COMMENTS ON THE 01/2025 GUIDELINES ON PSEUDONYMISATION

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Research Project EmpoderDat (https://empoderdat.proyectoscebes.es/)

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1) On the concept of pseudonymisation itself

The Guidelines insists that pseudonymised data, which could be attributed to a natural person using additional information, should be considered as information on an identifiable natural person (Recital 26 GDPR) and are therefore personal data subject to the GDPR.

This statement is also valid, according to the Guidelines, if the pseudonymised data and the additional information are not held by the same person. If the pseudonymised data and the additional information could be combined considering the means reasonably likely to be used by the controller or another person, then the pseudonymised data are personal data. Even if all additional information kept by the pseudonymising controller has been deleted, the pseudonymised data only become anonymous if the conditions for anonymisation are fulfilled.

In this respect, account should be taken of the Opinion of Advocate General Spielmann, delivered on 6 February 2025, according to which, 'if the dispute is analysed in relation to the data transmitted to Deloitte, I am of the opinion that, contrary to what the EDPS argues, it was necessary to determine whether the pseudonymisation of the data in question was sufficiently robust to conclude that the complainants (...) were not reasonably identifiable. In other words, in this context, if Deloitte had reasonable means to identify the complainants, it could be considered to be processing personal data'.

If the Advocate General's interpretation is finally adopted by the CJEU, whether the subjects are reasonably identifiable will not only be an objective question, but also a subjective one, i.e. it will be necessary that the reversal is objectively possible and that the recipient of the pseudonymised data is subjectively able to do so, by having adequate means.

2) On the impact of the concept of pseudonymisation on research using health data

Among the main objectives of the European Health Data Space Regulation (EHDSR) would be the following:

- Empower citizens to take control of their health data;

- Strengthening the principle of 'interoperability' in accessing patients' electronic health records; and

- Enhancing the exchange of health data in order to promote research and the shaping of public policy at EU level.

In this regard, consideration should be given to Art. 66.2 EHDSR ('Health data access bodies shall provide electronic health data in an anonymised format, where the purposes of the processing by the health data user can be achieved with such data, taking into account the information provided by the health data user') and especially 66. 3 EHDSR, according to which 'where the health data user has sufficiently demonstrated that the purposes of the processing cannot be achieved with anonymised data pursuant to Article 68(1)(c), health data access bodies shall provide access to electronic health data in pseudonymised format. The information necessary to reverse the pseudonymisation shall only be available to the health data access organisation or to an entity acting as a trusted third party in accordance with national law.

Because of the extensive concept of pseudonymised data maintained in the Guidelines, which overly narrows the concept of anonymised data not subject to the GDPR, research with health data may be negatively affected and become an obstacle.

Health data will in many cases be pseudonymised data, not anonymised. The use of pseudonymised data for secondary purposes requires, according to Art. 66.3 REEDS, a sufficiently proven or demonstrated need that the purposes of the processing cannot be achieved with anonymised data.