

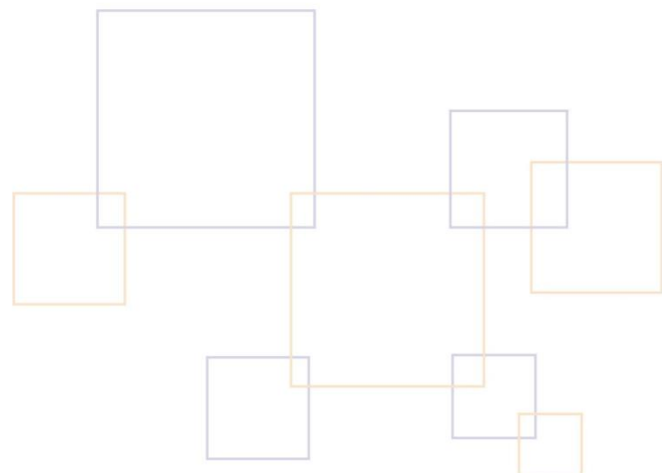
**ESIP position on  
the proposal for a Regulation on the European Health Data Space**

**European Social Insurance Platform (ESIP)**

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**ESIP aisbl**

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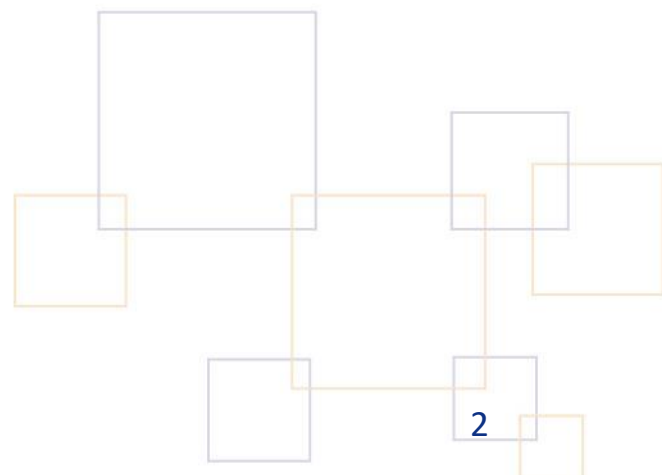


## About the European Social Insurance Platform (ESIP)

The [European Social Insurance Platform \(ESIP\)](#) represents 45 national statutory social insurance organisations in 17 EU Member States and Switzerland, active in the field of health insurance, pensions, occupational disease and accident insurance, disability and rehabilitation, family benefits and unemployment insurance. The aims of ESIP and its members are to preserve high profile social security for Europe, to reinforce solidarity-based social insurance systems and to maintain European social protection quality. ESIP builds strategic alliances for developing common positions to influence the European debate and is a consultation forum for the European institutions and other multinational bodies active in the field of social security.

*Statement regarding positions submitted by ESIP: ESIP members support this position in so far as the subject matter lies within their field of competence.*

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## ESIP key messages on the proposal for a Regulation on the European Health Data Space

The European Social Insurance Platform (ESIP), representing statutory social security institutions across the EU, **generally welcomes the establishment of the European Health Data Space (EHDS)**. We endorse the clear distinction between primary and secondary use of health data and accordingly the establishment of two separate infrastructures and a twofold governance mechanism where access is granted by national competent authorities, connected through an EU infrastructure.

According to the current, broad definition, **social security institutions** are to be considered data holders of medical administrative data. It is important to highlight that social security institutions are also key **data users of health data to support decision-making around the provision of healthcare**.

ESIP Members will play a crucial role in the implementation of the EHDS legislation. We therefore recommend to:

### Maintain complementarity with national data infrastructures

The EHDS Regulation must be designed in a such a way to ensure **compatibility with national governance frameworks on data access**; the EHDS infrastructure should be fully **interoperable with national IT infrastructures** already in place.

- In order to ensure the successful implementation of the EHDS Regulation, the administrative and legal burden for national data infrastructure to adapt to the new EU legislative framework should be minimised. The **transmission of health data from a data holder to the competent health data access body should be transparent and efficient**, avoiding duplication and errors.
- Where data holders from the public sector fulfil their data provision obligation by means of trusted data sharing services, those **delegated trusted competent services should remain in place**.
- As a way to preserve the highest possible level of data protection, the EHDS Regulation should duly take into account **consent and opt-out mechanism already in place at national level for access to health data for primary use**. Opt-out mechanisms have to be also considered for access to health data for secondary use.
- It must be ensured that **electronic health record (EHR) systems that have already been approved by a national body may continue to be operated when the Regulation takes effect**. Where applicable, EHR developed by health insurance funds should remain the preferred service.

### Preserve the highest level of data security

The highest level of data security should be preserved, ensuring **consistency and complementarity with national and European regulatory frameworks in the field of data**

**management and data protection**, namely Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data (General Data Protection Regulation – GDPR).

Whenever possible, data should be **anonymised or even synthesised**. The type of data format to be used for access should be clearly and legally defined according to the specific access circumstances and actors involved. This particularly applies to pseudonymised data.

### **Ensure the quality of data feeding into the EHDS infrastructure**

**We see with concern the inclusion of voluntary labelled wellness applications** within the scope of the Regulation, in the absence of sufficient quality parameters. Only health applications compliant with Regulation (EU)2017/745 and certified by an independent body should eventually be included.

### **Introduce stricter criteria and conditionalities for secondary use of health data**

Stricter criteria and enhanced transparency should be introduced for providing access to data users and particularly commercial entities, always taking into account the **patients' and public interest**.

The **tacit data permit mechanism** in article 46(3) should be deleted from the EHDS Regulation, as it would jeopardise a sound assessment of the data access application by the health data access bodies, eventually resulting in unconditional access.

**It is of utmost important to introduce conditionalities for data access.** Provisions on **return on investment** when publicly-held data are accessed for secondary use are currently not included in the EHDS Regulation and must be introduced particularly for research and development purposes. This should be combined with the **publication of results from research** based on data accessed through the EHDS infrastructure.

### **Entrust Member States with a stronger role with a view to establishment of the EHDS**

**We advocate for the deletion of Article 8 on telemedicine from this Regulation** as this is part of the scope of the legislation on the coordination of social security. In our opinion, this could eventually interfere with Member States' competences as to the organisation of healthcare systems.

With a view to implementing and delegated acts, **we strongly support a stronger participation of Member States in the drafting process of those acts**, through the examination rather than advisory procedure. Only by involving the institutions responsible for implementing the EHDS Regulation at national level can a viable, sustainable and successful implementation be ensured.