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European Federation of Pharmaceutical Industries and Associations

EFPIA response to the EDPB public consultation on Guidelines 1/2026 on the processing of personal data for scientific research purposes

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Introduction

EFPIA welcomes the opportunity to comment on the European Data Protection Board's draft Guidelines 1/2026 on the processing of personal data for scientific research purposes.

EFPIA supports the EDPB's objective of providing practical guidance on the application of the GDPR to scientific research. Scientific research involving health data is essential to the development of new medicines, the generation of real-world evidence, the improvement of patient outcomes, the monitoring of safety, and the development of innovative research tools, including AI-enabled analytical methods. A clear, proportionate and innovation-supportive interpretation of the GDPR is therefore essential for Europe's competitiveness and for the protection of public health.

Pharmaceutical research is already conducted within a highly regulated framework that protects participants, safeguards patient safety and ensures scientific integrity, including through Good Clinical Practice, ethical review where required, regulatory oversight, pseudonymisation, confidentiality, security, auditability and traceability. EFPIA therefore considers that GDPR guidance should complement these existing safeguards, rather than create duplicative or inconsistent requirements.

EFPIA welcomes several important elements of the draft Guidelines, including the recognition that scientific research can be carried out by private entities, that it may be conducted for profit, that further processing for scientific research purposes benefits from the presumption of compatibility, and that scientific research may constitute a legitimate interest under Article 6(1)(f) GDPR.

However, EFPIA is concerned that certain parts of the draft Guidelines may be interpreted in a way that is narrower, stricter, or more operationally burdensome than the GDPR requires. In particular, the draft Guidelines risk creating uncertainty in relation to the scope of scientific research, the distinction between research consent and GDPR consent, the practical use of

broad consent, secondary use of health data, transparency obligations, anonymisation, retention, and the allocation of controller and processor roles in collaborative research.

EFPIA therefore invites the EDPB to revise the Guidelines to ensure that they remain aligned with the broad interpretation of scientific research set out in Recital 159 GDPR, support responsible innovation, and provide a practical framework for health research while maintaining strong protection for individuals.

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Definition of scientific research

EFPIA welcomes the EDPB's attempt to identify factors that may help determine whether an activity qualifies as scientific research. However, the Guidelines should make clearer that these factors are indicative and non-exhaustive, and should not operate as a cumulative test or as a presumption against activities that do not satisfy all factors.

Recital 159 GDPR provides that the notion of scientific research should be interpreted broadly, including technological development and demonstration, fundamental research, applied research and privately funded research. The Guidelines should reflect this broad approach more consistently.

The current list of factors appears to be primarily designed with interventional clinical trials and academic or open-science research in mind. This creates risks for other types of legitimate scientific research.

For example, adherence to ethical standards is an essential component of responsible scientific research. However, the Guidelines should clarify that independent ethics committee review is required only where applicable law or relevant research governance rules require it. Ethics committee approval is required for certain types of interventional clinical trials, but not necessarily for all retrospective analyses, secondary use projects, non-interventional studies, technology development activities, or internal research tools. The Guidelines should not create a new, general GDPR-based requirement for independent ethics committee approval beyond what is required under applicable health research legislation.

Similarly, the Guidelines should avoid suggesting that research must always be peer reviewed, published, fully open, or carried out independently of commercial objectives in order to qualify as scientific research. In the pharmaceutical and life sciences sector, legitimate scientific research may involve intellectual property, trade secrets, confidential know-how, regulatory strategies, internal validation, or proprietary technologies. These features do not undermine the scientific nature of the activity.

EFPIA recommends that the Guidelines clarify that privately funded research, applied research, technological development and demonstration, internal research tools, AI-enabled research support tools, and secondary use of health data may qualify as scientific research where they follow a methodical approach, are directed at generating or applying knowledge, and are subject to appropriate safeguards.

Secondary use, purpose compatibility and interaction with Article 6 and Article 9 GDPR

EFPIA welcomes the recognition that further processing for scientific research purposes is presumed compatible with the original purpose under Article 5(1)(b) GDPR. This compatibility presumption is essential for the responsible secondary use of health data, including clinical trial data, real-world evidence generation, research using historical datasets, pharmacovigilance-related research, and the development of innovative research methods.

Secondary use of clinical trial data is important to advance general scientific knowledge and may also be considered an ethical imperative. Where individuals have participated in research, the results of that research should be used to the maximum extent possible, subject to appropriate safeguards. It would be undesirable, and in some cases ethically problematic, to require new experiments or new data collection merely to obtain data that already exists.

In this context, EFPIA considers that the final Guidelines should preserve the full practical effect of Article 5(1)(b) GDPR. Where secondary use of clinical trial data serves scientific research purposes and is allowed by Union or Member State law or pursuant to Article 5(1)(b) GDPR, the further processing should be considered compatible with the original use of the personal data. Article 5(1)(b) GDPR is not a stand-alone legal basis, but it allows processing for secondary scientific research purposes on the same basis as the primary use, provided that appropriate safeguards are applied in accordance with Article 89(1) GDPR and that any applicable Article 9 GDPR condition is satisfied.

This interpretation is also supported by Recital 50 GDPR, which provides that, where further processing is compatible with the purposes for which the personal data were initially collected, "*no legal basis separate from that which allowed the collection of the personal data is required*." The compatibility presumption for scientific research should therefore be understood as preserving the possibility to rely on the same Article 6 legal basis as the primary processing, rather than requiring controllers to identify a new or separate Article 6 legal basis for each further scientific research use. Where special categories of personal data are processed, EFPIA considers that the same logic should apply to the Article 9 GDPR condition relied on for the original processing, provided that the further processing is genuinely for scientific research purposes, remains compatible under Article 5(1)(b) GDPR, and is subject to appropriate safeguards under Article 89(1) GDPR. Otherwise, the compatibility presumption would risk being deprived of practical effect.

The Guidelines should therefore avoid suggesting that controllers must identify a new or separate Article 6 GDPR legal basis for secondary scientific research in all cases. Such an interpretation would risk depriving the compatibility presumption of practical effect and could make responsible secondary use of clinical trial data unduly dependent on consent in practice.

At the same time, EFPIA recognises that consent may also provide a valid route for secondary use in appropriate circumstances. In particular, consent may relate to a broad area of research activities, provided that it meets the requirements of Articles 4(11) and 7 GDPR and is accompanied by appropriate information in accordance with Articles 13 and 14 GDPR and, where special categories of personal data are processed, the requirements for explicit consent under Article 9 GDPR. However, consent should be treated as one possible route for secondary use, not as the default or preferred route where the GDPR compatibility presumption and Article 89 safeguards provide an appropriate basis for responsible scientific research.

The final Guidelines should therefore distinguish clearly between: consent to participate in a clinical trial or other research activity; consent as a GDPR legal basis under Article 6(1)(a); explicit consent as an Article 9(2)(a) derogation; broad consent for a sufficiently defined area of future research; the compatibility presumption under Article 5(1)(b); and safeguards under Article 89(1) GDPR.

Secondary use without consent should remain possible where the further processing serves scientific research purposes, is compatible with the original purpose under Article 5(1)(b) GDPR, and is subject to appropriate safeguards. These safeguards may include, in particular, a data protection impact assessment, strict data minimisation, additional pseudonymisation, technical and functional separation, access controls, confidentiality obligations, prohibitions on re-identification, appropriate security measures, scientific review where available or required, records of secondary-use processing, and dedicated staff training.

Transparency remains an important element of this safeguards-based approach. Where the secondary use is known at the time of collection, data subjects should be informed in the initial information notice. Where the secondary use was not known at that time, information should be provided in advance of the secondary use where feasible. However, where providing individual information is impossible, would involve disproportionate effort, or would seriously impair or render impossible the scientific research purpose, Article 14(5)(b) GDPR should remain available. This is particularly important where the sponsor or other research controller only has access to coded or pseudonymised data and cannot contact data subjects without obtaining additional identifying information.

Where reliance is placed on Article 14(5)(b) GDPR, controllers should document the rationale for doing so and the safeguards in place to protect data subjects. They should also provide information on the secondary use in a publicly accessible form, such as on a website, platform, registry or other appropriate transparency channel, including information on the research pursued, applicable rights and limitations, and a contact point.

EFPIA therefore recommends that the EDPB clarify that responsible secondary use of clinical trial data and other health data for scientific research should remain possible without consent where the conditions of Article 5(1)(b) GDPR are met, the same legal basis as the primary use can be relied upon, any applicable Article 9 GDPR condition is satisfied, and appropriate safeguards under Article 89(1) GDPR are implemented. Consent should remain available as an alternative route, including through broad consent where appropriate, but should not be treated as the default route for secondary scientific research.

Consent in clinical research

The Guidelines should take a more nuanced approach to consent in clinical research. In clinical trials and other health research settings, several different forms of consent may coexist and these should not automatically be equated with GDPR consent as a legal basis. The final Guidelines should also avoid creating ambiguity as to whether GDPR consent may be integrated into the same consent process or documentation as other health care, ethical or research participation consents. While paragraph 38 appears to suggest that a single consent process may cover both data protection and non-data-protection requirements, paragraphs 54 and 55 appear to require separate consent for data protection purposes and for legal or ethical research obligations. EFPIA recommends that the EDPB clarify that what matters is not necessarily the use of separate forms, but that the different consents are clearly distinguished, separately explained, and capable of being assessed against their respective legal requirements. At the same time, the Guidelines should not assume that consent in clinical research is always invalid or insufficiently freely given. The statement that controllers should refrain from relying on consent where a patient's capacity to provide consent is "severely affected" by their mental or physical medical condition may be difficult to apply in practice without further clarification. Clinical research already contains established mechanisms to address situations where medical professionals consider that a participant lacks capacity to provide ethical or research participation consent, including the involvement of a legally authorised representative where permitted by applicable law. In many clinical research contexts, the consent process is subject to extensive safeguards. Ethics committees and investigators assess whether participants can give informed consent, whether they are able to refuse or withdraw, whether additional protections are needed, and whether vulnerable participants require specific safeguards. In some cases, witnesses or legally authorised representatives may be involved.

The Guidelines should acknowledge that these safeguards may be relevant when assessing the validity of GDPR consent, where consent is relied upon.

EFPIA recommends that the Guidelines provide clearer guidance on the distinction between research participation consent and GDPR consent, and avoid creating incentives for controllers to

rely on GDPR consent where another legal basis would be more appropriate and more protective of research continuity.

Broad consent, biobanking and future research

EFPIA welcomes the discussion of broad consent, but the Guidelines should be more practical in relation to biobanking and future research.

In biobanking, participants may donate biological samples and associated data for future research. At the time of donation, it may not be possible to identify every future research project, research partner, methodology, or scientific question. Requiring repeated re-consent for each future project or each research partner would often be unrealistic and could significantly undermine valuable research.

The Guidelines should clarify that broad consent may be valid and appropriate in biobanking and comparable research infrastructures, provided that the consent is accompanied by suitable safeguards. These safeguards may include governance mechanisms, ethics or scientific review where appropriate, clear categories of research, transparency portals, points of contact, withdrawal mechanisms, and information on how participants can obtain updates about research uses.

The Guidelines should also clarify that the development, training, validation and use of AI systems, tools, platforms, datasets, models or infrastructures designed to support future research may itself qualify as scientific research or as ancillary processing for scientific research, where it is linked to genuine research objectives and appropriate safeguards. The Guidelines should provide at least a principle-based, sector-neutral framework distinguishing AI developed as part of scientific research from operational or commercial AI deployment unrelated to the research purpose, and clarify how purpose limitation, compatibility and transparency apply to AI model development, training, validation and deployment in scientific research settings.

Transparency and obligation to inform data subjects

EFPIA supports meaningful transparency for research participants and data subjects. However, the Guidelines should better reflect the practical and ethical realities of clinical research, particularly where sponsors do not hold directly identifying data.

In clinical trials, pharmaceutical sponsors receive coded or pseudonymised data from trial sites. They do not receive patient names, contact details, or direct identifiers. Those details are held by the clinical trial site and investigator. This separation is a key safeguard under Good Clinical Practice and the Clinical Trials Regulation. It protects participants and avoids unnecessary disclosure of identifying information to the sponsor.

The Guidelines appear to suggest that controllers should not delete contact details, or should collect contact details, where further research may be anticipated. This approach is problematic in the clinical trial context. Requiring sponsors to collect or retain patient contact details solely to provide future transparency notices would be inconsistent with data minimisation and necessity. It could also increase risks to participants, since contact details linked to clinical trial participation may themselves reveal sensitive health-related information.

The Guidelines should give greater weight to Article 11 GDPR, which recognises that controllers are not required to maintain, acquire or process additional information in order to identify data subjects solely for the purpose of complying with the GDPR, where identification is not otherwise necessary.

For clinical research, the Guidelines should recognise alternative transparency mechanisms as appropriate and often preferable. These may include information provided through trial sites, principal investigators, hospitals, public webpages, study registries, participant portals, transparency notices, contact points, or representative organisations. Such mechanisms may provide effective transparency without requiring sponsors to collect unnecessary identifying information.

EFPIA therefore recommends that the EDPB clarify that the obligation to inform data subjects should not require controllers to collect or retain additional identifying information where this is not necessary for the research and would increase privacy risks.

Further processing notices and material changes

The Guidelines adopt a broad view of what may constitute a material change requiring renewed notice, including changes to purpose, legal basis, partners, retention, or risk profile. EFPIA agrees that data subjects should receive meaningful information about significant changes. However, the Guidelines should avoid creating an obligation to provide repeated individual notices for routine, foreseeable, low-risk or operational changes.

In structured clinical research, providing a new notice to participants may be operationally complex and may require coordination with trial sites, investigators, ethics committees and national procedures. In some cases, re-contacting participants may be impractical, disproportionate, or ethically inappropriate, particularly after a study has ended or where participants are lost to follow-up.

EFPIA recommends that the Guidelines provide a more proportionate approach. Controllers should assess whether a change materially affects data subjects' reasonable expectations or risk profile. Where individual notice would be disproportionate or would require the processing of

additional identifying data, layered transparency, public notices, study websites, registries, or contact points should be recognised as valid alternatives.

Anonymisation and legal basis for anonymisation

The Guidelines should be revised to avoid suggesting that the process of anonymisation always requires a separate legal basis in a way that discourages anonymisation.

The GDPR recognises that effectively anonymised data fall outside the scope of data protection law and that anonymisation as an important privacy-enhancing measure. If the Guidelines are read as requiring an additional and burdensome legal basis analysis for the act of anonymising data, this could create a perverse incentive against anonymisation and in favour of continued processing of personal data.

EFPIA recommends that the EDPB clarify that anonymisation is a safeguard and risk-reduction measure. Where personal data are processed for the purpose of anonymising them, the required legal basis should be assessed in a practical and proportionate way, taking into account that the objective is to remove the data from the scope of the GDPR and reduce risks to individuals. in addition, the Guidelines should recognise that, where personal data **are** processed for scientific research purposes under Article 89 GDPR, anonymisation may be required by Article 89(1) GDPR where those purposes can be fulfilled by further processing that does not permit, or no longer permits, the identification of data subjects.

Storage limitation and retention for future research

EFPIA welcomes the recognition that longer retention periods may be compatible with scientific research. Long-term retention may be necessary to enable verification, regulatory scrutiny, reproducibility, pharmacovigilance, safety follow-up, longitudinal research, real-world evidence generation, and future scientific research.

However, the Guidelines should avoid requiring controllers to define future research purposes with a level of specificity that is incompatible with the nature of scientific research. It is often not possible to predict all future research questions at the time of collection or at the end of a research project. The value of health data often emerges over time, particularly as scientific knowledge, analytical tools and public health needs evolve.

The Guidelines should therefore allow retention for reasonably foreseeable categories of future research, subject to periodic review and appropriate safeguards. Controllers should be able to define retention criteria by reference to scientific, regulatory, ethical, safety, reproducibility and governance considerations.

Roles and responsibilities in collaborative research

EFPIA welcomes the Guidelines' confirmation that role allocation depends on the actual influence exercised over purposes and essential means, and not merely on labels. However, the Guidelines should avoid an overly broad interpretation of controllership in collaborative research.

The statement that active participation in drafting or defining a research protocol will normally make an entity a controller could create uncertainty in public-private partnerships, research consortia, advisory boards and expert consultations. Collaborative research often involves many partners providing scientific, technical or methodological input. For example, partners may suggest biomarkers, inclusion criteria, endpoints, statistical methods, technical standards, data quality measures, or scientific hypotheses. Such input is inherent to collaborative research and should not automatically mean that each contributor determines the purposes and essential means of processing.

Similarly, sponsors frequently consult external academic experts, key opinion leaders, bioethicists or patient representatives during protocol development. Providing expert advice should not, by itself, make those advisers joint controllers. Treating advisers or scientific contributors as joint controllers could discourage participation, complicate governance, and create disproportionate Article 26 GDPR obligations.

EFPIA recommends that the Guidelines draw a clearer distinction between:

- entities that determine the purposes and essential means of processing;
- entities that provide scientific, technical, ethical or methodological advice;
- entities that follow an already established protocol;
- processors acting on documented instructions; and
- participants in governance structures with genuine decision-making authority.

The Guidelines should clarify that scientific or advisory input alone does not amount to controllership unless the entity has actual decision-making power over the purposes and essential means of processing.

Appropriate safeguards under Article 89 GDPR

EFPIA supports the central role of Article 89 GDPR safeguards. Pharmaceutical and life sciences research already operates within robust safeguards, including governance frameworks, ethical oversight, scientific review, data minimisation, pseudonymisation, access controls, contractual restrictions, secure processing environments, audit mechanisms, confidentiality obligations, and transparency measures.

However, the Guidelines should clarify that safeguards must remain risk-based and context-specific. The list of safeguards should not become a checklist or a set of mandatory measures in every research context. Different safeguards will be appropriate depending on the nature of the research, the identifiability of the data, the role of the controller, the applicable regulatory framework, and the risks to data subjects.

The Guidelines should also recognise that pseudonymisation is often the most appropriate safeguard in clinical research, where full anonymisation may not be possible or desirable because of regulatory, safety, auditability, traceability, or scientific validity requirements. Directly identifiable data should be limited to what is necessary, but pseudonymised data should be recognised as a strong and practical safeguard in regulated health research.

Interaction with the EHDS and future EU health data framework

The Guidelines should better explain their interaction with the European Health Data Space and the broader EU policy objective of enabling responsible secondary use of health data.

The Guidelines recognise that further processing for scientific research may be presumed compatible, but they should avoid interpreting Article 6 and Article 9 GDPR requirements in a way that reduces the practical effect of that compatibility presumption. In particular, where further processing for scientific research is compatible under Article 5(1)(b) GDPR, controllers should not be required to identify a new or separate Article 6 legal basis, and the same logic should apply to the Article 9 GDPR condition relied on for the original processing, provided that appropriate safeguards under Article 89(1) GDPR are implemented. This is particularly important for consistency with the EHDS and the EU objective of enabling secure, governed and privacy-preserving secondary use of health data for research and innovation.

EFPIA recommends that the final Guidelines acknowledge the need for consistency with the EHDS and clarify that the GDPR should be applied in a way that supports responsible secondary use, subject to strong safeguards, rather than creating additional uncertainty or fragmentation.

Conclusion

EFPIA welcomes the EDPB's work on Guidelines 1/2026 and supports the objective of strengthening trust and legal certainty in scientific research. However, several aspects of the draft Guidelines should be revised to ensure that they remain aligned with the GDPR, reflect the broad interpretation of scientific research in Recital 159, and are workable in the context of regulated health research.

EFPIA therefore recommends that the EDPB:

- clarify that the factors for identifying scientific research are indicative and non-exhaustive;

- reflect the broad scope of scientific research, including applied research, privately funded research, technological development, non-interventional studies, real-world evidence, biobanking and AI-enabled research tools;
- avoid making ethics committee approval, publication, peer review or open-science dissemination general requirements for scientific research;
- clarify the distinction between research consent, broad consent, GDPR consent, Article 6 legal bases and Article 9 derogations;
- clarify that secondary use of clinical trial data and other health data for scientific research should remain possible without consent where the conditions of Article 5(1)(b) GDPR are met, the same legal basis as the primary use can be relied upon, any applicable Article 9 GDPR condition is satisfied, and appropriate safeguards under Article 89(1) GDPR are implemented;
- recognise consent, including broad consent where appropriate, as an alternative route for secondary scientific research, but not as the default or preferred route where the GDPR compatibility presumption and Article 89 safeguards provide an appropriate basis;
- ensure that transparency obligations do not require sponsors to collect unnecessary identifying information;
- recognise alternative transparency mechanisms, particularly in clinical research;
- adopt a proportionate approach to renewed transparency notices, particularly where individual notice would be disproportionate or would require the collection of additional identifying information;
- avoid discouraging anonymisation by imposing disproportionate legal basis requirements on the anonymisation process;
- clarify that Article 89 GDPR safeguards should remain risk-based and context-specific;
- recognise pseudonymisation as a key safeguard in regulated health research, particularly where anonymisation would undermine safety monitoring, auditability, traceability, regulatory compliance, longitudinal follow-up or scientific validity;
- support proportionate retention for foreseeable future research;
- provide a more nuanced approach to controllership in collaborative research; and
- ensure consistency with the EHDS and the EU objective of enabling responsible secondary use of health data.

EFPIA would welcome continued dialogue with the EDPB on how to ensure that the final Guidelines provide a high level of data protection while enabling socially valuable scientific research and innovation in Europe.