Proposals for amendments and additions to the draft Guidelines 1/2026 on the processing of personal data for scientific research purposes

1. Introduction of a new Example No. 3-bis (Scientific research scenario)

A company developing hospital management software collects pseudonymised data from several client hospitals with the aim of analysing factors associated with diagnostic delays in patients affected by rare diseases.

To this end, the company establishes a multidisciplinary working group composed of internal data scientists, academic epidemiologists and clinical experts. A methodological protocol is developed, setting out the objectives of the study, the data selection criteria and the statistical methodologies to be applied. The project is submitted to an independent ethics committee.

The stated objective is to identify organisational and clinical patterns that may improve the timeliness of diagnosis and contribute to scientific knowledge concerning diagnostic pathways for rare diseases. At the same time, the company envisages the use of the results for the development of additional functionalities to be integrated into its software products.

The main results are intended to be presented at scientific conferences and published in aggregated form. However, certain algorithms derived from the analysis remain proprietary and are not fully disclosed.

In such a scenario, a number of typical indicators of scientific research may be identified, including:

- a methodical and systematic approach;
- ethical oversight;
- the involvement of qualified researchers;
- the objective of generating knowledge and improving healthcare delivery;
- the envisaged dissemination of results.

Notwithstanding the presence of elements that may introduce a commercial dimension and give rise to interpretative complexity, the activity may, in principle, be considered as scientific research within the meaning of the GDPR, insofar as the key indicative criteria are met. Accordingly, the related processing of personal data may be regarded as processing for scientific research purposes.

2. Amendment to Recital 45

The following sentence is added at the end of Recital 45:

"The purpose of the processing should fall within the scope of the scientific research activities carried out by the controller requesting broad consent. For example, a controller conducting research in the field of orthopaedics should only request broad consent where the purposes of future research indicated in such consent fall within that field."

3. New Recital 45-ter

"Broad consent should indicate that the data will be stored for a period limited to what is strictly necessary, not exceeding 25 years from the time of collection, and may be processed within that period for the future research purposes specified in the broad consent."

4. New Recital 52-bis

"In order to facilitate a closer and longer-term interaction with data subjects, dynamic consent may, where appropriate, be collected through new technologies, such as mobile applications."

5. New Recital 75-bis

"The use of new technologies and Artificial Intelligence in scientific research"

The continuous development and use of new technologies, including Artificial Intelligence (AI), represent a key area of attention in the field of scientific research. The use of such technologies raises, on the one hand, questions regarding the protection of fundamental rights and, on the other hand, constitutes an important driver for scientific and societal progress.

In this context, such technologies may serve a dual role, giving rise to specific considerations with regard to the processing of personal data, including special categories of data.

In particular, such systems may be conceived as:
• tools for carrying out scientific research activities, in which case an appropriate legal basis for the processing should be identified at the outset, without prejudice to the need to implement appropriate safeguards, including, where required, a Data Protection Impact Assessment;
• the object of scientific research itself, where the purpose of the research is the development of new AI systems or technologies. In such cases, specific challenges may arise in identifying a suitable legal basis. In this respect, account should be taken of Regulation (EU) 2024/1689, and an assessment should be conducted in light of the specific context of use. By way of example, the processing may, where applicable, be based on Article 6(1)(e) GDPR and Article 9(2)(g) GDPR, where it is carried out for reasons of substantial public interest.

6. New Example No. 10-bis

Consider a scientific research project aimed at developing Artificial Intelligence systems for the purposes of prevention, diagnosis or treatment of diseases, or for the development of medical devices.
In the absence of consent, the processing of personal data, including special categories of data, necessary for the development of such tools may, in principle, be justified on the basis of a task carried out in the public interest or for reasons of substantial public interest, insofar as it contributes to the identification of new means for promoting and safeguarding public health and collective well-being.

7. Revised wording of Example No. 16

A consortium composed of universities, a patient association and a company developing artificial intelligence tools conducts a study aimed at the early identification of signals of psychological distress in young adults.
The researchers obtain publicly accessible data from a social media platform relating to approximately 500,000 users. The data are pseudonymised and analysed using natural language processing (NLP) techniques in order to identify linguistic patterns associated with depression, social isolation and suicide risk.
The researchers consider that individually informing all data subjects would involve a disproportionate effort and could alter the behaviour of the individuals concerned, thereby affecting the reliability of the results and the reproducibility of the research over time.
In assessing the impossibility or disproportionate effort of providing information, the following factors should be taken into account:
- organisational constraints;
- the risk of introducing bias;
- the adoption of appropriate alternative transparency measures.