



Evaluation roadmap and impact assessment for establishing a European Health Data Space

Opinion of the German Social Insurance
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The German Federal Pension Insurance (DRV Bund), the German Social Accident Insurance (DGUV), the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband), the national associations for statutory health and long-term care insurance funds and the Social Insurance for Agriculture, Forestry and Horticulture have all joined forces to form the "German Social Insurance – European working group" in view of their common European policy interests.

German Social Insurance represents the interests of its members vis-à-vis the bodies of the EU and other European institutions and advises the relevant players about the context of current legislative proposals and initiatives.

Germany's statutory insurance system, health and long-term care insurance, pension insurance and accident insurance offer effective protection against the consequences of major life risks.

I. Preliminary remarks

On the 23rd December 2020, the EC published a combined evaluation roadmap and impact assessment for the establishment of a European Health Data Space (EHDS).

The umbrella organisations of the German Social Insurance welcome the European Commission's intention to create a European health data space, in particular through:

- more binding cooperation between member states to improve the availability and interoperability of health data with added value for patients
- the creation of an institutionalised data governance structure, the R&D with regard to innovations and applying AI (Artificial Intelligence).



II. Comments

A data space for patients

A data space, which provides access to patients' health data in electronic health records, supports patient mobility in the EU. German Social Insurance is participating in the development of a pan-Europe infrastructure for exchanging treatment data (eHealth Digital Infrastructure, eHDSI). Greater commitments by member states and their social systems will support its widespread implementation. The design must be oriented to the added value for the medical care of patients.

A functioning EHDS requires common standards for data formats and semantics to promote comparability, compatibility and the interoperability of data. From the point of view of the German Social Insurance, the main challenges in pan-Europe networking are the clear identification and reliable authentication of the accessing entities, the authorisation of service providers in Germany and abroad and the guarantee of confidentiality of health data. The national systems are to be networked so that there is no interference with the national telematics infrastructures and the application of the EU General Data Protection Regulation (EU GDPR) is clearly regulated.

A data space for research, innovation and AI

The availability of data within the EU should be extended through an institutionalised data governance structure. Interaction between the data governance structure and the EHDS should play a decisive role in determining which data will be available for secondary use in the future. The proposal for an EHDS must clearly define access and usage rights as well as ensure consistent interpretation of the EU GDPR throughout the member states.

National social systems generate and process data to optimise national and regional care structures. Therefore, they should be considered not only as data providers but also as key players in the EHDS and be involved from the beginning. This also includes a say in the decentralised provision of anonymised data, which should be made available in a targeted manner for research purposes with real added value in care (e.g. rare or widespread diseases) and with a benefit for society as a whole.

Access to data is essential for research and the further development and use of AI applications. The German Social Insurance supports the demands of the white paper on AI to specify necessary conditions. This includes the stipulation of general preconditions for the use of AI, such as ensuring the integrity of life and basic human rights, the requirement of transparency, non-discrimination or final decision-making by humans, e.g. in therapy or claims decisions. The impact on the skills of doctors and other health professionals also needs to be considered. In doing so, it is important to ensure that the data is secure and that the data sovereignty of the patients and the control and traceability of AI-supported processes all comply with the EU GDPR.
