



THE EUROPEAN HEALTH DATA SPACE

EUROPEAN CANCER ORGANISATION COMMENTS TO THE DRAFT ENVI-LIBE REPORT OF 10 FEBRUARY 2023

MARCH 2023

Amendment suggestions to the Draft ENVI-LIBE Report of 10 February 2023

SECTION OF 10 FEBRUARY ENVI-LIBE DRAFT REPORT	SUGGESTED AMENDMENT	JUSTIFICATION
Suggested New Recital	<ul style="list-style-type: none"> - <i>Having regard to the Commission communication of 3 February 2021 on Europe’s Beating Cancer Plan (COM(2021)0044),</i> - <i>Having regard to the EU’s Framework Programme for Research and Innovation 2021-2027 (Horizon Europe) and the dedicated Horizon Europe Mission on Cancer,</i> - <i>Having regarded the European Parliament resolution of 16 February 2022 on strengthening Europe in the fight against cancer – towards a comprehensive and coordinated strategy (2020/2267(INI)) and the work of the Special Committee on Beating Cancer (BECA) in its mandate;</i> 	The European Health Data Space should be complementary to Europe’s Beating Cancer Plan and the EU Research Mission on Cancer.
Amendment 5	<i>“Specifically relevant fields in the EHR should be clearly marked, such as patient ID, allergies, laboratory data, medical alerts, co-morbidity, and current medication”</i>	Co-morbidity is important information for quality care in all therapeutic areas, including cancer.
New Amendment 10	<i>This would be also important for introducing additional functionality for handling public health crises, such as support for contact tracing for the purposes of containing infectious diseases. Furthermore, in accordance with the strengthened role of the European Center for Diseases Control and Prevention (ECDC), Member States should ensure that the ECDC receives real-time and comparable data on vaccination including vaccination coverage listed on the ECDC vaccine schedule and vaccine-preventable disease surveillance. (...)</i>	Amendment to recital 26 of the European Commission proposal 3 May 2022. ECO recommends that the European Health Data Space supports lesson learning from the COVID-19 pandemic including improving vaccine tracking. For example, the successful ECDC

		COVID-19 tracker could be applied to other vaccines such as HPV vaccination.
Amendment 61	<i>5 a. The Member States shall determine the selection procedure for health stakeholders referred to in paragraph 5, taking into account a need for openness, transparency and inclusivity in approach.</i>	Appointment of health stakeholders to data governance bodies, at both European and national level, should be conducted via open and transparent process.
Amendment 71	<i>Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2) after consultation with the EHDS Board and other relevant stakeholders.</i>	Implementing Acts will be vital to the implementation success of the European Health Data Space. For the assurance of a high trust environment stakeholders should be openly consulted on the implementing acts alongside the EHDS Board.
New Amendment 88	<i>(c) to produce national, multi-national and Union level official statistics as defined in Regulation (EU) 223/2009 related to health or care sectors; such as levels of vaccination coverage both for cross-border health emergencies and routine immunisation;</i>	Amendment to Article 34, paragraph 1 (point c) of the European Commission proposal 3 May 2022. ECO recommends that the European Health Data Space supports lesson learning from the COVID-19 pandemic including improving vaccine tracking. For example, the successful ECDC COVID-19 tracker could be applied to other vaccines such as HPV vaccination.
Amendment 99	<i>4 a. Member States shall determine the selection procedure for health stakeholders referred to in paragraph 3, having regard to the need for openness, transparency and inclusivity in approach.</i>	Appointment of health stakeholders to data governance bodies, at both European and national level, should be conducted via open and transparent process.
Amendment 102	<i>Following open and public consultation, the Commission shall adopt guidelines on the functioning of the health data access bodies to ensure coherent processes among them.</i>	Guidelines will be vital to the implementation success of the European Health Data Space. For the



		assurance of a high trust environment stakeholders should be provided opportunity to input to Commission guidelines.
Amendment 158	<p><i>1a. After two years from the entry into force of this Regulation, the Commission shall carry out an evaluation on the Union funding attributed to the setting up and working of the EHDS, notably as to the ability of Union bodies to carry out their tasks under this Regulation and of Member States to apply the Regulation in a uniform and coherent manner. The Commission shall submit a report on its main findings to the European Parliament and to the Council, the European Economic and Social Committee and the Committee of the Regions, accompanied, where appropriate, by legislative proposals. Stakeholders should be consulted in the preparation of the evaluation report.</i></p>	Patients and healthcare professionals are key end users of the European Health Data Space. Their perspective on whether the European Health Data Space is, and has, achieved purpose and/or could be improved, will be crucial to achieving an accurate evaluation picture.