



Associazione Farmaceutici Industria
Società Scientifica

AFI — ASSOCIAZIONE FARMACEUTICI INDUSTRIA SOCIETÀ SCIENTIFICA ETS

Scientific society recognised by Ministerial Decree of 23 September 2021

Contribution to the public consultation on the EDPB Template for the DPIA

(Template version 1.0 and Explainer, adopted on 10 March 2026; consultation open until 9 June 2026)

Observations from the perspective of the pharmaceutical industry

Introduction

AFI – Associazione Farmaceutici dell’Industria (the Italian association of pharmaceutical-industry professionals) is a scientific society founded in 1960. Its members hold science degrees and work across the pharmaceutical and parapharmaceutical industry, in universities and research institutes, in public bodies, and at the suppliers of goods and services to the pharmaceutical sector, alongside the sector’s own companies. By Ministerial Decree of 23 September 2021, AFI was added to the list of Scientific Societies and Technical-Scientific Associations of the Healthcare Professions. The Association promotes cultural initiatives, scientific monitoring, and practical professional development, and pursues cooperative exchange with health authorities and with comparable scientific organisations in Italy and abroad. It acts as a technical interlocutor before the Italian Ministry of Health and the Italian Medicines Agency (AIFA).

AFI’s interest in this public consultation — on the EDPB Template for the Data Protection Impact Assessment (DPIA) under Article 35 of Regulation (EU) 2016/679 (General Data Protection Regulation, “GDPR”), in version 1.0 and its accompanying Explainer, adopted on 10 March 2026 — follows directly from how the Association is organised. Its work runs through dedicated areas, including Research & Development and Clinical, Regulatory & Medical Devices, and Quality. These areas oversee the very processing activities that the EDPB model addresses. We welcome the move towards standardisation: a common European model helps pharmaceutical operators that work across several Member States and that run, on a single dataset, activities governed by multiple sectoral rules.

This contribution is made from the standpoint of the industrial pharmaceutical sector — medicines development and manufacturing, clinical research, pharmacovigilance, the management of Patient Support Programmes (PSPs), Real World Evidence studies, and post-marketing lifecycle management. It flags three specific areas where the Template, as currently drafted, does not yet work fully for the sector’s typical processing. For each area, we set out a targeted proposal, focused on the Explainer so as to leave the sector-neutral base Template untouched.



Point 1 — Aligning the DPIA with sector-specific pharmaceutical rules

The pharmaceutical industry already operates under a regulatory framework that requires risk and impact assessments for many of the processing activities falling within Article 35 GDPR. As drafted, the Template offers no guidance on how the DPIA relates to those sectoral assessments. The risk is either duplicated documentation or, conversely, separate and inconsistent assessments.

Clinical trials and Regulation (EU) No 536/2014 (Clinical Trials Regulation, “CTR”). The CTR requires the sponsor to assess the study’s risks and benefits (Article 6 CTR), to carry out an ethical assessment, and to submit a Protocol that already describes the processing of trial subjects’ data. The dossier is assessed by the Ethics Committee under Italian Legislative Decree No. 52/2019. The DPIA partly overlaps with this pathway, yet the Template does not clarify: (i) whether the Protocol may be cross-referenced for the descriptive sections (Sections 1.1–1.3); (ii) how to align the necessity and proportionality assessment (Sections 3.2–3.3) with the ethical opinion the Committee has already issued; and (iii) how this coordinates with the legal basis under Article 6(1)(e) GDPR and with the “Ethics rules for processing for statistical or scientific research purposes” (Garante decision No. 515 of 19 December 2018).

Pharmacovigilance, EudraVigilance, and Good Pharmacovigilance Practices (GVP) Module VI. Pharmacovigilance processing rests on a web of obligations flowing from Regulation (EU) No 1235/2010, Italian Legislative Decree No. 219/2006 (Italian Medicines Code, Articles 129–134), the EMA’s GVP, and the ICH E2A–E2F guidelines. Article 9(2)(i) GDPR — public interest in the area of public health — is the established legal basis for processing the data of patients named in suspected adverse-reaction reports (Individual Case Safety Reports, “ICSRs”). Yet the Template gives no worked example for a case this common in the sector. Pharmacovigilance processing also has distinctive features — a purpose imposed by law, the impossibility of obtaining the data subject’s consent, mandatory long-term retention, and systematic transfer to EudraVigilance — that would warrant dedicated guidance.

Pharmaceutical Quality Systems (PQS) and data integrity. For decades, pharmaceutical operators have applied the ALCOA+ principles (Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring, Available) and the FDA / EMA / MHRA / PIC/S data-integrity requirements to all process, laboratory, and management-system data. The controls under Annex 11 to the EU GMP (Computerised Systems) and under the US 21 CFR Part 11 conceptually overlap with the Article 32 GDPR security measures required by Section 2.3.e of the Template. An explicit nod to this convergence — noting that GMP-validated systems can be documented in Section 2.3.e by reference to their audit trails and Computerised System Validation — would avoid duplicating documentation.

Proposed amendment

We suggest adding to the Explainer a “Sector-specific guidance: pharmaceutical industry” section clarifying:



- that, where sectoral documentation already exists (a clinical study Protocol, a Pharmacovigilance System Master File, a Quality Management System), it may be cross-referenced in the descriptive sections of the DPIA (Sections 1.1–1.3 and 2.3.e), avoiding transcriptions that add no informational value;
- the relevance of Article 9(2)(i) GDPR — public-interest purposes in the area of public health — as the typical basis for pharmacovigilance processing, while flagging the need to check national implementing rules (in Italy, in particular, Articles 75–76 of Italian Legislative Decree No. 196/2003 (Italian Personal Data Protection Code) and the safeguard measures adopted by the Italian Data Protection Authority (Garante));
- the methodological coordination between the DPIA and the ethical and regulatory assessments already carried out under Regulation (EU) No 536/2014 and the GVP, pointing towards a non-duplicative approach.

Point 2 — Real World Evidence, secondary data reuse, and the EHDS

A critical line of development for the sector is Real World Evidence (RWE) — observational studies, secondary data use, and evidence generation from sources such as the Electronic Health Record, administrative databases, registry data, wearable data, and patient-reported outcomes. The recently adopted Regulation (EU) 2025/327 (European Health Data Space, “EHDS”) expressly governs the secondary use of health data for research, for the development of medicines and medical devices, and for Real World Evidence.

Sections 1.1.c (Secondary or compatible uses) and 2.1.a (Legal basis) of the Template touch on this, but only in general terms. Three issues arise.

No coordination with the EHDS. Regulation (EU) 2025/327 introduces a harmonised framework for secondary use, with legal bases, permitted purposes, and data-access mechanisms distinct from those of the GDPR. A DPIA carried out on RWE processing must necessarily dovetail with the EHDS regime, yet the Template (version 1.0) does not mention it. We note that the EHDS Regulation entered into force after work on the EDPB Template had begun; the Explainer, however — designed to be updated over time — can readily take its references on board.

Compatibility of further processing under Articles 5(1)(b) and 6(4) GDPR. Section 1.1.c asks the controller to state “under what conditions and assessment of compatibility” the reuse takes place. For the pharmaceutical industry’s typical cases — reusing data collected in an interventional clinical trial for pharmacovigilance, for RWE, or to develop new therapeutic indications — the compatibility assessment raises non-trivial methodological questions. For example: was the further purpose foreseeable to the data subject at the point of collection? Are the Article 89 GDPR safeguards adequate? Does the consent given cover the reuse? The Explainer offers no assessment framework.

Pseudonymisation and anonymisation in RWE datasets. The difference between pseudonymised data (which remain within the GDPR) and anonymised data (which fall outside its scope) has



substantive consequences for RWE studies. Recent European case law — the Court of Justice of the European Union (CJEU), judgment of 4 September 2025 in Case C-413/23 P, EDPS v SRB — together with EDPB Opinion 28/2024 on AI models, has consolidated a dynamic reading of identifiability. That reading would call for explicit guidance in the Template, particularly in Sections 1.1.a and 2.2.a.

Proposed amendment

We suggest supplementing the Explainer with: (i) a paragraph on DPIA / EHDS coordination for RWE and secondary-use processing, identifying the typical legal bases; (ii) an assessment framework for the compatibility test under Article 6(4) GDPR, tailored to the sector's typical cases (clinical trial → pharmacovigilance; clinical trial → RWE; PSP → scientific research); and (iii) a section on the practical distinction between pseudonymisation and anonymisation that reflects the most recent case law.

Point 3 — Cross-border processing and group structures in multinational pharmaceutical companies

The pharmaceutical industry is structurally multinational, its organisation included. Personal-data processing — pharmacovigilance, clinical trials, and Patient Support Programmes in particular — routinely crosses national borders. The Italian affiliate of an international group works in a continuous flow with its parent company (often based in the United States, Switzerland, or the United Kingdom) and with other European affiliates, through global information systems and shared Pharmacovigilance System Master Files.

Section 1.1.d of the Template touches on this, asking whether the processing is cross-border and whether transfers outside the EU are envisaged. But it offers no operational guidance on three issues central to the sector.

Identifying the controller and the relationship with intra-group processors. In a typical pharmaceutical group, each affiliate is an independent controller for the processing of data collected in its own territory (for example, Italian ICSRs, or subjects enrolled in Italian studies), with onward transfer to the parent company. The Template does not clarify whether a separate DPIA should be prepared for each group entity, or a single DPIA listing the entities involved. Section 0.1 (Controller) provides a table for each controller but does not address the group scenario.

Transfers to third countries: the sector's standard mechanisms. Pharmaceutical groups routinely use Standard Contractual Clauses ("SCCs") under Commission Implementing Decision (EU) 2021/914 and Binding Corporate Rules ("BCRs") approved by the lead authority. Adding a Transfer Impact Assessment (TIA) for each transfer, in line with EDPB Recommendations 01/2020, is settled practice. Section 2.3.c of the Template (Safeguards for international transfers) should be paired with operational guidance: the DPIA may cross-reference the existing TIA and the approved BCRs, without rebuilding the whole assessment.



Associazione Farmaceutici Industria
Società Scientifica

Cooperation with the sponsor's supervisory authority. For multinational clinical trials, the one-stop-shop principle under Article 56 GDPR applies with practical difficulty, especially where the sponsor is established outside the EU and operates through affiliates with varying decision-making autonomy. The Explainer would helpfully refer to the role of the EU representative under Article 27 GDPR for non-EU sponsors, and to identifying the competent authority for prior consultation under Article 36 GDPR — avoiding uncertainty when conducting DPIAs on multi-country studies.

Proposed amendment

We suggest supplementing the Explainer with: (i) a paragraph on the DPIA in multinational pharmaceutical groups, setting out how to structure it across group entities (a single DPIA versus separate DPIAs); (ii) a reference to the possibility of drawing on existing TIAs, BCRs, and SCCs without duplicating documentation; and (iii) a clarification on identifying the competent authority for prior consultation under Article 36 GDPR in multi-country studies with non-EU sponsors.

Closing remarks

The observations above aim to make the EDPB Template fully workable for the industrial pharmaceutical sector.

The experience that AFI members have built in applying Good Pharmacovigilance Practices, Good Clinical Practice (ICH E6(R3), 23 July 2025), Annex 11 to the EU GMP, and the data-integrity rules shows that the sector already holds a settled body of method for handling sensitive data. That body of method can usefully complement — rather than duplicate — the impact assessment required by the GDPR.

AFI remains available to the EDPB for any further discussion of the proposals set out here. Through its Study Groups on Pharmacovigilance, Clinical Research, Real World Evidence, and Quality, it can also provide anonymised case studies to help finalise the Explainer.

Milan, 09 June 2026

For AFI – Associazione Farmaceutici Industria Società Scientifica ETS

The President

Dott. Giorgio Bruno