way to do it.

1-061-0000
**Wolfgang Hiller,** *Director, EPRS.* – Thank you very much. I now turn to Dr Lingman. Dr Lingman, you have been talking about data being fragmented and, linked to this, we know that data is being stored locally. I would like to ask you to elaborate a bit more on what the actual implications and consequences of that fragmentation of data are.

1-062-0000
**Markus Lingman,** *Senior consultant cardiologist and Chief Strategy Officer, Board member at Halland Hospital Group.* – Thank you for your question. The implications are quite vast because the benefits of machine learning methods are actually seeing patterns in complex data amounts and the human being and the health care system are two complex adaptive systems where AI advantages are great. That's why neural networks were built from the beginning. In order to be able to see these complex patterns in your health or in your health care system, the model during training needs access to the necessary data, and if you store the data in different silos that access is very difficult to achieve. Also, you need not only access to your health-related data but also to your system-related data, because another issue going forward with the development of health care is actually to also take care of the resource perspective.

We need to be able to build precise health care systems that are also sustainable from a resource perspective, so being narrow brings us only to an even more fragmented health care system, which probably will not be sustainable and which would definitely not be able to use AI tools and benefit from them in the way we would like.

1-063-0000
**Wolfgang Hiller,** *Director, EPRS.* – Now, Professor Hopkins, you are leading a global pharmatech company, and you have been outlining the huge potential to drive innovation to address health needs. Of course, we are very interested in Europe, in the role of Europe and in the potential for Europe.

Dr Noé has already said that if we don't want all our companies to be owned by the US and China, we may need to do something.

So my question specifically to you is: if we are relatively good in science development in Europe, how does this all translate with regard to the European position competition-wise vis-à-vis the US and China?

1-064-0000
**Andrew Hopkins,** *Chief executive officer of EXSCIENTIA, Chair of Medicinal Informatics and SULSA Research Professor of Translational Biology.* – That's a really important question actually, and I think Frank's idea is a very interesting one given the scale of the issue.

In terms of where we sit relative to America and China, in particular, with skills, in the field I know best – AI pharma techs – European companies and actually the European academic base has been at the cutting edge of the field. In fact, this field has been developing in Europe and the UK far earlier than when it actually took off in the US and in China.

But now that the potential has been shown, and now with everything that we've talked about and heard this week with alpha folds and all the other things Frank talked about, we are now starting to see that there is significant capital to be deployed in the USA and China to these companies. In fact, there is a real danger that although we are very good at start-ups and very good at seeing the ideas, actually where we are weaker is actually scaleup and actually taking them to become global companies.

A good example of the scale of these opportunities is when, in September, the Chinese company Baido raised USD 2 billion to build an AI-driven biotech company. This dwarfs any of the

investments that we've seen in Europe and the very large funding rounds in the US right now, which are often in excess of USD 150-250 million per round per company.

So, despite the initial lead from the EU and the UK, there's now a very deep concentration of capital coming into these fields in China and the US. This is a more common problem we have with tech generally in Europe and in the UK; it is actually the scaleup stage which we are weaker at, due to a lack of concentration of available capital within it.

The other advantages which somewhere like America has are in terms of talent. America has a huge talent advantage, not just in terms of local excellence in academia and universities, but more importantly America's ability to attract talent from the rest of the world, particularly Europe and China.

If you look across most of the AI-driven companies in America, you see a very strong contingent from Europe and China as part of a US-based ecosystem. Talent is obviously one of the key things.

In terms of ambition, we do see that we have got the ambition in the EU. The fact that we're having this conversation, the fact that we see very strong infrastructure developments, like the European health database starting to come about, are important, but I would not underestimate the importance of talent and skills in a population to actually be one of the key advantages in the economy and risk base.

I do believe fundamentally that AI has the firm ability to accelerate innovation within the health care sector in Europe. The creation of technology ultimately is a direct function of the availability of people with the right skills and the right talent available to that economy.

For example, in our HQ in Oxford, nearly 50% of our staff are international and the vast majority are from Europe. Obviously, we are worried about the potential impact of Brexit on the free movement of talent, but I cannot underestimate the importance of training and education as well in Computer Science, Data Science and machine learning to produce a skilled workforce for Europe to be competitive with the US and China.

If we can combine talent with creative ways to make scaleup capital available, then actually we have got a very strong a fighting chance. We are actually often the originators of many ideas and original talents. It is actually in converting those ideas into the next generation of important economic engines and companies that has so often been where the challenge actually is.

1-065-0000

**Wolfgang Hiller,** *Director, EPRS***.** – Now, my question to Ms Malinina on the consumer perspective of things.

Well, we all are consumers: it's not just the production side. So, based on what we know, we all agree probably, that there's a huge potential for both production and, at the end of the day, for consumers in AI and digitalisation. But there are conditions to the full use of this potential, and one of them you already mentioned, and that was trust. The other one, I wonder, is maybe digital literacy or competences in using this also at the end of the process by patients, by healthcare professionals and so on.

Is there anything we can do besides raising the trust to make things work better for consumers?

1-066-0000

**Jelena Malinina,** *Digital Health Policy Officer at the European Consumer Organisation (BEUC)***.** – Yes, certainly health literacy is very important, but it's not only in the context of consumers and patients – I think we should speak about digital literacy of the whole society,

because we moved to the digital age. But our mentality didn't move yet; we do not have the subjects – well, in some countries they do, they have subjects in school – which explain digital rights, for instance, how to ask for consent, how to give consent and things like that.

At the same time, I must emphasise that we should not put all the responsibility on patients and consumers, especially when it comes to utilisation of AI tools, for instance if we speak about some kind of apps or connected devices, which would facilitate health care outside of clinical settings. It should not be up to the consumer who has an IT degree to understand how the algorithm works. Neither it should be the doctor.

I totally agree with the point, which was made previously, that there needs to be IT education for doctors too, but they are primarily healthcare professionals, not IT professionals. Perhaps we should speak about intermediaries between doctors and patients, who would know how the particular device functions, how to act in case the device is misbehaving, and so on and so forth. Because this is very important. For instance, if we speak about such devices as, for instance, a digital insulin pump, which is connected, and it gives insulin into your blood based on some kind of measurements it reads from your body. In that sense, if something goes wrong, if the algorithms, some kind of error occurs, the person can die or some tragic consequences to health can occur.

So there is a need for someone in between human doctors, patients and machines. I totally agree that the whole level of literacy – and not only digital but also health literacy – must be raised, because a lot of people feel still, based on certain surveys, do not know which side the heart is on. So how can we speak about AI when we still do not know where our heart is located? So it's a combination of both.

1-067-0000

**Chair.** – Thank you very much, Wolfgang, for again setting the scene for our discussion and interaction with the members. We now start our round with the EPP, Mr Jörgen Warborn. Again, the rules remain the same. Please try to use smartly your five-minute slots, be quick with the questions and please indicate who you would like to reply to your questions.

1-068-0000

**Jörgen Warborn (PPE).** – I'd like to start by thanking our invited experts for your fantastic and pioneering work. It's been very interesting to get a short glimpse of your achievements. I'm happy that you have come here to share them with us. I'm particularly glad to have Dr Lingman here, and I feel highly optimistic and confident living in the Swedish region where Markus Lingman and his colleagues manage the healthcare for me and my fellow citizens.

By combining the huge amount of information that a healthcare provider has and linking together datasets that are normally separated, health care becomes more safe, efficient and priceworthy. Initiatives such as the one Dr Lingman presented – one of a kind in Europe – will be crucial for our ability to provide good-quality health care in the future. Rightly used, AI cannot just improve lives, it can also save lives.

But Europe has a long way ahead before all healthcare providers apply AI in the same efficient way. Many are still stuck in old-fashioned, non-digital systems, and this must change to meet the needs and demands of patients in the digital age.

So my questions go to Dr Lingman. I would like you to share your best advice to the committee and those listening. What potential do you see to adopt your approach to AI in other regions, avoiding the need to reinvent the wheel, and what current obstacles hinder you to help other healthcare providers to start using AI in the same way?

Could your methods provide the economy of scale needed to ensure high-quality, efficient and priceworthy healthcare to the entire European Union, and if so, what can the European Parliament do to help?

1-069-0000
**Chair.** – The connection with Mr Lingman is not working. We will move to the next speaker.

1-070-0000
**Christel Schaldemose (S&D).** – I hope that Mr Lingman will be connected again because one of my questions would go to him. But first I would like to thank all the speakers. It is really interesting, and I think we learned a lot about all the challenges but also all the opportunities we see with AI.

My first question goes to Mr Frank Noé. I clearly understand the need for investments to help start-ups in this area and especially in the beginning of a new era with AI. However, being a politician, I ask myself how: can we choose between which start-up has an opportunity to develop something good and who hasn't? Don't you think that it is primarily private investments that need to help us here? Because it is really risky. And isn't it a problem if we left it to taxpayers' money to invest in these areas? I think we really need to consider how we do this. It is for the benefit of society, but still we also need to be aware that we cannot just invest in everything that has the slightest interest. We need to focus. So could you give us a couple of ideas about how to prioritise and what we should look after?

My second question goes to Mr Lingman, and I hope that he is on again. You talked about how AI can predict adverse events. Could you give us some examples of how that works? Because I find it very interesting and it could be really helpful in the health system. So maybe some more concrete examples of how you in Halland use AI in the health system. And then you also talked about access to data and the need of doing more in this area. But I suppose even in Sweden – at least it's the situation in Denmark – people are very concerned about giving away their health data because they don't know where they end. So how can we create better access to data and at the same time really create trust for patients that their data will only be used for the purpose they have given consent for and that the data will not move outside either the hospital, the country or at least the EU? I would like to hear more about this.

1-071-0000
**Frank Noé,** *Professor for Artificial Intelligence in the Sciences, Freie Universität Berlin***.** – Thank you for this question. Yes, I fully agree. Investing in start-ups is a very risky business and most start-ups fail. So you have to hedge your bets by just investing first a little bit in many and then more in less. This is how venture capitalists work and, if they're doing well, venture capitalists are actually making money out of this by hedging their bets in the right way. Of course you need expertise and there's absolutely no way what to invest in which company can be a political decision. That's clear. In my opinion, it has to be a privately managed fund that really aims at also making a profit, because otherwise it would probably not be managed well.

But I don't agree that it always has to be private investors or investments going into these funds because this is, for example, not what you see in China. In China, the government is really putting trillions directly into AI and so it could be conceivable that there's something between the American and the Chinese system that works for Europe, because we cannot create private investors out of thin air. This is not going to happen in the next few years.

So we have to decide if, as the European Union, we want to take a big stride and make an investment in our future rather than concentrating on investment structures that have been built up in the past. These are also important to keep alive, but we have to invest in the future.

1-072-0000
**Chair.** – The connection with Mr Lingman is not working. We will move to the next speaker.

1-073-0000
**Svenja Hahn (Renew).** – Thank you Chair, and thanks to all the experts. Today I will speak in German.

The Corona crisis is currently giving us a very clear message: we need to get out healthcare systems up to speed, particularly with regard to digitalisation. I am quite convinced that artificial intelligence can make a valuable contribution to the well-being of our citizens. The potential benefits of artificial intelligence are enormous, whether it be in research into illnesses, discovering new therapies, or diagnostics.

But for this to happen, we must think in a uniform, European way, and our task as politicians is to create the right framework conditions. We want to promote and not obstruct innovation whilst at the same time protecting the personal data of our citizens to the highest standards, as it is only by engendering trust in new technologies that we will ensure that they benefit everybody. I am sincerely grateful to all of today's experts for their input.

I would like to return to the topic of data in particular, where I especially welcome the Commission proposal to establish European health databases. And here I would be interested in your views on the following points. This is aimed at all the experts, and I would be happy for any of them to respond as they see fit: How do you think we might best increase the flow of data? What do we need to bear in mind here, and what is the current state of play from a technical point of view, in both research and practice, with the anonymisation of personal data?

And now I have two specific questions for our experts Mr Lingman and Ms Malinina, who might have some input for us: How do you suggest we deal, in terms of data protection requirements, with mixed datasets, which also contain personal data?

And a question for Mr Hopkins: Where do you see a danger arising from over-regulation, and which policy regulations would you like to see introduced, aside from venture capital?

1-074-0000
**Frank Noé,** *Professor for Artificial Intelligence in the Sciences, Freie Universität Berlin***.** – Sorry, but the first question was on how to deal with private data, personal data. Is that right? Is that the question you want me to answer?

1-075-0000
**Chair.** – Yes, Svenja has confirmed in the chat box that this is the one for you.

1-076-0000
**Frank Noé,** *Professor for Artificial Intelligence in the Sciences, Freie Universität Berlin***.** – So, this is especially important for clinical data, of course. When we are thinking about, let's say, breast cancer diagnosis with AI, and using MRI images from patients.

I think it is important to have some standards which essentially define what needs to be done in order to keep data private and safe. I think, in principle, the technological side is not really the problem here. It is in principle known how to do this and it is just something where one needs to decide what data we are happy to share and what data we are not happy to share.

I would just say that we have to be perhaps a little bit more optimistic about the possibilities and less afraid of the abuse of data, because honestly we are sharing so much data already with American companies by using phones for which we have no European alternative for the operating system, and also apps.

So I think we have to be a little bit more pragmatic in Europe. One example of this is the coronavirus app. There's no real very successful and functional version of that. I think Germany has the most downloaded version, but in practice it manages so little data, and it forces people

so little to actually input anything into the system, that it has little consequence in actually practically preventing COVID. I think we need to be a little bit more pragmatic and solution-oriented rather than always being super careful.

1-077-0000
**Chair.** – Thank you very much. I would kindly ask that you compact the replies a bit.
Ms Malinina, the question related to data protection was directed to you. If you could give a very brief answer, and then we will move directly to Mr Hopkins for the third question, relating to risks of over-regulation and the expectations that we have from policymakers.

1-078-0000
**Jelena Malinina,** *Digital Health Policy Officer at the European Consumer Organisation (BEUC)***.** – So, we do have the GDPR, which covers personal data, but we have nearly nothing which covers non-personal data. As you rightly mentioned, anonymisation is often technique recommended to ensure privacy. But the big question is how can we speak about truly anonymised data if we always have the source, which is personal, so we can easily backtrack.

To solve this, we need to come up with legally-enforceable standards for anonymisation so it is clear which criteria anonymisation should match to be as secure as possible, because there are different anonymisation techniques – some of them are good, some of them are not.

The second point is that we have to go beyond the GDPR when it comes to secondary health data uses, because now we do have a problem that there is a divergent view among the Member States on how to apply GDPR derogations on secondary health data uses for research.

This was done deliberately in the GDPR due to the difference in competencies between national health authorities in the EU, but we face a problem when it comes to transnational research. Researchers often do not know which rule to apply. Whether it's a question of a GDPR renewal, I'm not sure. We might want to speak about a specific regulation for health data, and this would mean that Member States would need to adjust their national laws on research. It will be a very complex debate, but we face a need for this debate to start and result in an enforceable and common agreement to approach this issue.

1-079-0000
**Chair.** – Mr Hopkins, for a very brief reply on over-regulation and expectations from politicians.

1-080-0000
**Andrew Hopkins,** *Chief executive officer of EXSCIENTIA, Chair of Medicinal Informatics and SULSA Research Professor of Translational Biology***.** – Yes, it is a potentially worrying situation and we need to be careful that we don't over-regulate AI. Particularly, healthcare and drugs is already an incredibly well-regulated environment and should be.

In many ways, what we expect is for products to be regulated in the same way. It's the outcomes and the safety outcomes which are important for us to consider. So sometimes it isn't necessarily extra regulation that is required on a productionable system, but actually to make sure that we are still following the same regulatory hurdles we expect for all of the healthcare products and new drugs which we are bringing to market. For this we've already got the EMEA, which is a very strong defender of human rights and patient protection.

In terms of what else is required, I think creating the right environment and creating the right ecology of an economy is where politicians actually make the biggest difference.

For example, it's about the discussions around the digital space for healthcare and creating a digital single market which is incredibly important. We must not forget how fragmented most countries are – the US and China, one of their Achilles' heels is how fragmented their data systems are between their hospitals. This is actually one of the key advantages potentially

Europe could get a huge creative position on, if we can create a single digital market for healthcare. That then would create an environment actually for start-ups and other companies and big companies to then flourish and try to control it. So, it's about creating that new fertile ground in which new economies can grow.

The other key thing for politicians to focus on is the supply of talent and the skills and education and making sure we have the workforce then that can actually generate those new start-ups and also be the employees of the future for this new world. That's actually one of the key advantages of not only growing our own talent at home but also making sure that we are open and are not just as an exporter of talented people to the US but also that we're making sure that we can recruit talented researchers from China and America to Europe as well.

So those I think actually are the key things. It's more than just money. It is making sure we build the right environment and create the right market space for companies to flourish.

1-081-0000

**Markus Lingman,** *Senior consulting cardiologist and Chief Strategy Officer, Board member at Halland Hospital Group***.** – The original question was 'can we scale this to other healthcare systems?'; the is answer is 'yes'. Healthcare is generic, and healthcare challenges are generic. There is no secret source at Halland on how to develop this. We were able to gather the right competencies, the right talent, in order to leverage the value of AI and translate data into information to act upon.

But the important thing is that, when you as a healthcare system want to act upon an individual person's need, you need the information from that person in order to understand what will come, because one of the benefits from AI is that it's a predictive tool, so we can foresee the future and act upon events before they actually take place.

Scaling is super important in this case. Working together with other healthcare systems will only leverage and improve the capabilities because AI development is very data hungry. You need a lot of data, and you need a lot of sensitive data, so being able in a safe and secure and legal way to work together across healthcare systems will definitely help all our fellow healthcare systems to move forward. This is not based on geography. This could be spread out all over Europe. We are in contact with several health care systems across Europe.

But you need to do the fundamentals first, and that is building the platform on which to apply your AI models, and even before you have the AI capabilities, that platform is very valuable because that's when you can do variability analysis, return on investment calculations, etc.

AI is almost the topping, the cream, after having done a lot of pre-work. So yes, this is clearly doable. This is definitely scalable; it needs to be scalable in order to take the next step. We are happy to work with whomever.

We're also writing a book on this topic currently to spread our experiences and knowledge in order to find friends across Europe to work closer with.

1-082-0000

**Chair.** – There is a question remaining from our S&D colleague, but I'm hoping that maybe it will find itself in some of the other interventions so that we can address it then. If not, I will bring it forward to you at the end.

1-083-0000

**Christine Anderson (ID).** – My question is primarily addressed to Professors Noé and Hopkins, but I would also ask Ms Malinina to comment on any matters relating to consumer protection, if necessary.

One of the previous speakers just made an eminently valid point: public health is a fundamental prerequisite for a functioning, productive and sustainable society. The politicians' task is therefore to take the measures required to safeguard public health.

The authority responsible for authorising and regulating medicines in the UK, the MHRA, expects the roll-out of a COVID-19 vaccine which is likely to take place in the near future to cause serious side-effects and wants to use artificial intelligence to keep track of them. With that aim in view, on 23 October 2020 the MHRA issued a call for tenders on the EU website TED (Tenders Electronic Daily). The MHRA is urgently looking for software which uses artificial intelligence to process and store details of the expected high number of undesirable side-effects. The MHRA also states that, if software of this kind cannot be used, it will not be possible to process properly information about the side-effects which do occur, with the result that the work of identifying potential problems with the COVID-19 vaccine at an early stage will be hampered, posing a direct threat to the lives of patients and public health.

Hence my questions to you: Are you aware of this call for tenders? How do you assess the potential of AI in general, and software of this kind in particular, to generate value added for public health in society as a whole? And how exactly can AI achieve this?

1-084-0000

**Andrew Hopkins,** *Chief executive officer of EXSCIENTIA, Chair of Medicinal Informatics and SULSA Research Professor of Translational Biology***.** – It's a very interesting approach. And no, we are not aware of it and we are not directly involved in any of that work. We are focused on the design of new medicines and not the monitoring of health care, but it's a very interesting initiative nonetheless.

More broadly, what I can tell you beyond what has been applied here potentially in Covid is, as was mentioned by a previous speaker, the huge potential of these platforms to provide surveillance systems, and actually that potential could be a very important health benefit to people.

Traditionally when we've looked for adverse events and issues like this, monitoring actually has been very slow over several years – reporting often sometimes self-reporting by general practitioners, etc., to feedback, and the review process then has been incredibly slow and cumbersome.

As was mentioned by another speaker, once, as part of the regulatory process, the product is onto the market, then it's almost as if the review process disappears. One key advantage we could have with a better surveillance system is we could bring drugs to the patient population sooner, because we would have further faith in our ability to detect efficacy and safety.

This would benefit both the patients, by having access to medicines sooner on a conditional sort of licence, but also then would benefit the whole economics of how drug development works, because actually we could start bringing in revenues far sooner in the lifecycle, and that would massively reduce the investment costs.

So it actually potentially opens up not just benefits for consumers but also economic benefits for both the payers and the developers.

1-085-0000

**Alexandra Geese (Verts/ALE).** – Good morning to everybody and thank you very much for your very interesting contributions. I would like to come back to the question that my Green colleague asked in the first round and I would like to hear your answers as well and that was the question of bias. We know that there is a huge lack of data on women's health and that for that reason women are very often misdiagnosed and mistreated and I would like to direct this

question first to Dr Lingman, as a cardiologist. In cardiology this is a big issue. I heard that AI will strongly enhance the speed of development of drugs and this is obviously a very welcome development for humanity but it means that we don't have much time to catch up with the data gap between women and men, and also between the white population and minorities, for example. What would you advise us to do in terms, for example, of funding of research or of regulatory environment in order to compensate for that gap to make sure that women are not left behind, because I would like to remind you that there's a loop, because the results of the AI-assisted research will go into further AI tools and therefore the data gap becomes worse if we don't act on this.

My second question is to Mr Hopkins or Professor Noé, whoever feels competent to answer it. Talking about funding of AI-assisted research or AI research we know – and we spoke about venture capital – that 92% of private venture capital and a huge part of public venture capital goes to male-only companies and we know that male-only companies very rarely invest in products for women or women's health. What should we do in that area? How can we make sure that AI tools in health are really directed to the whole population – men and women and also low income and high income people? We have a strong tradition in Europe of public universal healthcare. How can we support that in the future as well?

1-086-0000
**Chair.** – We start with Dr Lingman. How do we address these biases and this gap in data related to women? And maybe I'll hook on the issue of trust that was also raised by our colleague from the S&D Group. How can we ensure trust in the data of our patients and that it's not misused by those that hold it?

1-087-0000
**Andrew Hopkins,** *Chief executive officer of EXSCIENTIA, Chair of Medicinal Informatics and SULSA Research Professor of Translational Biology***.** – It's really an interesting question and actually it's a big problem in tech generally, in terms of the very strong male bias we see in tech companies, in terms of founders and boards of executives, etc. It's also a problem which we all as individuals are fully aware of those biases and want to try to change the situation.

A small contribution I can say is from our own personal perspective is that in the next couple of days we will be announcing a big new collaboration with the Gates Foundation on women's health and applying AI in that space to look for new approaches to non-steroidal contraception, particularly for applications in the developing world. That is interesting because it obviously is an area where we have philanthropy trying to step in to drive what I consider to be a market failure in this area, particularly if you look across more generally. Start-ups often occur where they see a large perceived market, and in terms of healthcare and biotech that market is often driven by the big pharma companies as defining the market in that space because of the cost and risk of clinical trials.

What you're starting to see now is potentially some of these large philanthropists like the Gateses now stepping in where we see actually that market is not being served and what we're starting to do now is not just see investment of the companies in this space but actually the creation of new technologies, specifically trying to deal with women's health.

I think other things that are important more generally in tech areas such as the recent developments about representation of women on boards and in executives and boards have a more broader societal impact more generally, and I think the tech companies actually welcome those developments.

1-088-0000
**Kosma Złotowski (ECR).** – I would also like to add my thanks and put a question to Mr Lingman. More and more devices connected to the internet have functions which gather medical data or data which is in some way connected to users' health: data such as heart rate, body

temperature or even ECG monitoring. At the moment these are mainly smartphones and smart watches, but there are sure to be a larger number of similar devices in the near future. How can these data be used safely in preventive health care? Are there tools which can anonymise this data in a secure way so that it can be reprocessed and used for further research?

And I have a question for Ms Malininy. The danger here is that this data might be traded between tech corporations. This is one reason why the European Commission objected to the acquisition of a sports band manufacturer by Google. How great is the risk that data on users' health will be sold without their owners' knowledge and used, for example, for targeted advertising on the internet? And finally, is there a possibility for medical data collected by similar devices to be used securely in the process of evaluating insurance benefits? Similar mechanisms operate today with car insurance, whereby drivers agreeing to their driving style and compliance with the regulations being monitored may pay lower premiums. In the case of health, people with a healthy lifestyle who agree to be monitored might also incur lower health insurance costs. This would be an incentive for prevention, and the data gathered would serve analytical and diagnostic purposes – although it could also be used for nefarious purposes.

1-089-0000

**Chair.** – Since it is already 12 o'clock and we risk remaining without interpretation, I would also take the question from GUE, whose speaker is our last from the Members, and then I will come back to the panellists and ask them to reply in English and we will all have to do with English for the remainder of the session.

1-090-0000

**Markus Lingman,** *Senior consulting cardiologist and Chief Strategy Officer, Board member at Halland Hospital Group***.** – I'll start with the sensitive issue and that's ethical bias and introducing bias into algorithms. That is a clear issue and we need to safeguard against that. One way of doing that is actually doing population-wide studies, so that we make sure that on the population the patient group where the algorithm is supposed to work is actually included in the training part of these algorithms. The other way of securing transparency and avoiding bias is to continue developing explainable AI, where you can actually understand how the model came to a certain conclusion. So these are two research fields.

I understood also and that there was an anonymisation issue on for example ECGs and that's a crucial question, because when data is combined with other data it might again become re-personalised, meaning that anonymisation is not as simple as just removing identifying numbers or names, because you need to make sure that the data cannot be re-combined in other settings to reveal the identity.

But there are methods for that, and as I said in my introductory talk, I think we need third parties with insight on the development of the models used in healthcare, in order to maintain trust in them and make sure that they comply with ethical guidelines and guidelines of trustworthiness issued by the EU recently.

1-091-0000

**Jelena Malinina,** *Digital Health Policy Officer at the European Consumer Organisation (BEUC)***.** – So the question of the possible data abuse is a very valid point. Because you mentioned the Fitbit Google case I want to mention why, for instance, we consider it potentially not a very good development. It's not because something is wrong with the data, but it's from the competition point of view. Data abuse can be solved by many means: by consent, by respect for the GDPR and many other things. But this is only valid in Europe.

If we speak about the more and more big tech companies, which are coming from the US, developing tools here, we also can speak about the fact that part of our data goes to the US. It was also already mentioned and it's a question linked to data sovereignty: where we want it to

be, but not only that. It's also the difference of laws applying in the States, in Asia, here, so it's not the same standards.

And to minimise data abuse we also need to allow a high amount of competition, so it should not only be Google and Fitbit developing healthcare tools based on AI. It should be also European companies doing that and oversight can be done in a better way if these companies are based in Europe.

# 4. Closing remarks

1-093-0000

**Axel Voss (PPE),** *rapporteur***.** – Thanks to all who contributed to this wonderful hearing with these diverse approaches on all these topics. Unfortunately, I made my comments here and my conclusion in German, but I will try now to translate.

Why are we convinced that we need a European health data space? Because it's giving us the possibility for our health systems, and the health of our citizens to improve and also to find solutions for diseases and AI can play a very important role here. And so for the control of health in the distance, in pandemic situations, in having a better resilient healthcare system, less costs and therapies, diagnoses, prognoses and also fighting the COVID-19, the prevention and self-management, electronic health record and the developing of medical treatment.

What are the challenges now? We have a fragmentation of the practical handling of data in the Member States. We are missing a legal framework, especially to the artificial intelligence, we do not have so far a general platform or infrastructure for our patients throughout the EU. We do not have the kind of free traffic of digital health services throughout the EU, and we have to have in mind the questions of data protection, cyberattacks and the protection of ethical standards.

What might be a solution? In a very general overview, we have more or less four steps to go to realise our common market for health so first it's governance and rules, second it's infrastructure, third it's quality of data and fourth it's facilities and skills. At the end, we need a European solution, a European common goal and a European strategy for a European digital single market so that we can have, at the end, a European health data space.

We have to make sure that interoperability is given between the Member States, between the hospitals or the stakeholders involved in the health system, we need infrastructure, we need the control and scrutiny and we need these equality of data. Of course it's all about trust here in this area, but data protection is not the only solution to create a health data space. We have to think about anonymisation and pseudonymisation and probably we can have here some solution in approaching this with different steps. We need some liability rules for the digital health and for the AI in digital health and we need the ethical fundamentals like what was mentioned, meaningful human control, transparency, explainability, non-discriminatory, equality and fairness and the access and availability of data in real time is necessary. We have to think about the access to data, it's secure, efficient and practical. Do we need the portability question, the European infrastructure here also the technological infrastructure and in cybersecurity issues we need this step-by-step approach regarding prevention, detection and reaction.

And then of course and I have been very grateful also for mentioning the competition situation the European Union is into. Already the big tech companies are already very successful. We have to do a lot in a very short time and we shouldn't waste the time, not only in discussing data protection and ethical standards. We need to move forward if we would like to be a competitor in the digital health system. China and the US have taken the global competition and we have a big deficit in the EU regarding the investments. Here we can do a lot as a

European Parliament if we want to, if we have the strong will and therefore we should ask for all of these issues regarding also the investments, we need also risk investments, we need talent and also then we have to force or to push our Member States to build up the infrastructure.

So this, all in all, is kind of a conclusion of this wonderful debate and hearing that we have had.

1-094-0000
**Chair.** – Thank you very much Mr Voss for your conclusions. I would only add two points from my side. We should not forget about biases. I think we had at least two of our colleagues who raised this issue of biases, men, women but not only. And I think that's an important point that we have to put up there among the challenges. Very importantly also, I don't think we have to ignore in our work as policy makers the issue of benefits. I think we've clearly heard how AI can actually help our healthcare systems, from developing new drugs, to managing better our patient flows, to managing better our hospitals, to more precisely target treatments, and so on and so forth. And this issue of benefits I also feel is one of our responsibilities because this is how we can also encourage uptake of these technologies and how we can instil trust in technology and its use in the health sector.

With that I close the session of today, thanking everyone for their participation. I remind you of the fact that we agreed that at the end of such hearings we will provide, at the level of the committee, a first draft with the main findings, the main conclusions of the discussions, where also political groups can add their statements. We will circulate that first draft very quickly so that you can then provide your input and that will then generate a final document that will sum up the hearing today. This is what we will do from now on for all these thematic hearings.

And one last announcement, our next hearing is scheduled for 27 January and will be focusing on AI and sustainability, AI and the Green Deal. Thank you very much. Have a good afternoon and also have a very good holidays even if challenged by the current restrictions. Thank you and see you all in the coming year.

*(The hearing closed at 12.15)*