



THE EUROPEAN HEALTH DATA SPACE AND THE OPT-IN VERSUS OPT-OUT DISCUSSION: ECO STATEMENT OF VIEW

March 2023

The European Cancer Organisation congratulates MEP Tomislav Sokol and MEP Annalisa Tardino for bringing forward [a balanced and improved draft report of the European Parliament on the proposed Regulation](#) to create a European Health Data Space. Amendments to the proposal, if accepted, would, for example, ensure stronger stakeholder involvement in the governance of the European Health Data Space, support clear targets for implementation, and give attention to the funding support required to help Member States meet the new obligations together. These are all highly welcomed and [very much in line with key points of potential improvement expressed by the European Cancer Organisation](#).

Subsequent to the publication of the draft report, the European Cancer Organisation has become aware of an important debate concerning the **right of citizens and patients to be able to exercise an opt-out from the European Health Data Space in respect to the use of their health data for secondary uses**, such as research. There is some suggestion presently that this protection of citizen rights should even be further secured via the use of an **opt-in** mechanism instead.

Understanding the criticality of this matter, and having consulted with its [member societies](#), [Patient Advisory Committee](#) and [Digital Health Network](#), the European Cancer Organisation makes the following commentary.

- The opt-out option, as proposed in [the Draft ENVI-LIBE Report of 10 February 2023](#), is supported as a pragmatic approach that balances the need to respect citizens and patients' right to control access to their data, with the need to achieve a strong European Health Data Space that will bring about important improvements for patients and health systems, including in respect to health research.
- We recommend that the opt-out mechanism be applied in practice in a consistent manner across Europe, and therefore subsequent EU guidance on this matter be developed and published before the Regulation comes into full legal application.
- The opt-out mechanism is supported by pre-existing safeguards in respect to data privacy and data ownership put in place by such frameworks as the General Data Protection Regulation. However, confidence in the operation of the opt-out mechanism would be further secured by ensuring:



1. Open and transparent governance for the European Health Data Space, including in respect of the composition of the EHDS Board.
 2. Enabling citizens and patients to be updated and informed about the ways in which their data has been accessed and used.
- Amendments proposed in the Draft ENVI-LIBE Report of 10 February 2023 are reassuring in this respect.