

ERS position on the European Health Data Space (EHDS) regulation

The European Respiratory Society (ERS), the largest scientific and clinical organisation in respiratory medicine in Europe, calls on the European co-legislators to ensure that the European Health Data Space framework will allow Europe to remain at the forefront of medical research and enable the free flow of scientific data where medical researchers are central to Europe's health and competitiveness.

ERS supports the initial proposal of the European Commission and believes that it already provides the necessary safeguards to ensure the privacy of citizens by facilitating data sharing either in anonymised or when necessary in pseudonymised format.

The opt-out mechanism, defined by article 33, could be the way forward only if supported by detailed governance compliance rules and uniform implementation across Europe. Conversely, an opt-in mechanism would not allow the EHDS to develop and would actively prohibit progress on a truly borderless health data exchange.

In view of the discussions within the European Parliament and later the inter-institutional negotiations, ERS calls the co-legislators to consider that the opt-out mechanism may not work for all types of data; moreover, it could add an additional burden to healthcare professionals, who should receive the proper guidance to be able to assist their patients in making informed decisions.

ERS strongly encourages guaranteeing the European Health Data Space that is efficient and well-functioning by removing the barriers to health data sharing to foster research and innovation.