EFPIA Position on opt-out in the EHDS Regulation

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The European Health Data Space (EHDS) Regulation aims to provide a consistent framework for secondary use of data keeping the right balance between safeguarding the privacy of citizens and unlocking the value of data to benefit society. The text proposes an "opt-out", which consists of the right for data subjects to opt-out from the secondary use of their personal electronic health data within the EHDS framework. In this paper, EFPIA highlights key challenges and suggestions that should be taken into account when **implementing the opt-out mechanism in EU Member States. In particular, EFPIA stresses the importance of avoiding fragmentation and bias, clarifying the scope of the opt-out by limiting it to personal data and creating a centralised system for the exercise of the opt-out.** This is with a view to ensuring an **appropriate balance between individuals' privacy and access to high quality, unfragmented, and representative data for research and innovation in Europe.**

1. Avoiding fragmentation

The agreed text sets out the principle of the opt-out, with Member States providing their own mechanism for exercising the opt-out right within the EHDS framework. **Standardisation and harmonisation of opt-out modalities should be key priorities**. If not, all stakeholders, notably patients and data holders, will face significant challenges in navigating opt-out systems that vary across different Member States. It is critical for patients to have consistent communication of the opt-out and its impacts across Member States so that they have the same information available to make their decision.

In addition, while the text allows Member States to adopt stricter measures and additional safeguards for some data sets (Art. 33(5)), EFPIA calls on Member States not to introduce an even stricter opt-in right for certain categories of data sharing under the EHDS. Such a requirement would only increase fragmentation in the EU and would significantly affect the availability and representativeness of the data, as discussed below.

2. Avoiding data bias

The opt-out could undermine the representativeness of the data, increasing the risk of bias (for example, if an important number of individuals in a particular age band or from a particular ethnic minority opt out). This would affect how data users, including healthcare decision makers, can benefit from the EHDS. Problems could arise for example for rare diseases where the patient sample would not be sufficient to conduct scientific research. It would be important that the health data access bodies (HDAB) communicate **information about the percentage of opt-outs for each data set** to **data users in order for them to assess how representative the data is.**

3. An opt-out limited to personal data

In practice, the application of the opt-out may not always be possible or is likely to create a significant burden on stakeholders, in particular the healthcare system. This may be true especially for personal

data that already receives special protection, such as data processed by data holders in pseudonymised form only.

The EHDS provides that the opt-out applies where individuals "can be identified in a dataset". Re-identifying data subjects would not be possible, for example, in a fully terminated clinical trial, where the data holder (the sponsor) holds only pseudonymised data and cannot identify a data subject in a dataset without the assistance of the clinical trial site holding the correspondence table between the patients' identifiers (code) and their identity. Seeking the assistance of clinical trial sites for each opt out request within the EHDS would be extremely burdensome on the healthcare system and does not seem feasible. We would therefore assume that the data holder would be considered unable to effectuate the optout and thus be exempt from applying it in this context.

Further, EFPIA believes that the **opt-out should not apply to data made available to a data user when the data has been anonymised.** Article 35f(2a) makes clear that the opt-out prevents the "making available" of *personal data* (*i.e.*, to the data user) or the processing of *personal data* "pursuant to a permit" (*i.e.*, by the data user).

4. An HDAB-centric opt-out system

The agreed text provides that "natural persons shall have the right to opt-out **at any time** […] from the processing of personal electronic health data relating to them for secondary use under this Regulation" and that the right is reversible. It also provides that the opt-out must be "accessible and easily understandable". These requirements for a flexible, easy to use and reversible opt-out right almost inevitably call for a centrally managed system, probably under the direction of the HDAB which could then extract the data of individuals who decided to opt out and respect any changes in their preferences. In contrast, a decentralised opt-out system (*e.g.*, per category of data holder or dataset) risks complicating matters significantly for all stakeholders concerned. Individuals would have to opt out several times with varying scopes, the opt-outs may conflict over time, it may be difficult to reconcile by the HDAB or even to communicate to the HDAB. Moreover, in some cases, an overly detailed opt-out may constitute special health data in itself (*e.g.*, when it reveals participation in a particular clinical trial or the use of a particular medical device).

Although EFPIA considers that clinical trial data can be exempted from opt out, to avoid any burden, we would recommend a centralized approach for receiving the opt-out for all data categories. Both centralised and decentralised approaches would face challenges when the "source data" available to data holders is already pseudonymised and only available to them in that form. Reconciliation with (name-based) opt-out registers would require a burdensome intervention by healthcare systems. For example, in the context of clinical trials, if a clinical trial participant was offered a right to opt out at the time of entering a clinical trial and did not exercise that right (i.e., did not opt out), but then declares a general opt-out two years later, respecting this opt-out would impose a significant administrative burden on the healthcare professionals holding the re-identification keys. All hospitals involved in the trial would need to cross-check their trial participants' data against opt-out lists, identify the relevant patient codes, and inform the clinical trial sponsor of the opt-out. The sponsor would then need to filter the relevant data out before sharing it with the data access body, creating an immense burden, **in particular,** on healthcare systems. In a

decentralised system, this burden risks being exponentially higher because of the numerous stakeholders involved (clinical trial sponsors, medical device manufacturers, biobank managers, register owners, *etc.*) who would all have to interact with the healthcare system for reconciliation purposes. **In a centralised system, the HDAB would be tasked with verifying if, given the particular circumstances of the case, individuals who opted out can be identified in the dataset received from the data holder and whether such identification is reasonably possible or presents a disproportionate burden on the stakeholders involved, notably the healthcare system.**

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EFPIA understands that the objective of the opt-out is to maintain trust in the healthcare and research system by granting citizens a level control over their personal data. However, the practical implementation of the opt-out raises concrete questions that will need to be addressed. The opt-out system should be simple, easily applicable, and not constitute an unnecessary burden for data holders, HDABs, and national health systems. It needs a clearly defined scope to avoid any misinterpretation. EFPIA has concerns about the operationalisation of the EHDS opt-out. Its roll-out will require pragmatism concerning its scope, common sense, and probably the broad deployment of new identity management technologies. The approach will have to strike a proper balance between the rights of individuals and the needs of the research community. EFPIA looks forward to working with Member States and the European Commission to ensure the successful implementation of the EHDS Regulation.