



## AIM CEO SEMINAR : THE EUROPEAN HEALTH DATA SPACE 19 September 2022

On 19 September 2022, AIM organised a CEO seminar on the European Health Data Space. The objective was to show to the CEOs of the members of AIM what specific legislation at European level can impact their clients and their organisation. With this seminar, AIM wanted to create a platform for our CEOs to directly share information and expertise as well as questions and answers to high-level representatives of the European Commission.

Speakers were Ms Sandra Gallina, General Director from DG SANTE, European Commission and Dr Andrzej Rys, Director responsible for Health Systems, Medical Products and Innovation at the Directorate-General for Health and Food Safety (DG SANTE) at European Commission. From Finland, we had Dr. Persephone Doupi, Development Manager, Finnish Institute for Health, and Welfare.

### Opening statement

Mr. Loek Caubo, AIM President opened the meeting by welcoming the audience and by emphasizing that health insurance funds and health mutuals sit on many data and are therefore very important stakeholders when it comes to the regulation for a European Health Data Space. Although the benefits of a European Health Data Space are obvious, especially in times of a pandemic, the primary and secondary of use health data, must be clearly explained to patients,

according to the AIM President. Trust and confidence of patients in the system will make them cooperate and to understand the benefits are important. However, trust might sometimes still be lacking. Loek Caubo highlights that it is very different in the various Member States due to culture and history of health systems. An in-depth analysis of these differences and possibilities for exchange of best practices is necessary, according to the AIM President.



*“Trust and confidence of patients in the system will make them cooperate and to understand the benefits are important.”*

Loek Caubo  
AIM President

## Keynote speeches: A common European Health Data Space: An ambitious vision for healthcare in Europe

### Ms. Sandra Gallina, General Director, European Commission

The General Director of the Directorate-General from the European Commission, Ms. Sandra Gallina, recognised that AIM is an extremely important stakeholder since not-for-profit health insurers sit on a pile of health data. AIM members play an essential role: They can explain to the European Institutions what is working and what is not working. Therefore, AIM's opinion matters to the European Commission. She thanked AIM for its early input to the preparatory phase of the European Health Data Space. Ms. Gallina referred to other legislative acts at European level, which are all linked with the European Health Data Space, for example the Data Act ("the "mothership") and the Data Governance Act. The European Commission is not going to harmonize the national systems, but all Member States need to be interoperable, according to Ms. Gallina. Member States can decide how to go about. The European Commission had tried to do it at a voluntarily level but has soon realized that it is not enough. Therefore, the Commission came

up with a legislative proposal. The patient is the center but for the moment crossing borders with health data is not easy. This impacts especially patients with rare diseases. It will be a long journey before the EU will be able to exchange health data across borders, said Ms. Gallina. Even hospitals in the same country don't communicate with each other. But innovative treatments need good data. The fragmented landscape of health data calls for actions.

Ms. Gallina referred to the AIM position paper on "[Improvement of healthcare through the exchange of health data – but how?](#)" and compared it to the legislative proposal from the European Commission. According to Ms. Gallina, the Commission did not follow all of AIM's demands but some of them. For example, they provided rules for a precise legal framework and a clear legal mandate for the reuse of health data, a clear overarching governance framework for the use of health data, clear rules for the quality of data and incentives to share the data.

***"National health systems will not be harmonized, but all Member States need to be interoperable."***

*Sandra Gallina  
Director-General for Health and Food Safety  
European Commission*



### Mr. Andrzej Rys, Director, DG SANTE

Mr. Andrzej Rys continued to answer the questions on behalf of the European Commission. On the question on how the Commission copes with the different levels of interoperability in the various Member States, Rys explained that the Commission expects a transitional period of 10

years. They expect the regulation for a European Health Data Space to be put in place by 2025. To achieve this, the regulation needs to enter into force in the 2nd half of 2023 at the end of the Spanish Presidency. It will be followed by a one-year implementation phase.

## Dr. Persephone Doupi, Development Manager, Finnish Institute for Health, and Welfare

Dr. Persephone Doupi gave a best practice example from Finland. She presented the work of the [Finnish Institute for Health and Welfare](#), which operates under the Ministry of Social Affairs and Health. It acts as a statistical authority, responsible for the national registries of the Finnish Institute and maintains the Institute's Biobank and numerous high-quality data sets. It promotes interoperability and versatile utilization of information resources.

For the electronic data management of health and wellbeing Finland developed an entity of digital services, called [Kanta](#). It produces digital services for the social welfare and healthcare sector. Finnish inhabitants can access the Kanta services wherever they live in Finland. The services include citizens, pharmacies, healthcare services and social welfare services.

It started with e-prescriptions; the data was available to the pharmacy staff. A lot of

standardisation was necessary to achieve interoperability. Today, many different national services are supporting Kanta. On the question on how Finland managed to gain trust, Dr. Doupi answered that collaboration is a very important factor. In addition, Finland had constant dialogues at international and European level. It was a long journey, which had already started in the 90's. Before Kanta, Finland already had a huge data collection, which goes back until the early 60's. Finally, Dr. Doupi explained [Findata](#), the Social and Health Data Permit authority. It grants permits for secondary use of social and healthcare data. It is as well a help desk for information on secondary use. Findata accesses data such as patient records in primary and special healthcare, e-prescriptions and social services. It has access to various national registers, among them the Social Insurance Institution. Biobanks and genome data are not included yet, but it will soon come.



*Constant dialogues at international and European level as well as collaboration of all actors are important to gain trust."*

*Dr. Persephone Doupi  
Development Manager, Finnish Institute  
for Health, and Welfare*

### Discussion

The Commission was asked when for the implementation. They expect the adoption of the recommendations to other countries regarding health data spaces would be, she answered that Finland has learned a lot through international cooperation. According to her it is important:

When Dr. Doupi was asked what she expects the implementation of the regulation into national law of Member States. Mr. Rys said that the Czech Presidency (second half of 2023). When asked how the Commission will cope with the interoperability of the Member States, Mr. Rys said that it will most likely take ten years for the transition.

- To reflect on the benefits rather than the risks

- To not to expect too much at the beginning
  - To have in mind that trust is a cultural issue, therefore, you cannot do the same approach everywhere, it must fit the country
  - To be transparent
  - To have many dialogues and do a lot of communication
  - To include stakeholders in big projects (very positive experience in Finland)
- During the discussion, it came up that the Health Commissioner Kyriakides had said in a press conference that the General Data Protection Regulation (GDPR) should be strengthened. The question to the Commission was how they would do it. Mr. Rys explained that the proposal on the European Health Data Space is *lex specialis* to the GDPR. Indeed, the text of the proposal of the European Health Data Space refers many times to the GDPR. It is not foreseen to change the GDPR. On the question about how about a fee for accessing data and whether it will give different levels of access, Dr. Doupi answered that the Finnish permit authority, Findata, has introduced different kinds of fees and that it has caused discussions in Finland. Mr Rys said that the Commission was hoping for “data solidarity” in the EU, that not every access to data should be compensated financially. On the other hand, if someone asks for health data, it does not mean that this person will automatically get it. Another question referred to the permit authorities and whether they have to follow the same principles to avoid “data shopping”. Dr. Doupi replied that the data access bodies will communicate with each other. In addition, there will be ethic committees in some countries. Dr. Doupi was asked how the Finnish stand towards the secondary use of data. According to her, the interest of the Finnish in sharing data has definitely increased. But this comes together with trust and the secure use of the data. She added that the benefit will come by itself. There will be better treatment, better management of funding. In Finland, some patients have already felt the benefits in person, e.g., patients with rare diseases. But the time will show.

*“The benefit of the European Health Data Space will come by itself. There will be better treatment and better management of funding. People with rare diseases experience the benefits first.”*

*Dr. Persephone Doupi  
Development Manager, Finnish Institute  
for Health, and Welfare*



**AIM**

The International Association of Mutual Benefit Societies (AIM) is an international umbrella organisation of federations of health mutuals and other not-for-profit healthcare payers. It has 52 members from 28 countries in Europe, Latin America and Africa and the Middle East. AIM members provide compulsory/and/or supplementary health coverage to around 230 million people around the world, including close to 200 million people in Europe. Some

AIM members also manage health and social services. AIM Members are either mutual or health insurance funds. They are private or public legal entities; solidarity based; not-for-profit orientations: surpluses are used to benefit the members and improve services; democratically elected members play a role in the governance of the organisation.

**More information:** [www.aim-mutual.org](http://www.aim-mutual.org) -Twitter: @AIM\_healthcare

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## AIM FACTSHEET

### What is the European Health Data Space about?

On 3 May 2022, the European Commission presented its long-awaited proposal for a European Health Data Space to improve access to health data for everybody and its use in research and policy. The EU claims that the EU will have savings to the amount of €11 billion, half coming from the exchanges in the healthcare and the other half for the use of health data in research and policy. The EU has lined up € 810 million in funding to build the necessary infrastructure. But more important is the trust and willingness of people to share their sensitive data.

### Objectives of the proposal

#### *Using the power of data*

The proposal will support Member States of the EU to exchange its health data, which are supposed to be a goldmine. Health data can help with the development of treatments, lead to better care of patients, save doctors and patients time and contribute to better functioning health systems. Therefore, data needs to be accessible across the EU by researchers and organizations. One of the challenges is that Member States are at different levels.

#### *Facilitating cross border healthcare*

Patients in different Member States should be able to access a prescription in a local pharmacy in another Member State or a doctor in an emergency in Spain to access a Finnish patient's basic health information. Infrastructure for this already exists in the form of MyHealth@EU. But the proposal foresees to expand it to lab results and MRI scans. There will be mandatory requirements on interoperability and security. Patients would have immediate access to health

data, which is free of charge and easily readable. The fear of Member States is that the EU might take over control over this infrastructure.

#### *Using data for research and policy*

Different standards and limited interoperability, hinder providers of the digital health services to enter the market of other member states and gives them additional costs. Therefore, the new EU legal framework foresees new health data access bodies in the EU's member countries, which will evaluate data access requests for secondary use, and grant permits for specific purposes. The use of such data for commercial advertising, designing harmful products or increasing an insurance premium is prohibited.

#### *Getting public trust*

To get the public trust that their data is safe, the new legal framework is *lex specialis* to the EU General Data Protection Regulation. The EU claims to have put in place strong rules that guarantee data protection. It defines the rights of

citizens concerning their health data in article 3. Health data access bodies grant permits only for specific purposes, and processing data only can happen in “secure” environments.

A new European Digital and Health Data board will also be set up, chaired by the Commission and consisting of digital health authorities and health

data access bodies as well as observers. But some stakeholders already warn to also includes patient associations, researchers, industry and health care professionals, otherwise trust will never be there. Commissioner Kyriakides clarified that there would be patient representatives on the board.

## Next steps at EU level

The Parliament and Council now discuss the legal framework. The Commission is confident that the regulation will enter into force in 2023/2024 and that the application will be in 2025. That’s when the first results will start to show, especially for the exchange of data in health care itself, the MyHealth@EU program. Pilot projects are on the way. Two-thirds of the member states are on board at the moment. The Commission hopes to have all of them on board by 2025.

In the European Parliament, the Civil Liberties, Justice and Home Affairs Committee (LIBE) and the -Environment, Public Health and Food Safety Committee (ENVI) are the leading committees. In the LIBE the far-right Identity and Democracy (ID) group will provide a rapporteur, the ENVI committee it will be the conservative European People’s Party (EPP) group.

## Next steps at AIM

AIM had already published a position paper on the improvement of healthcare through the exchange of health data - But how? in April 2021 and since then lobbied the European Commission. AIM had also answered several consultations of the European Commission. Currently, AIM is analysing the text of the proposed legal framework in its eHealth task force. A publication will be foreseen until the end of this year. Meanwhile, AIM will lobby the Council and the European Parliament.