FARMINDUSTRIA

Consultation on EDPB Guidelines 1/2026 on Processing of Personal Data for Scientific Research Purposes

Farmindustria welcomes and appreciates the approach outlined by the European Data Protection Board (EDPB) in its Guidelines on processing of personal data for scientific research purposes.
The Guidelines expressly acknowledge the value of scientific research, including research funded by private entities, as a means of promoting and safeguarding the public interest. They also recognize the need for a consistent interpretation and application of the GDPR provisions governing the processing of personal data for scientific research purposes across the European Economic Area.
The Guidelines are of particular relevance to pharmaceutical companies, as they clarify that research conducted by private entities, including research pursued for commercial purposes, falls within the concept of "scientific research" under the GDPR.
At the same time, due consideration should be given to avoiding the introduction of additional organisational and documentary requirements that could unnecessarily delay research activities, ultimately slowing patients' access to new therapeutic opportunities and innovative treatments.

Set out below are some observations regarding specific issues addressed in the Guidelines.

Definition of Scientific Research – Section 2

The EDPB Guidelines identify six "key indicative factors" for determining whether a processing activity is carried out for scientific research purposes.
This definition appears overly restrictive and does not seem to fully reflect the broad interpretation set out in Recital 159 GDPR, which expressly states that the term should be understood as encompassing "*technological development and demonstration, fundamental research, applied research and privately funded research," while also taking into account the Union's objective of achieving a European Research Area pursuant to Article 179(1) TFEU*."
The Guidelines establish a presumption that an activity qualifies as "scientific research" where certain requirements are met (*e.g.*, compliance with ethical standards, transparency, and verifiability by third parties), while effectively placing the burden of proof on the controller in cases where not all such elements are simultaneously present. This approach does not sufficiently recognise the value of activities that are ancillary or instrumental to scientific research. In practice, it may cast doubt on the scientific nature of activities which, although based on a rigorous scientific methodology, do not result in publication and are therefore not subject to peer review.
With regard to observational, non-interventional and Real-World Evidence (RWE) studies, it is important to avoid restrictive interpretations that could call into question their qualification as scientific research where they are conducted on the basis of a research protocol, a recognised methodology, and with the objective of generating clinical, epidemiological, regulatory or public health evidence.

In conclusion, although the concept of scientific research expressly includes research funded by private undertakings, in practice research activities carried out by private entities may not always satisfy all six "key indicative factors".
In this regard, the Guidelines should adopt a more practical and proportionate approach, avoiding an unduly restrictive interpretation of the concept of scientific research.

Research Data Infrastructures (Section 2.2) and Future Research
The Guidelines clarify that personal data may be processed within a "research data infrastructure" (also referred to as a research repository or database) for the purpose of making such data available for future research projects within a specific field of research.
It would be desirable for the Guidelines to expressly acknowledge that such infrastructures and databases may also contain and make available biological and genetic data for future research purposes, following the model of established initiatives such as the UK Biobank. This should, of course, be subject to appropriate safeguards ensuring high standards of physical and cybersecurity protection, as well as robust guarantees regarding digital sovereignty and data governance.

Further Processing of Personal Data for Research Purposes (Secondary Use) – Section 3
Public interest and legitimate interest should be recognised as appropriate legal bases for the secondary use of personal data for scientific research purposes.
Relying exclusively on consent—even where obtained in the form of broad consent—may not be sufficient. The outcomes of subsequent research projects could be affected if data collected in the primary study could not be fully reused, creating a risk that the quality, robustness and representativeness of the results generated by the new research may be compromised.
Furthermore, secondary use presupposes that the processing activity falls within the notion of scientific research as defined in Section 2 (to which the comments above apply). As a consequence, certain non-medical studies or analytical activities may not satisfy all the criteria set out in that definition, potentially creating uncertainty as to their qualification for research purposes.

Need for Regulatory Harmonisation – Section 3.1.1, Paragraph 25
Scientific research requires a harmonised regulatory framework that appropriately balances the various interests involved, while ensuring coherence among the relevant supranational and national rules. Such a framework is essential to fostering a competitive and innovative environment within the European Union and its Member States, encouraging investment in research, innovation and the responsible use of research data.
In the context of clinical research, a coordinated, consistent and proportionate approach by Legislators and Competent Authorities is particularly important. The Guidelines should therefore promote greater harmonisation in the application of Articles 9(2)(j) and 9(4) GDPR across Member States, also with a view to ensuring greater alignment with the European Health Data Space (EHDS), the Digital Omnibus package and the proposed Biotech Act.

Broad Consent – Section 4

The provision on broad consent is welcome. Together with the provisions relating to transparency, it may facilitate scientific research in a number of contexts. This is particularly relevant for biobanks, where consent obtained at the time of collection for the use of a human biological sample cannot realistically encompass the specific details of future research projects that are not yet known at the time the sample is collected.

The broad consent, with the possibility of supplementing additional information made available through a dedicated website or a designated contact point (*e.g.*, the biobank), addresses the practical impossibility of re-contacting participants for each individual research project conducted on the sample by different researchers over time.

The Guidelines also refer to dynamic consent, which enables separate consent requests to be made for specific research projects or research phases when the purposes become more clearly defined or where the processing activity falls outside the scope of the original broad consent.

For pharmaceutical companies, these mechanisms may represent useful tools in the context of biobanks, research infrastructures, longitudinal studies and Real-World Evidence (RWE) databases. However, they also entail significant operational and compliance burdens, including ongoing information updates, preference management, digital infrastructure requirements, independent oversight arrangements and extensive documentation obligations.

It is therefore important to identify solutions that are proportionate, practical and sustainable, particularly in the context of international multisite clinical trials, federated research infrastructures, rare disease research and retrospective RWE projects.

Legal Bases: Public Interest – Section 4.2; Legitimate Interests – Section 4.3

With regard to the legal bases available for the processing of personal data for scientific research purposes, greater harmonisation across Member States is necessary.

EU and national legislation should expressly regulate, pursuant to Articles 9(2)(i) and 9(2)(j) GDPR, the circumstances under which the processing of special categories of personal data for research purposes is permitted, as well as the safeguards applicable to such processing. In particular, legislation should provide greater clarity regarding the specific situations in which research-related processing may be lawfully carried out, including, for example, retrospective studies.

Such an approach would be consistent with the broader legislative developments currently taking shape at EU level. In this regard, it is noteworthy that compliance with a legal obligation and the performance of a task carried out in the public interest are identified as the default legal bases under the proposed Biotech Act framework.

Greater legal certainty and consistency in the application of these legal bases would facilitate scientific research across the European Union while ensuring a high level of protection for individuals' fundamental rights and freedoms.

Harmonisation of Privacy Roles: Sponsors, Clinical Sites, CROs, Data Holders and Research Partners – Section 7

The Guidelines should provide more practical and operational criteria for distinguishing, within the typical models of pharmaceutical research, between situations involving independent controllership, joint controllership and processor relationships.

Particular attention should be given to the allocation of roles and responsibilities among sponsors, clinical sites, contract research organisations (CROs), scientific societies, data holders, technology providers and federated research infrastructures.

A lack of consistency in the qualification of these actors may create contractual and operational uncertainty, particularly in the context of international multisite clinical trials, cross-border research projects and Real-World Evidence (RWE) initiatives. Greater clarity in this area would support a more harmonised application of the GDPR across Member States, while facilitating effective collaboration among the various stakeholders involved in scientific research.

Anonymisation and Pseudonymisation – Section 8

Ongoing cooperation and dialogue between Data Protection Authorities, Regulatory Authorities, Member State Governments and relevant Agencies (*e.g.*, EMA and national competent authorities) would be highly desirable in order to promote a common understanding of the anonymisation and pseudonymisation standards applicable to data processing in the research context.

Such coordination should seek to ensure an appropriate balance between the protection of patients' data, the quality and usability of research data, and the ability to share and reuse data for legitimate scientific research purposes.

Greater alignment on these standards would enhance legal certainty and operational clarity for all stakeholders involved in the research ecosystem, facilitating compliance while supporting scientific innovation and the effective use of health and research data.