

## **Multi stakeholder meeting with officials from the European Parliament and council of the EU regarding the potential adoption of opt out to the secondary uses of health data via the EHDS**

### **Summary**

1. A multi-stakeholder group representing 32 organisations from the European healthcare community met MEP Sokol, Co-Rapporteur and other European Parliament officials, as well as representatives of the current trio of presidencies of Council on 6 September 2023 to discuss how the European Health Data Space (EHDS) could facilitate secondary use of personal electronic health data to create tangible benefits for patients and society. While the stakeholder group understands the spirit of protecting the interests of natural persons from improper secondary use of personal electronic health data, the group fears the unintentional side-effects of implementing an opt-out or opt-in mechanism.
2. In line with their consensus statement of June 2023, the multi-stakeholder group expressed concern about the possible scope of an opt-out mechanism, the challenges of ensuring inclusivity and equity, and related operational challenges. The group reiterated its concern that the risk posed by an opt-out or opt-in is that it may amplify rather than help to correct data bias – exaggerating inequalities and disparities through incorrect inferences from the data, leading to health strategies and treatments that are poorly suited to certain groups.
3. Specific areas being discussed in the EP that raises concerns is that there is a political compromise to introduce an opt-out mechanism combined with an opt-in for certain categories of data (such as data from biobanks or genetic data). The exact scope of an opt-out has not yet been detailed and there is discussion about what can be achieved by the Regulation and what should be detailed by implementing acts. On the other side, Member States may be reluctant to accept a detailed top-down prescription of an opt-out for technical and political reasons. However, there was no prevailing view on whether an opt-out would be applied only to the EHDS2 mechanism or whether it would have implications for all secondary use of personal electronic health data.
4. On a more positive note, the EU officials agreed that it would be important to ensure that the EHDS does not exacerbate data bias, because the costs involved with putting the EHDS system in place would be a waste if it increases inequalities and health systems cannot meet the needs of everybody. They acknowledged that more and better use of data by national authorities may have led to less mistakes in health-related policy making during the COVID-19 pandemic. The EU officials called for significantly more funding and incentives for digitalisation, infrastructure development, interoperability and training to support the implementation of the EHDS. There was also consensus among officials that the timeline of implementation will need to be extended.
5. During the meeting:
  - a. BBMRI-ERIC reminded that the EHDS requires not only a new regulation and technical solutions, but also a social and cultural change backed by patients regarding the potential value of data linkages in the context of responsible research and innovation.
  - b. Cancer Patients Europe sees EHDS as an opportunity to homogenise how electronic health data may be processed across the EU and warned about a possible bias in how

data are collected, stored or used, as this would impede clinical developments in cancer research.

- c. European Cancer Organisation echoed the problem of data bias in cancer research and pointed out the need to learn from evidence obtained from data, understand country disparities, and implement a governance mechanism that will ensure trust in the EHDS.
- d. European Society of Cardiology called for access to high-quality and complete data to monitor the safety and efficacy of treatments, as there are significant gaps in evidence that poses a barrier for effective policy making.

## Detailed report

A group representing the 32 organisations that signed a statement in June 2023 on the proposals to include opt-out provisions to the secondary use of health data via the EHDS, met with EU officials from the European Parliament and the Council of the EU to highlight support for the EHDS and raise key issues that need further discussion.

The meeting, held on 6<sup>th</sup> September 2023 in Brussels, was attended by representatives of the EU stakeholders including speakers from the European Association of Urology, the i-HD Institute, BBMRI-ERIC, Cancer Patients Europe, the European Cancer Organisation and the European Society of Cardiology. They were joined by MEP Tomislav Sokol, other European Parliament officials and representatives of several Permanent Representations that cover the upcoming presidencies of the Council.

The stakeholders' position was that the Commission proposal for the Regulation already contains provisions that ensure appropriate, trustworthy and secure secondary use of data. EHDS foresees the use of datasets rendered anonymous wherever possible, and anonymised data do not fall under the scope of the EU General Data Protection Regulation. For pseudonymised data, which is necessary for longitudinal (tracking research results across time) or horizontal research (linking data, for example hospital with registry or screening data), researchers need linked data, but don't need to know who people are. The Commission proposal makes provision for use of this data on the basis of a clear scientific justification, ethics committee approval, Health Data Access Body (HDAB) approval, data usage within a secure processing environment and audited and transparent use. Although the details are still to be worked out, the process proposed seems to find the appropriate balance between privacy protection and the need for European scale evidence for research, public health insights and health service improvement. Nonetheless, there have been suggestions to include an opt-out model in the EHDS for the secondary use of data and the stakeholders consider that this needs further discussion and clarification.

The moderator distilled the consensus statement into three main areas for discussion with the EU officials.

1. **Scope** - What is the scope of opt-out? Does it apply exclusively to secondary use of pseudonymised data provided on the basis of the EHDS Regulation, within and across borders, via HDABs or does it apply also to existing pseudonymised data use inside as well as between countries? Does the Regulation therefore place an emergency stop on all data learning opportunities and research that use other legal routes than the opt-out, until the proposed opt out is fully operational across Europe?
2. **Inclusivity and equity** – Opt-in sounds like a softer approach, but it is not. The difference between opt in and opt out is only how non-response is treated – as a default of no or a default

of yes to the question. All 'opt' choices have almost the same delivery challenges, whether they are opt-in or opt-out, and need to provide the same – equitably accessible - solutions:

- How are citizens all across Europe going to be reached, and provided with adequate information to make a choice, per intended data use (as required by the GDPR), across all layers/parts of society?
- Who prepares and provides appropriate information in an accessible form?
- What is an acceptable method to exercise and collect people's decisions, recognising the diversity of literacy, digital literacy, digital capability?
- What are the mechanisms for reassurance and transparency, including which actors in each country will be charged and resourced to respond to citizen queries and concerns?

So opt-out is not a simple question of providing a link to a website and a tick box app, it is about a whole system transformation.

The stakeholder group was concerned about how these provisions can be implemented both across and within all EU MS in an equitable way. We already have concern that data is not representative of certain groups, including vulnerable groups in society. It is recognised that persons from lower socio-economic groups and ethnic minorities, as well as refugees are less likely to have longitudinal structured and coded electronic health records, and therefore will be under-represented in real world data sets used for public health and research. The risk with opt in, and to some extent also with opt-out, is that it may amplify rather than help to correct for this data bias – exaggerating inequalities and disparities through incorrect inferences from the data, leading to strategies and treatments that are poorly suited to certain groups.

3. **Operations** – how do we do we implement opt-out in complex and adaptive health systems and societies? How do we deliver this at scale? Lots of European projects have experimented with dynamic consent tools etc, but they only work in well defined projects with limited patient numbers and a few data uses - none of them have reached the scale to meet the needs of 500 million European citizens and pan-European research activity. Who will be mandated and trained to guide citizens? Health care professionals (HCPs) don't have training and capacity to do this unless they are given more resource. Much more investment will be needed if this is going to be implementable, and a considerable time is needed to achieve Europe wide awareness and choices.

### **BBMRI – bio banking research infrastructures**

This research infrastructure catalogues all the biobanks over 20 European countries. After 10 years, much has been achieved at national level, but connection of data at European level still not easily done. A key issue is ensuring that those involved have the right training and tools to perform the tasks required. Agreeing on technical aspects regarding data linkage is crucial and very complex, and it needs to happen in line with social and cultural change. Patients and citizens that entrust data to biobanks want it to be used, they are enthusiastic and do not want to be told that legislation stops their data from being used. In the case of biobanking, consent is in place. The best infrastructure is when you don't know it exists, it is when you can take it for granted and trust it. Research Infrastructures already have a lot of experience - they know what works – please build on our experience and expertise.

Michaela Mayrhofer: "The EHDS is an ambitious undertaking. It requires not only technical solutions and new regulation but complementarity to existing laws, operational governance frameworks and societal aspects. In research, such a cultural change will require financial and personnel resources, the support of patient groups and citizens, whilst striking a balance for responsible research and innovation."

## **Cancer Patients Europe**

Our role is to safeguard the rights of cancer patients to have equal access to the best treatment and care possible, wherever they live across Europe. Innovative treatments are heavily dependent on research and we, as patients, understand the importance of health data sharing for secondary use for the benefit of clinical trials, biobanks, and European health registries.

Clinical trials are often the only hope for certain cancer patients, for instance for pancreatic cancer patients. European health registries are an important source of data to help us advocate for equal access to treatment across Europe. We cannot afford to have a bias in how data are collected, stored, or used. Homogeneity or an alignment among Member States is fundamental for us.

We look at the EHDS regulation as an opportunity to homogenize how data are collected and stored across Europe and to reduce inequalities across Member States. Member States should all be aligned with very little to no derogation power.

We do understand the spirit of protecting the opt-out right of the patients from improper secondary use of data, but we fear more the unintentional outcome of this protection. We cannot afford to take the risk of slowing down or impeding research development. Learning from the GDPR, we do not want to become the excuse for introducing administrative burdens that in the end increase rather than decrease inequalities across Europe.

## **European Cancer Organisation**

Both HCPs and members of the ECO patient advisory committee (PAC) agree the EHDS has a lot of promise.

Why do we need the EHDS? Much is still unknown about the causes of cancer. For example, we see rising cancer incidence among under 50s – why is this happening? The only way we can answer questions like this is by learning from evidence obtained from the data. We also need to understand more about country disparities. We need to learn more about how to detect cancers earlier and to share knowledge across countries. Croatia lung cancer screening is a good example of this learning.

Data bias is a problem for cancer researchers. We have gaps of evidence on race and ethnicity and it is important not to exacerbate the inequalities there already are.

From discussions with ECOs PAC, we know that cancer patient groups are not pushing for opt-in/out but that their views are more in line with the original Commission proposal. They see the need for research and data linkage to bring evidence based cancer care and treatments. Governance is a really important mechanism to address trust, GDPR also already provides a strong regulatory basis, that is why ECO has called for patient and HCPs involvement in the EHDS Board and also at HDAB level.

## **European Society of Cardiology**

Our medical society has just met at our annual congress bringing together 30 000 medical professionals in cardiovascular health to discuss scientific developments. Much effort has been put in by the medical society to have registries that can monitor the safety and efficacy of treatment. ESC is addressing this by using real world evidence datasets as well as clinical trials to update clinical practice guidelines. So, even when a medicine is approved, we monitor its long term evidence to see if it is effective and safe.

If it proves not to be effective, we use this knowledge to adjust our clinical practice guidelines, which go out to all our members.

We really need access to high quality and complete data, similarly to cancer. There are still significant gaps in evidence that are a barrier for effective policy making.

It is really important to balance rights relative to other areas of society today. Reporting is necessary because it is important to understand the underlying health / societal issues we are facing - this is normal practice for many areas for society, such as road safety.

### **Discussion with EU officials**

There was much agreement from the EU officials that it would be important to ensure that the EHDS does not exacerbate data bias. The costs involved with putting the EHDS system in place will be a waste if it increases social inequalities and imbalances.

It is really important to have health systems and services that meet the needs of everyone. Reliable and inclusive data is needed in order to design policies to protect and care for everyone.

The opt-out system is not perfect, but it is a compromise between different parties and committees with different interests and concerns and is likely to be the approach that will gain an overall majority in the EP.

Opt-in for certain specific categories of data, in particular biobanks and genetic data is still under discussion. These are categories which are seen as particularly sensitive data, but it is also the area where new research is needed the most.

They recognised that universal (consistent) interpretation of GDPR is lacking across the EU which is a barrier to cross border linkage.

There is a proposal on the table to include stakeholders (industry, HCPs and patients) at EHDS governance level, and only patients and HCPs at national level decision making, but this is not agreed to by all parties.

More and better use of data by national authorities may have led to less mistakes health related policy making, such as were made during the COVID-19 pandemic. It has been agreed that agencies like EMA and ECDC and public bodies need fast track access to data in emergencies, and measures will be put in place to enable this.

Not all healthcare providers have the same interest in secondary use of data. GPs/ primary care are traditionally less directly involved in research, but may be at the front line in counselling patients regarding an opt out.

Digitalisation and interoperability of data should be incentivized. EU funding / financing was raised as one of the most important incentives. There was an acknowledgement that for the infrastructure and training needed to implement the EHDS, the amounts proposed by Commission are absolutely not enough. Funding on the current MFF was not available because EHDS was not yet proposed, but we will need an earmarked EHDS budget in the next MFF.

The concern of the burden on HCPs in supporting their patients in making opt out decisions, and responding to concerns including waves of anxiety when data breaches are publicised, was recognised. How the opt-out is implemented will depend on health system set up. Thus it is rather difficult for the

Regulation to define scope of the opt-out. Therefore, the exact scope of the opt-out has not yet been detailed and there is discussion about what can be achieved by the Regulation and what should be detailed by implementing acts. A top down prescription in the Regulation is not ideal because of the differences in health systems across the EU, but on the other hand, heterogeneity of interpretation is also a barrier to data linkage. This has happened with the GDPR.

There was general consensus that the timeline for implementation mentioned in the Regulation will need adjustment – more time will be needed than in the original Commission proposal.

Scope of the EHDS opt-out was a point of discussion – there was no prevailing view on whether it would be only applied to the EHDS mechanism or whether it could have implications for all national data processing in a *de facto* way.

The costs and time needed to implement opt-out were recognised. The group mentioned the possibility of transitional arrangements defined in the Regulation, including governance of these mechanisms. It might be good to define starting points, such as what data categories and/or purposes of use the EHDS can start with, piloting and testing all elements.

#### Requests

- our statements are read and considered by all – important
- Bridging gap between privacy NGOs and health sector important
- Make the message known in media – nationally as well as Brussels bubble.