

Feedback of the European Social Insurance Platform (ESIP) on the Combined Evaluation Roadmap/Inception Impact Assessment on a European Health Data Space

3 February 2021

The European Social Insurance Platform (ESIP) welcomes the Commission's intention to improve access to and exchange of health data, via the establishment of a European Health Data Space (EHDS).

We support a reinforcement of the legislative and governance framework to

- Increase cooperation among Member States on the exchange of health data for primary use, also as a preventive measure for future cross-border health threats;
- Establish an institutionalised infrastructure for data governance and exchange for secondary use, for the common good and in full respect of GDPR.

This would benefit access to healthcare especially but not exclusively in cross-border situations. We call for a **EHDS that provides real added value for healthcare delivery, need-driven R&D and policymaking.**

To ensure that sensitive health data are exchanged and used in a responsible way the following preconditions must be met:

- **Harmonised standards**

Harmonised standards for data formats – for exchange, quality & anonymisation – should be established to ensure comparability, compatibility and interoperability. The Recommendation on a European Electronic Health Record (EHR) exchange format is a first step in this direction.

Security standards should be defined to process sensitive health data. Standardisation of access protocols should also be considered.

- **Conditions for access and use**

Building on the **eHealth Digital Service Infrastructure**, an EU digital space for health data, accessible also to patients, would support the provision of cross-border healthcare and patients' mobility. Access to the data space should be given upon identification and authentication by authorised actors and service providers, to ensure data safety & confidentiality.

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Regarding data used for R&D, the new legislative framework should determine which data will be available for secondary use, as well as clarify ownership, access, users' rights and ensure a uniform interpretation of GDPR.

ESIP believes that different technological solutions and separate governance frameworks are needed for primary and secondary use of health data.

- **A code of conduct**

In the development and evaluation of digital technologies including AI, attention must be given to ethical issues. A code of conduct should be developed to ensure ethical use of data and promote common understanding of data protection. Access to and use of sensitive health data must comply with GDPR and the proposal for a EHDS should not neglect informed consent and the right to be forgotten.

Harmonised legal measures preventing possible unwarranted, opportunistic and malicious use of health data need to be considered.

- **Solidarity-by-design**

While seizing the opportunities of data science, consideration should be given to its downstream risks (e.g. algorithmic injustice, ethnic profiling & pervasive data tracking). Machine learning enables the assessment of (health) risks on a case-by-case basis thereby fundamentally changing the principle of solidarity in all domains of social security including healthcare coverage.

The EHDS should build on the ethical principle of fairness-by-design, providing an ecosystem of measures that protect end-users, reflecting the central European value of solidarity.

- **Involving public authorities in the design of EHDS**

Public authorities – importantly statutory health insurances – should not be considered only as data providers, but as key actors in the establishment of the EHDS, data standards and conditions for use of data. Health insurers could support the development of digital healthcare solutions to ensure real added value for patients and increased health systems' sustainability.

As part of the **e-health stakeholders' group**, ESIP's national experts provide essential insights into the design of appropriate and effective legal, governance and technical frameworks for data exchange.

ESIP looks forward to expanding on this feedback in targeted & public consultations.

You can find the submitted response on the European Commission's website [here](#).