Associazione Farmaceutici Industria
Società Scientifica

Comments on the EDPB Guidelines 1/2026 on processing of personal data for scientific research purposes

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Introductory section

About AFI

AFI (Associazione Farmaceutici Industria – Società Scientifica ETS) is the Italian association of pharmaceutical industry professionals, representing technical, scientific and regulatory functions within innovator and generic pharmaceutical companies operating in Italy. Founded in 1960, AFI brings together corporate members and individual professional members engaged in research and development, manufacturing, regulatory affairs, pharmacovigilance and quality assurance. AFI participates regularly in regulatory consultations at national and European level on matters affecting the pharmaceutical industry.

Scope of this contribution

AFI welcomes the opportunity to contribute to the public consultation on the Guidelines 1/2026 on processing of personal data for scientific research purposes adopted by the EDPB on 15 April 2026. This contribution is intentionally focused on those segments of the Guidelines that are operationally relevant to industrial pharmaceutical research, namely: (i) the qualification of industry-led research as scientific research within the meaning of the GDPR; (ii) the legal bases applicable to medical research, with particular reference to legitimate interest; (iii) the derogations from the prohibition on processing special categories of personal data under Article 9 GDPR; (iv) the controllership pattern between sponsor, trial sites and Contract Research Organisations (CROs); (v) the not-yet-addressed treatment of real-world data (RWD); and (vi) the regime applicable to large-scale research datasets.

Other sections of the Guidelines — such as the detailed treatment of ancillary processing operations, the modalities of providing information to data subjects, and the safeguards applicable to genetic and biometric data — are not addressed in this contribution. Their omission is not to be read as a position on those provisions, but as a deliberate scoping choice.

General appreciation

AFI welcomes the EDPB's effort to provide a unitary interpretive framework for the processing of personal data for scientific research purposes. In particular, AFI considers as positive: (i) the explicit recognition that scientific research may be conducted by private entities and may also serve commercial interests (paragraphs 10 and 61); (ii) the clarification of the presumption of compatibility under Article 5(1)(b) GDPR (paragraphs 19-25); (iii) the confirmation that sponsors of clinical trials qualify as controllers (or joint controllers) even where they process primarily pseudonymised data (paragraph 136); and (iv) the systematic guidance on broad consent and dynamic consent (paragraphs 40-52).

The comments that follow are organised in three parts. Part I addresses provisions that AFI welcomes but on which improvements are suggested. Part II addresses provisions that, as currently drafted, are not workable for industrial pharmaceutical research and on which AFI proposes alternative formulations. Part III addresses topics not (adequately) covered by the current draft, on which AFI invites the EDPB to develop dedicated guidance — most notably real-world data and large-scale research datasets.

Part I — Provisions that are welcome but should be improved

I.1 The six key-indicative factors for qualifying scientific research (paragraphs 11-12)

AFI welcomes the analytical effort of identifying six key-indicative factors as aid for controllers in determining whether processing of personal data is conducted for scientific research purposes. The factors articulated at paragraph 11 are consistent with the prior interpretive output of the EDPB — including the Guidelines 05/2020 on consent (paragraph 153) — and with international standards such as the Frascati Manual 2015 referred to in footnote 11. AFI also welcomes the express recognition, in factor (v), that the pursuit of commercial interests does not exclude scientific research within the meaning of the GDPR.

Factor (iv) — 'Autonomy and independence' — as currently formulated, however, raises an interpretive uncertainty that may have material consequences for industry-led research. Paragraph 11(iv) provides that 'the research team has the freedom to define research questions, identify methods by which problems are solved, choose and develop scientific theories', and that researchers must operate 'in an environment free from undue pressures'.

In industrial pharmaceutical research, scientific research questions, hypotheses, primary and secondary endpoints, and methodological design are typically defined by the sponsor in cooperation with regulatory and scientific advisors, scientific advisory boards, and (where appropriate) regulators themselves through Scientific Advice procedures. Investigators contracted to perform research at trial sites adhere to a protocol drafted by the sponsor; they do not determine research questions or methodology in full autonomy. This operational reality is recognised by the regulatory framework: Article 28(1)(c) of Regulation (EU) 536/2014 (CTR) presupposes a sponsor-defined investigational plan; Annex I of Directive 2001/83/EC, referenced at footnote 24 of the Guidelines, refers to clinical particulars enabling the formation of a 'scientifically valid opinion'; and ICH GCP E6(R3) explicitly contemplates sponsor-defined protocols subject to independent ethics committee review.

Read literally, factor (iv) might be construed as excluding industry-led research from the perimeter of 'scientific research' within the meaning of the GDPR, with the consequence of excluding such research from the specific regime provided by Articles 5(1)(b), 5(1)(e), 9(2)(j), 14(5)(b), 17(3)(d), 21(6) and 89 of the GDPR. This would have a destabilising effect on industrial research that operates under regulatory frameworks expressly designed to ensure scientific quality and integrity through mechanisms different from researcher autonomy in the academic sense.

Drafting suggestion. AFI proposes that the EDPB clarify factor (iv) by adding to paragraph 11(iv) — or alternatively to paragraph 12 — the following text (or substantively equivalent wording):

"Where the research activities are conducted under a regulatory framework that ensures scientific quality and integrity through independent ethical review (such as the framework provided by Regulation (EU) 536/2014 on clinical trials, Regulation (EU) 2017/745 on medical devices, or comparable national or international frameworks), and through the scientific evaluation by competent authorities (such as the procedures referred to in Annex I of Directive 2001/83/EC), the requirement that researchers operate 'autonomously and independently' is satisfied through the structural independence of the scientific assessment, regardless of whether the researchers contractually report to the sponsor."

Additionally, the reference in factor (iv) to 'academic (e.g. a PhD title) or scientific qualifications (e.g. proven experience or recognition)' should be reformulated to focus on the functional adequacy of qualifications under sector-specific frameworks — including Good Clinical Practice training under Regulation (EU) 536/2014 and the qualification regimes provided under Regulation (EU) 2017/745.

I.2 Presumption of purpose compatibility under Article 5(1)(b) GDPR (paragraphs 19-25)

AFI welcomes the EDPB's unambiguous restatement that further processing for scientific research purposes is presumed compatible with the initial purpose(s) of processing, and that no separate

compatibility assessment under Article 6(4) GDPR is required (paragraph 19). This is a critical operational anchor for industrial research that builds on data lawfully collected for other purposes — including clinical trials, post-authorisation studies, and routine healthcare interactions.

Paragraphs 19-25 do not, however, explicitly address the most economically and scientifically relevant secondary-use scenarios for industrial research, namely: (a) the secondary use of clinical-trial data for further analyses (post-hoc analyses, integrated summaries of safety and efficacy, meta-analyses) once the primary clinical study report has been completed; (b) the use of clinical-trial data for hypothesis-generating activities concerning new indications, new populations, or new combinations; (c) the use of clinical-trial data for the development of statistical models — including machine-learning models — supporting future research; and (d) the boundary between further processing for scientific research purposes and further processing for pharmacovigilance obligations under Regulation (EC) 726/2004 and Title IX of Directive 2001/83/EC.

Drafting suggestion. AFI proposes that paragraph 25 be supplemented by an additional paragraph along the following lines:

"Where personal data have been lawfully collected in the context of an investigational clinical trial under Regulation (EU) 536/2014, an investigation under Regulation (EU) 2017/745, or comparable frameworks, further processing of such data for additional scientific research purposes within the same or a related therapeutic area benefits from the presumption of compatibility under Article 5(1)(b) GDPR. The same applies to further processing for hypothesis-driven post-authorisation safety or efficacy studies conducted under a documented research protocol, subject to the appropriate safeguards under Article 89(1) GDPR. Further processing of personal data for the fulfilment of pharmacovigilance obligations of mandatory legal nature is, however, governed by the legal basis applicable to those obligations and is outside the scope of the presumption of compatibility for scientific research purposes."

I.3 Sponsor's role as controller in clinical trials (paragraph 136)

AFI welcomes the explicit confirmation at paragraph 136 that the sponsor of a clinical trial qualifies as controller (or joint controller) for the processing of personal data in the trial, including where the sponsor processes primarily pseudonymised data. This is the operational reality of industrial clinical research and the position long sustained by industry stakeholders. The reference at footnote 201 to Article 58(48) of the proposed European Biotech Act, which would expressly designate sponsors as controllers for certain processing operations, is also welcome.

The Guidelines, however, address the matter in a single paragraph and with reference to a single illustration (Example 25, which involves joint controllership in a research consortium). The pattern of separate (rather than joint) controllership — sponsor as controller, trial site as separate controller for healthcare purposes, individual investigators acting under the authority of the controller — is not analytically developed.

The operational impact of this gap is significant. The default qualification of the sponsor-site relationship affects: (i) the cascade of contractual obligations between sponsor, sites and CROs; (ii) the information obligations under Articles 13-14 GDPR; (iii) the channel through which data subjects exercise their rights; and (iv) the liability allocation under Article 82 GDPR.

Drafting suggestion. AFI proposes that paragraph 136 be supplemented by an analytical grid — or, alternatively, by an additional example in Section 7 — distinguishing the three principal configurations of sponsor-site relationships in industrial clinical research:

(i) Sponsor as sole controller, sites as processors. Applicable where the site contractually agrees to follow sponsor instructions without exercising independent decision-making on purposes or essential means. This is typical of fully outsourced, sponsor-driven trials with limited investigator latitude.

(ii) Sponsor as controller for the trial purposes, sites as separate (independent) controllers for healthcare delivery purposes. Applicable where the site provides healthcare under national law independently of the

trial, and processes the same data for two distinct purposes governed by two distinct legal bases. This is the configuration most consistent with the analysis in the existing Example 26, where university hospitals are treated as independent controllers for healthcare provision under national law and outside the scope of the observational study.
(iii) Sponsor and site as joint controllers. Applicable where the protocol is jointly designed (typically in investigator-initiated studies with industry contribution) and where the parties jointly determine purposes and essential means in the sense of paragraph 140.
The qualification should not result from a default rule of joint controllership where a common protocol exists, but from a substantive assessment of who determines purposes and essential means.

I.4 Research data infrastructures (paragraphs 13-15)

AFI welcomes the recognition at paragraph 13 that personal data may be processed in a research data infrastructure for the purposes of making the data available for future research projects, and that such processing may itself qualify as scientific research within the meaning of the GDPR. This is a critical anchor for biobanks, research registries, and the data infrastructures being progressively developed in support of European research initiatives.
The treatment of research data infrastructures is, however, confined to a single paragraph (paragraph 13) plus Example 4. This is, in AFI's view, insufficient given (a) the strategic role of research infrastructures in the European Research Area, (b) the parallel evolution of the European Health Data Space framework under Regulation (EU) 2025/327 — which establishes Health Data Access Bodies and secure processing environments specifically for secondary use — and (c) the proposed European Biotech Act (COM(2025) 1022 final), referenced multiple times in the Guidelines themselves.
Paragraph 13 does not address: the qualification of the operator of a research infrastructure as controller, processor, joint controller, or — under emerging frameworks — trusted data holder; the interplay between the access conditions to the infrastructure and the legal basis on which the infrastructure operator processes the data, as compared with the legal basis on which access-requesting researchers process the data; the relationship between broad consent and the access regime of the infrastructure; and the relationship between the safeguards under Article 89(1) GDPR adopted by the infrastructure operator and those that may be required of access-requesting researchers.
A more systematic treatment is therefore advisable. AFI presents in Part III.2 of this contribution a developed proposal on the treatment of large research datasets, which addresses also the gap noted here at I.4.

Part II — Provisions that, as drafted, raise operational concerns

II.1 Factor (iv) as gateway to the scientific research regime (paragraph 11)

AFI's substantive concern on factor (iv) is addressed at I.1 above, where a drafting suggestion is proposed as the primary alternative. Should the EDPB decline to redraft factor (iv) along the lines proposed at I.1, AFI submits that an alternative — and more limited — fall-back wording would still be advisable to avoid the systemic risk of excluding industry-led research from the scientific research regime.
Fall-back drafting suggestion. AFI proposes that paragraph 12 be supplemented by the following clarification:
"The absence of researcher autonomy in the academic sense — where research questions, hypotheses and methodology are determined by the entity funding or sponsoring the research — is not in itself sufficient to disqualify the activities from constituting scientific research within the meaning of the GDPR. The controller must demonstrate that the integrity and quality of the scientific assessment is otherwise assured, for example through independent ethics committee review, peer review, or scientific evaluation by competent regulatory authorities."

II.2 Article 6(1)(f) GDPR coupled with Article 9(2) derogation in medical research (paragraph 75)

Paragraph 75 states that reliance on Article 6(1)(f) GDPR in the context of medical research (such as clinical trials) requires also the application of a derogation under Article 9(2) GDPR. The Guidelines indicate Article 53(1)(e) EHDS as one example of a Union law providing such a derogation.

AFI recognises the systematic correctness of this construction: data concerning health are special categories of personal data under Article 9(1) GDPR and their processing always requires a derogation under Article 9(2). However, the combined operational effect of paragraph 75 is significant. In Member States where the implementation of Article 9(2)(j) GDPR through national law is restrictive — as is the case of Italy, where Section 110 of the Personal Data Protection Code confines the derogation for scientific research to specific configurations — industrial controllers conducting medical research outside the perimeter of CTR-authorised investigational clinical trials, and outside the perimeter of EHDS Article 53 secondary use, are left with very limited operational space for the legitimate-interest basis.

The Guidelines acknowledge at paragraph 75 that Article 53(1)(e) EHDS is an example of a Union-level provision under Article 9(2) GDPR. The perimeter of EHDS Article 53 secondary use is, however, bounded by Articles 33-71 EHDS and does not cover the full spectrum of industry-led medical research — in particular, it does not cover non-EHDS-mediated processing carried out directly by the sponsor on data lawfully held by the sponsor.

The cumulative effect is that legitimate interest under Article 6(1)(f) GDPR — which the Guidelines themselves recognise as a valid basis for scientific research at paragraphs 61-75 — becomes, in practice, available only to controllers that already have a Union-law or Member-State-law channel under Article 9(2) GDPR. This significantly compresses the practical relevance of paragraphs 61-75 for industrial medical research.

Drafting suggestion. AFI proposes that paragraph 75 be reformulated along the following lines:

"Where the controller relies on Article 6(1)(f) GDPR as the legal basis for processing of personal data for medical research purposes, the controller must identify and document the applicable derogation under Article 9(2) GDPR. Union-level provisions that may be relied upon include Article 53(1)(e) EHDS (within the EHDS secondary-use perimeter) and Article 9(2)(i) GDPR (where the processing is necessary for reasons of public interest in the area of public health), in addition to any applicable Member State law under Article 9(2)(j) GDPR. Where neither a Union-level nor a Member-State-level derogation is available, the controller may consider the explicit consent of the data subjects under Article 9(2)(a) GDPR. The EDPB encourages the EU legislator and Member States to ensure that the operational space for legitimate interest in scientific medical research is not unduly compressed by the absence of an applicable derogation under Article 9(2) GDPR."

This reformulation maintains the systematic correctness of the analysis while signalling to the EU legislator and to Member States the need for adequate implementation channels.

II.3 Cumulative safeguards for broad consent (paragraphs 43-50)

AFI welcomes the EDPB's recognition that broad consent is available in scientific research (paragraph 40), that it covers processing in future research projects within certain areas of scientific research (paragraph 43), that it may cover several controllers (paragraph 43), and that it extends to collection, curation, storage, provision and subsequent processing operations within the relevant research area (paragraph 47).

AFI's concern relates to the cumulative formulation of safeguards in paragraphs 48-50. The Guidelines list, as relevant safeguards to compensate for the lack of purpose specification: detailed information available on an ongoing basis through a webpage; measures to enable data subjects to subscribe to a newsletter; use-and-access controls such as an independent data trustee; time-limited validity of consent; an independent oversight body composed of a representative of the research participants,

scientific experts, data-protection experts and the DPO; and an effective technical tool empowering data subjects in the exercise of their consent.
The cumulative reading of these requirements — combined with the prefatory wordings 'In particular' (paragraph 48), 'Safeguards may include, among others' (paragraph 49), and 'Finally, controllers should assess if it may be useful to provide an effective technical tool' (paragraph 50) — produces interpretive uncertainty as to whether the listed safeguards are alternatives or cumulative obligations.
The operational impact is significant. Many research datasets built on data lawfully collected in clinical trials, or in the context of patient-support programmes, already operate under high-standard safeguards — including independent ethics committee review, secure processing environments, contractually enforced confidentiality, dedicated data protection officers, and restricted access. The introduction of a presumptive requirement of an additional oversight body and an independent data trustee may make the operation of such datasets disproportionately burdensome, without a commensurate gain in data-subject protection.
Drafting suggestion. AFI proposes that paragraph 49 be reformulated to make explicit that the listed safeguards are illustrative and to be selected and combined by the controller in a risk-tiered manner:
"Controllers should assess whether they should implement safeguards to compensate for the lack of purpose specification. The selection and combination of safeguards should be calibrated to the risk profile of the processing — including the categories of personal data processed, the scale of the dataset, the scientific research area, the identifiability of data subjects, and the existing organisational and technical safeguards. Examples of safeguards that may be considered include, among others: (i) use and access controls (such as an independent data trustee); (ii) time-limited validity of consent; (iii) an independent oversight body; (iv) ethical review of individual research projects; (v) restrictive contractual terms of use for researchers; and (vi) confidentiality obligations for researchers and other staff members with access to the personal data. Where the controller already operates under a high-standard governance framework that includes independent ethical oversight and a dedicated data protection officer, the additional adoption of an oversight body within the meaning of this paragraph may not be necessary."

II.4 Article 17(3)(d) GDPR exception to erasure (paragraphs 119-120)

AFI welcomes the existence of the Article 17(3)(d) GDPR exception, which is necessary to preserve the integrity and reproducibility of scientific research. AFI is, however, concerned with the very restrictive interpretation expressed at paragraph 120, according to which the exception should only be applied 'in limited circumstances' and only where erasure 'is likely to render impossible or seriously impair the achievement of the scientific research purposes'. The Guidelines further illustrate that requests for erasure of personal data from 'a large number of data subjects' may not make it impossible or seriously impair the achievement of the scientific research purposes, and that the exception applies more readily where the personal data of each data subject is of significant importance.
This interpretation, read together with the requirement that the controller 'must also assess the individual circumstances in each request' (paragraph 120), produces an operationally unworkable model for large datasets. In a research database with hundreds of thousands or millions of data subjects, the controller cannot meaningfully assess the importance of each individual data subject's data to the overall scientific results: by construction, in large-N studies, no single data subject is individually decisive, yet the dataset as a whole has substantial scientific value. Under the interpretation expressed at paragraph 120, the Article 17(3)(d) exception would almost always be unavailable to controllers operating large datasets.
This outcome is in tension with two other elements of the Guidelines themselves: paragraph 8, which recognises that research using personal data in registries can 'improve the quality of life for a number of people'; and paragraph 47, which acknowledges that broad consent extends to collection, curation, storage and provision of data within a research infrastructure. If broad consent is intended to enable

large-scale data infrastructures, but the Article 17(3)(d) exception is unavailable to such infrastructures, the operational viability of large-scale research infrastructures is undermined.
Drafting suggestion. AFI proposes that paragraph 120 be reformulated along the following lines:
"Article 17(3)(d) GDPR provides for a specific exception from the right to erasure where the processing is necessary for scientific research purposes, in accordance with Article 89(1) GDPR. The controller must assess, on the basis of objective criteria documented in the research protocol or in equivalent documentation, whether erasure is likely to render impossible or seriously impair the achievement of the scientific research purposes. Where the controller operates a large research dataset, and has documented that the structural integrity of the dataset — including the absence of selection bias arising from the removal of records, the reproducibility of statistical results, and the auditability of the dataset for regulatory or peer-review scrutiny — is necessary for the validity of the scientific results, the controller may apply the exception under Article 17(3)(d) GDPR on a dataset-wide basis, without an individual assessment of each request, provided that appropriate safeguards under Article 89(1) GDPR are in place and that data subjects are duly informed of the application of the exception when transparency obligations are fulfilled. Conversely, where the dataset is small, or where the data of individual data subjects is not structurally indispensable to the validity of the scientific results, the controller should grant the erasure request in line with Article 17(1) GDPR."

II.5 Joint controllership in research consortia (paragraphs 140-145)

AFI welcomes the EDPB's framework on joint controllership in scientific research. The concern relates not to the principles articulated at paragraphs 140-141 — which faithfully reflect the case law of the CJEU — but to the default presumption that participation in the drafting of a research protocol determining purposes and essential means may suffice for joint controllership, even if the actual processing is carried out by only some of the parties (paragraph 141).
In industrial pharmaceutical research, the typical configuration is that: (i) the sponsor drafts the protocol unilaterally, drawing on internal scientific and regulatory expertise; (ii) trial sites or investigators adhere to the protocol on a contractual basis through clinical trial agreements; (iii) investigators or trial sites may contribute scientific feedback during protocol development through investigator meetings, but do not jointly draft the protocol; (iv) the CRO performs operational tasks (monitoring, statistical analysis, document management) under sponsor instructions.
Under the analytical default of paragraph 141, the involvement of multiple sites in protocol-design discussions could be construed as triggering joint controllership, with the resulting cascade of Article 26 GDPR obligations across potentially dozens of sites. This is in tension with paragraph 142, which recognises that 'agreeing to and consequently adhering to an already established research protocol or study, without participating in the determination of the purposes and means of processing, is not always sufficient to create a situation of joint controllership'.
The CJEU case law referenced at footnote 215 (C-25/17 Jehovan todistajat) and footnote 200 (C-210/16 Wirtschaftsakademie) was developed in non-research contexts — respectively, the dissemination of religious materials and the use of social media analytics — and does not specifically address the multi-site research configurations typical of pharmaceutical clinical investigations.
Drafting suggestion. AFI proposes the addition of a new paragraph (141-bis or equivalent) along the following lines:
"Where the research protocol is drafted unilaterally by one entity (typically the sponsor), and other participating entities (typically trial sites or investigators) adhere to the protocol on a contractual basis under a framework that ensures scientific quality and integrity (such as Regulation (EU) 536/2014 or Regulation (EU) 2017/745), the default qualification of the relationship is sponsor as controller, sites as separate controllers (for healthcare delivery purposes) or processors (for trial-specific purposes). Participation of sites in scientific advisory meetings, investigator meetings, or protocol-design

consultations does not, in itself, constitute joint determination of purposes and essential means of processing within the meaning of Article 26(1) GDPR. Joint controllership in scientific research, within the meaning of paragraph 140, requires the substantive joint determination of purposes and essential means of processing, and should not be presumed solely from the existence of a common research protocol."
This reformulation provides operational clarity without departing from the principles of paragraph 140 and aligns with the CJEU's emphasis (cited at footnote 219, C-604/22 IAB Europe) on the differentiated assessment of responsibility according to the actual involvement of each entity at each processing stage.

Part III — Topics not (adequately) addressed

III.1 Real-world data (RWD) and real-world evidence (RWE)

The Guidelines do not address real-world data or real-world evidence as a discrete category. The closest analytical anchors in the current draft are paragraph 13 (research data infrastructures), paragraphs 19-25 (presumption of compatibility for further processing), and paragraph 24 (further processing of special categories of personal data). None of these provisions, however, specifically addresses the RWD/RWE configurations that are increasingly central to industrial pharmaceutical research and to regulatory science.
The strategic relevance of RWD/RWE warrants dedicated guidance. The European Medicines Agency and the Heads of Medicines Agencies have, in recent years, established a coordinated framework for the integration of RWE into regulatory decision-making, including the DARWIN EU network (Data Analysis and Real World Interrogation Network), which provides evidence on the use, safety and effectiveness of medicines from real-world healthcare databases across Europe. The EHDS framework expressly contemplates the secondary use of electronic health data for scientific research and regulatory activities (Articles 33 and 53-71 of Regulation (EU) 2025/327). The proposed European Biotech Act (COM(2025) 1022 final), referenced multiple times in the Guidelines, also recognises the role of RWD in biotechnological research.
The absence of specific guidance on RWD/RWE creates interpretive uncertainty on several operational questions: (a) whether the processing of personal data from electronic health records, claims databases, disease registries or patient-generated health data — when conducted under a documented research protocol — qualifies as scientific research under the six factors of paragraph 11, in particular factor (iv); (b) whether the use of RWD for hypothesis-driven post-authorisation safety studies (PASS) and post-authorisation efficacy studies (PAES), as referred to in Article 21a of Directive 2001/83/EC and Article 10a of Regulation (EC) 726/2004, falls within the scientific research regime or within the pharmacovigilance regime; (c) whether the use of RWD for label-extension studies, indication-broadening submissions, and other regulatory-science activities qualifies as scientific research within the meaning of the GDPR; and (d) whether the legal basis for the secondary use of RWD held by healthcare providers — outside the EHDS secondary-use channel under Articles 53-71 — may rely on Article 6(1)(f) GDPR coupled with an Article 9(2) derogation.
Proposed framework. AFI invites the EDPB to develop a dedicated sub-section on RWD/RWE within Section 2 of the Guidelines (or alternatively within Section 3.1.1 on presumption of compatibility), along the following lines:
"Real-world data (RWD) and real-world evidence (RWE). Real-world data consist of personal data relating to patient health status, healthcare delivery, or both, collected in routine healthcare or other settings outside the controlled environment of investigational clinical trials. Sources of RWD include, among others, electronic health records, claims and reimbursement data, product and disease registries, patient-reported outcomes, and data from connected devices. Real-world evidence is the clinical evidence derived from the analysis of RWD.

"The processing of RWD for the generation of RWE may qualify as processing for scientific research purposes within the meaning of the GDPR, provided that the six factors at paragraph 11 are met. In particular, processing conducted under a documented research protocol, with adherence to recognised methodological standards (such as the guidance issued by the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance, or the Guidelines on Good Pharmacoepidemiology Practices), with independent ethics review where applicable, and with verifiable and shareable results, will normally satisfy factors (i), (ii), (iii) and (vi).

"The boundary between RWD-based scientific research and the mandatory regulatory activities of pharmacovigilance and post-authorisation surveillance is to be determined through a purpose-based analysis: (a) pharmacovigilance activities of mandatory legal nature — including signal detection, periodic safety update reports, and individual case safety reports — under Regulation (EC) 726/2004 and Title IX of Directive 2001/83/EC are processed under a legal-obligation basis (Article 6(1)(c) GDPR coupled with an Article 9(2) derogation such as Article 9(2)(i) GDPR); (b) post-authorisation safety studies and post-authorisation efficacy studies imposed by competent authorities under Article 21a of Directive 2001/83/EC or Article 10a of Regulation (EC) 726/2004 are processed under the legal basis applicable to the regulatory obligation, but the corresponding scientific research activities may also fall within the scientific research regime to the extent they meet the six factors at paragraph 11; (c) hypothesis-driven post-authorisation studies, label-extension studies, comparative-effectiveness research, and other RWD-based scientific research that is not the direct fulfilment of a legal obligation fall within the scientific research regime, provided that the conditions at paragraph 11 are met."

III.2 Large-scale research datasets and the interface with the EHDS

Linked to the gap identified at I.4, AFI submits that the treatment of large-scale research datasets requires a dedicated section. The Guidelines currently address dataset-related issues across multiple paragraphs — paragraph 13 on research data infrastructures, paragraph 47 on broad consent for collection and curation, paragraph 162 on combining datasets, Example 25 on consortium-based datasets, paragraph 168 on safeguards for genetic data — without offering a consolidated analytical framework.

Industrial research increasingly relies on large datasets built through one or more of the following modalities: (a) pooling of clinical-trial data across multiple trials within the same therapeutic area or compound; (b) pooling of clinical-trial data with RWD from healthcare providers, claims data, or registries; (c) federated analytics on distributed datasets without centralisation; (d) use of secure processing environments and synthetic-data techniques to mitigate identifiability risks; and (e) participation in or operation of research consortia that pool data across academic, public-sector and industry participants.

These configurations raise specific questions of: (i) qualification of the dataset and of its operator; (ii) legal basis for the operator's processing and for access-requesting researchers' processing; (iii) interplay with the EHDS framework; and (iv) interplay with the Data Governance Act (Regulation (EU) 2022/868), in particular the regime of data intermediation services and data altruism organisations.

Proposed framework. AFI invites the EDPB to develop a dedicated section — for example as a new Section 2.2-bis, between current Section 2.2 (research data infrastructures) and Section 2.3 (ancillary processing operations) — addressing the points below.

Qualification of the operator. The operator of a large-scale research dataset may qualify as: (a) controller, where the operator determines the purposes and essential means of the processing within the dataset; (b) joint controller with other entities contributing data, where the determination of purposes and essential means is shared; (c) processor, where the operator processes data on behalf of one or more controllers; or (d) trusted data holder, where the operator acts as a neutral intermediary in the sense of Article 10 of Regulation (EU) 2022/868, without determining purposes or essential means. The

qualification depends on the substantive analysis of decision-making over purposes and essential means, in accordance with the criteria set out in Section 7 of the Guidelines.
Legal basis for the operator's processing. The legal basis for the operator's processing within the dataset is to be assessed separately from the legal basis applicable to access-requesting researchers. The operator's processing may rely on broad consent under Article 6(1)(a) GDPR (and Article 9(2)(a) for special categories of data); on a Union or Member State law under Article 6(1)(e) and Article 9(2)(g), (i) or (j) GDPR; or on legitimate interest under Article 6(1)(f) GDPR coupled with an Article 9(2) derogation, where applicable.
Interplay with the EHDS framework. Where the processing falls within the secondary-use perimeter of Articles 33-71 of Regulation (EU) 2025/327, the Health Data Access Body system applies, with the specific legal bases provided by Article 53 EHDS. Where the processing falls outside the EHDS secondary-use perimeter, the general regime of these Guidelines applies.
Federated analytics and secure processing environments. Where the operator implements federated analytics — meaning that researchers obtain analytical results from queries executed on distributed datasets, without obtaining access to or transfer of the underlying personal data — the qualification of the operator and the legal-basis assessment should account for the reduced re-identification risk inherent in federated configurations. Where the operator provides access to personal data through a secure processing environment within the meaning of Article 50 EHDS, the safeguards provided by the secure processing environment constitute appropriate safeguards within the meaning of Article 89(1) GDPR.
Broad consent and the EHDS opt-out. Where the dataset is built on data covered by broad consent under these Guidelines, and where the same data also fall within the secondary-use scope of the EHDS, the interplay between broad consent and the EHDS opt-out under Article 71 EHDS should be clarified through coordinated guidance from the EDPB and the relevant Health Data Access Bodies.

III.3 International transfers in pharmaceutical research (cross-cutting note)

The Guidelines address international transfers only in passing — at footnote 161 and at paragraph 108, in the context of changes to processing operations requiring additional information to data subjects. International transfers are, however, a structural feature of industrial pharmaceutical research, which is typically conducted by global sponsors with trial sites, CROs, and regulatory submissions in multiple jurisdictions.
AFI does not propose a comprehensive treatment of Chapter V GDPR in the Guidelines — the topic is properly governed by existing EDPB instruments, notably the Guidelines 05/2021 on the interplay between Article 3 and Chapter V — but invites the EDPB to add a short cross-reference clarifying the interaction between the scientific research regime and the international-transfer framework.
Drafting suggestion. AFI proposes the addition of a short sub-section, for example at the end of Section 7, along the following lines:
"International transfers of personal data processed for scientific research purposes — including transfers between sponsors, trial sites, CROs and affiliates in third countries, and transfers to non-EU regulatory authorities (such as the U.S. Food and Drug Administration, the United Kingdom Medicines and Healthcare products Regulatory Agency, and the Japanese Pharmaceuticals and Medical Devices Agency) for the purposes of marketing-authorisation submissions — are subject to Chapter V GDPR. Controllers should refer to the EDPB Guidelines 05/2021 on the interplay between Article 3 and Chapter V, and to the applicable standard contractual clauses. The application of Chapter V GDPR is not affected by the qualification of the processing as scientific research, and the safeguards under Article 89(1) GDPR are additional to — not substitutive of — the safeguards required for international transfers."

Associazione Farmaceutici Industria
Società Scientifica

Closing statement

AFI thanks the EDPB for the opportunity to contribute to this public consultation. The Guidelines 1/2026 represent an essential interpretive instrument for the European research community, and AFI welcomes the analytical rigour and breadth of the EDPB's work.
The comments above are submitted in a constructive spirit, with the aim of ensuring that the final version of the Guidelines fully reflects the operational reality of industrial pharmaceutical research — which contributes substantially to the European Research Area and to the development of medicines and treatments for European patients.
AFI remains available for any further dialogue with the EDPB Secretariat or with individual Members of the Board on the points raised in this contribution.

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