**Healthcare community calls for action:**

**Do not fail patients and undermine the full potential of the European Health Data Space**

*A diverse range of stakeholders in the European health ecosystem will meet European Parliament and Council decision-makers in a call to maintain the core principles of the European Health Data Space and adopt a consistent, EU-wide approach to unlock the potential value of using health-related data for secondary purposes in order to bring tangible benefits for patients in the EU.*

6 September 2023, Brussels – A multi-stakeholder group consisting of 32 European patient organisations, medical associations, research organisations, data collaborations and industry associations are meeting EU officials involved in the legislative negotiations for a Regulation on the European Health Data Space (EHDS). Attendees include: MEP Tomislav Sokol, Co-Rapporteur, as well as other EU Parliament officials and the representatives of several permanent representations that will hold upcoming Presidencies of the Council of the European Union.

The informal group of organisations have formed a partnership due to a shared concern that the European Commission’s proposal for the EHDS could lose some of its impact and potential value in the co-legislative negotiations. In October 2022, the group put forward [recommendations](https://uroweb.org/news/7-recommendations-for-the-european-health-data-space-to-improve-patient-outcomes-empower-citizens-and-strengthen-health-systems) calling for consistent legislation and a successful implementation of the EHDS. In June 2023, the group issued a [joint statement](https://uroweb.org/news/joint-statement-health-organisations-define-ehds-opt-out-required-for-life-saving-research) expressing support for the Commission’s original proposal that strikes a balance between the protection of personal data while allowing the secondary use of electronic health data to enable the creation of tangible benefits for patients in the EU.

In that joint statement, the group raised concerns about the risk that data bias would become systematic within the EHDS from its inception and thus undermine its principal value for secondary use purposes, if an opt-out or opt-in mechanism were added, and called for an impact assessment of those policy options. Should the legislative negotiations move towards adopting an opt-out mechanism, the statement outlined challenges and recommendations for implementing an effective opt-out mechanism.

**Participating organisations (all signatories of the preceding joint statement):**

[Alliance for Regenerative Medicine](https://alliancerm.org/)

[Association of European Cancer Leagues](https://www.cancer.eu/)

[Associazione Italiana Cistite Interstiziale](http://www.aicionlus.org/)

[BBMRI-ERIC](https://www.bbmri-eric.eu/)

[Biomedical Alliance in Europe](https://www.biomedeurope.org/)

[Cancer Patients Europe](https://cancerpatientseurope.org/)

[DIGITALEUROPE](https://www.digitaleurope.org/)

[Digital Health Society](https://thedigitalhealthsociety.com/)

[Europa Uomo](https://www.europa-uomo.org/)

[European Alliance of Associations for Rheumatology](https://www.eular.org/)

[European Association of Urology](https://uroweb.org/)

[European Cancer Organisation](https://www.europeancancer.org/)

[European Confederation of Pharmaceutical Entrepreneurs](https://www.eucope.org/)

[European Connected Health Alliance Group](https://echalliance.com/)

[European Federation of Nurses Associations](https://efn.eu/)

[European Federation of Pharmaceutical Industries and Associations](https://efpia.eu/)

[European Health Telematics Association](https://www.ehtel.eu/)

[European Hematology Association](https://ehaweb.org/)

[European Infrastructure for Transnational Medicine](https://eatris.eu/)

[The European Institute for Innovation Through Health Data](https://www.i-hd.eu/)

[European Organisation for Research and Treatment Cancer](https://www.eortc.org/)

[European Respiratory Society](https://www.ersnet.org/)

[European Society of Cardiology](https://www.escardio.org/)

[European Society of Human Reproduction and Embryology](https://www.eshre.eu/)

[Fertility Europe](https://fertilityeurope.eu/)

[Fundació HiTT](https://fhitt.org/)

[International Painful Bladder Foundation](http://www.painful-bladder.org/)

[MedTech Europe](https://www.medtecheurope.org/)

[OPTIMA](https://www.optima-oncology.eu/)

[PHA Europe – European Pulmonary Hypertension Association](https://www.phaeurope.org/)

[PIONEER](https://prostate-pioneer.eu/)

[World Federation of Incontinence and Pelvic Problems](https://wfipp.org/)