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

1. Introduction

Mölnlycke Health Care AB ("**Mölnlycke**") welcomes the EDPB's draft Guidelines 1/2026 (the "**Guidelines**") and supports their objective of providing practical clarity on the application of the GDPR to scientific research. Overall, Mölnlycke considers that the Guidelines represent a constructive and timely contribution to the interpretation of the GDPR, reflecting the importance of scientific research as a key driver of innovation, public health advancement and European competitiveness. In particular, Mölnlycke welcomes the following important clarifications:

(a) Provide meaningful clarification on the use of broad consent, recognizing that research purposes cannot always be fully specified at the start;
(b) Clarifying that scientific research can include research infrastructures and ancillary processing; and,
(c) Emphasise risk-based safeguards under Article 89(1) GDPR, allowing controllers to tailor protective measures to the specific context and risks of the research activity.

The comments set out below are intended to further support the objective of the Guidelines by addressing certain areas where additional clarification would enhance their practical applicability, in particular for industry-led, cross-border, and collaborative research environments.

2. Key requests and concerns

2.1 Key-indicative factors presuming scientific research

The six key-indicative factors (Section 2.1) provide a helpful structure to define whether an activity can be presumed to constitute scientific research. However, several of these elements may be difficult to apply in non-clinical or industrial R&D contexts:

- While acknowledging the fundamental aspects of ethical standards in research, ethical committee review and formal ethical standards may not exist in many early internal R&D environments, especially in scientific research relating to AI and digital development;
- Autonomy and independence, including the ability to publish, may be constrained by intellectual property considerations; and
- The expectation that researchers hold academic or formally recognized qualifications may be misinterpreted to favour conventional, academic or clinical research, not reflecting industry practice, especially in scientific research relating to AI and digital development.

Although the Guidelines clarify that these are only indicative factors and create a presumption rather than strict requirements, there is a risk that they are applied too strict by supervisory authorities. This may lead to the exclusion of legitimate research activities, in particular industry-driven or non-clinical R&D. As another example, primary research/early-stage research may still qualify as legitimate scientific research albeit never being in scope of a publication or peer review.

An overly strict application of these factors risks creating unintended discrimination between different types of research, whereby academic or publishable research is favoured over industrial or proprietary research. Such an outcome would be at odds with the GDPR's explicit recognition that scientific research should be interpreted broadly, including e.g., applied research and privately funded research (Recital 159 GDPR).

In addition, several of the listed factors, such as adherence to ethical standards, independence and oversight, are already reflected as appropriate safeguards under Article 89(1) GDPR and further elaborated in Section 8 of the Guidelines. While these elements are important considerations to ensure safeguarded processing, their inclusion as part of the definition of the research purpose itself risks confusing (i) the qualification of an activity as scientific research, with (ii) the conditions under which such processing should be carried out.

Request for clarification:

- Clarify more explicitly that failure to meet individual or all factors does not *preclude* qualification as scientific research, in line with para. 12.
- Clarify the relationship between Section 2 (concept of scientific research) and Article 89(1) safeguards (Section 8), to avoid overlap and unintended elevation of safeguards into eligibility criteria for the purpose definition assessment.
- Provide additional examples of non-clinical industry research, including internal R&D, to illustrate how the factors should be applied in practice.

2.2 Fragmentation due to Member State law

The Guidelines explicitly state that the application of Member State law is outside their scope (Introduction; Section 1; para. 4). While we acknowledge and understand the limitations of EDPB's competence, this omission is a key practical challenge for industry:

- Diverging national rules under Articles 9(2)(j) and 9(4) create significant operational friction, especially for cross-border research.
- This undermines the objective of a European Research Area, as recognized in Article 179(1) TFEU (also referenced in Section 1).

Request for clarification:

- The EDPB should provide additional guidance or best practices on navigating cross-border divergence, even if formal harmonization is beyond scope.
- At minimum, the Guidelines should acknowledge more explicitly that fragmentation poses a significant barrier to research and encourage harmonisation.

2.3 Lack of guidance on borderline research activities

The current examples in the Guidelines provide helpful illustrations of the scope of "scientific research" by contrasting:

- Clearly *qualifying* research activities, such as clinical trials conducted by pharmaceutical companies (Example 1), which satisfy all key-indicative factors; and
- Clearly *non-qualifying* activities, such as internal marketing analytics conducted by a retail company (Example 3), which fall outside the concept of scientific research.

While these examples are useful, they represent opposite ends of the spectrum. As such, they do not adequately address the large category of intermediate or borderline cases that arise in practice.

In particular, the Guidelines do not sufficiently address activities such as:

- Internal product development projects involving the testing, validation or improvement of medical technologies;
- Exploratory or early-stage R&D activities that are methodical and knowledge-seeking, but not subject to formal ethical review or external oversight;
- Research activities that are not intended for publication, for example due to intellectual property considerations;
- Research conducted within corporate environments where teams may not have formal academic titles but nevertheless operate using recognized scientific methodologies.

Example 2 (AI research by a start-up in collaboration with a university) demonstrates that non-traditional research settings can qualify as scientific research, even when conducted by private entities. However, that example still relies on elements such as ethical review and publication, which may not be present in many purely internal R&D contexts.

Request for clarification:

- Include additional examples illustrating borderline or intermediate scenarios.
- Provide more detailed guidance on how to apply the key-indicative factors in such borderline cases, including how they should be weighed where some are not present.

2.4 Transparency obligations vs. data minimisation (Articles 12–14 & Article 11 GDPR)

The Guidelines suggest that, in long-term scientific research contexts, data subjects should be given the opportunity to voluntarily provide contact details in order to receive updates on the processing of their personal data (Section 5.1). Furthermore, in the context of further processing, controllers are expected to make “reasonable efforts” to obtain contact details where they are not available (Sections 5.3-5.4).

At the same time, the Guidelines emphasise that controllers should implement pseudonymisation or anonymisation wherever possible and limit the use of directly identifying data (Section 8.3). Mölnlycke also recognises the notion of Article 11 GDPR, which is only briefly mentioned in a footnote reference (ref. 137) in the Guidelines. Under Article 11 GDPR, controllers are under no obligation to maintain, acquire or process additional information for the purpose of identifying data subjects, where identification is no longer necessary for the processing purpose.

In many research settings, controllers deliberately design their processing operations to avoid holding directly identifying data (either due to legal obligations prohibiting identification or as a privacy-enhancing safeguard), for example by structuring roles so that only healthcare providers retain identifiers. However, the Guidelines may be interpreted as requiring controllers to:

- Retain or collect contact details even where not necessary for the research purpose;
- Re-identify or attempt to re-identify data subjects in order to fulfil transparency obligations;
- Systematically assess external sources (e.g. registries) to obtain identifiers where none are held.

There is a risk that this creates a de facto obligation to identify data subjects, which would conflict both the letter and the underlying rationale of Article 11 GDPR, as well as the data minimisation principle (Article 5(1)(c)). There is also a risk that pseudonymisation as a safeguard would be undermined if controllers are expected to retain or recover identifiers to ensure ongoing communication.

Request for clarification:

- Clarify explicitly that controllers are not required to obtain, retain or recreate contact details were doing so would contradict Article 11 GDPR or the data minimisation principle.
- Clarify the interpretation of "reasonable efforts" under Article 14(5)(b):
    - Such efforts should be assessed in light of Article 11 and Article 5(1)(c), meaning that controllers should not be required to acquire identifiers where this would involve disproportionate interference with the principle of data minimisation.
- Provide guidance on how Article 89(1) safeguards, including pseudonymisation, should be balanced against transparency requirements in a risk-based manner.
- Recognise that, in EHDS-type scenarios, transparency may be fulfilled through institutional or systemic mechanisms, rather than direct communication with each data subject.

2.5 Interaction with the European Health Data Space (EHDS)

While the Guidelines recognise the importance of scientific research and refer to Union instruments such as the EHDS (e.g. Section 4.4.3), several provisions, when applied cumulatively, risk undermining the data access and reuse frameworks that the EHDS is designed to enable.

Paragraph 29 states that where future research purposes are not fully specified, controllers must still define purposes within a "specific area of research" and that generic storage for future scientific use is not permissible. While Mölnlycke agrees that purpose limitation must be respected, this interpretation appears overly restrictive and difficult to reconcile with the EHDS framework, which is explicitly designed to enable broad, future-oriented secondary use of health data, including via large-scale data lakes and infrastructures. In practice, EHDS-type infrastructures instead allow access to authorised users based on established governance mechanisms, rather than pre-defined purposes at dataset level.

Request for clarification:

- Clarify that storage for future scientific research within a sufficiently defined research area, combined with governance and safeguards, is compatible with Article 5(1)(e) GDPR.

2.6 Application of the Guidelines in multi-controller scenarios (Example 22)

The Guidelines include several examples involving multiple independent controllers cooperating in scientific research settings (e.g. where one entity provides data and another determines the purpose of research). While these examples are helpful in illustrating role allocation, they do not sufficiently explain how each controller is expected to comply in practice with the cumulative obligations under the Guidelines. This lack of clarity creates significant uncertainty in common research setups, particularly where responsibilities for transparency, retention, and safeguards are distributed across multiple entities/roles.

In multi-controller environments, the initial controller may not always know the full scope of downstream research uses at the time of collection or storage. Subsequent controllers may also define research purposes after data has been collected and shared. This creates uncertainty as to how the initial controller can ensure compliance with purpose limitation requirements when the downstream research purposes are dynamic, evolving, or only partially defined at the beginning.

Furthermore, the Guidelines impose extensive transparency obligations, including:

- Informing data subjects about further processing;
- Providing updates over time;
- Making "reasonable efforts" to obtain contact details where they are not available (paras. 87–88).

At the same time, the Guidelines encourage pseudonymisation and minimisation of identifiers (Section 8.3), and Article 11 GDPR mandates that controllers are not required to maintain or acquire identifying data. In practice, this leads to a structural dilemma, i.e., how transparency obligations are to be fulfilled effectively and proportionately where no single controller both determines the purposes and holds the means of identification.

Request for clarification:

- Provide clear guidance on how obligations should be fulfilled across multiple independent controllers, such as in the scenario provided as Example 22.

2.7 Interpretation of the storage limitation principle

The interpretation of the storage limitation principle in Section 3.2 of the Guidelines, particularly as articulated in paragraph 29 raises significant practical and legal uncertainty when applied to concepts like data lakes and EHDS-like scenarios. Paragraph 29 permits controllers to store personal data for future scientific research purposes where the specific purposes are not yet fully defined, *provided* that the envisaged future uses are "reasonably foreseeable" at the time of storage.

In practice, scientific research, especially in rapidly evolving fields such as medical technology, digital health and AI, is inherently iterative, exploratory, and dynamic where:

- Data may be reused across multiple research projects with differing objectives;
- The value of datasets often lies precisely in their ability to enable future, currently unknown research questions.

The re-use of existing datasets is widely recognised in industry as a way to promote ethical use of data (by reducing the need to collect new personal data from individuals and maximising the value derived from already collected data) and as a way to minimize burdens on data subjects, particularly in sensitive contexts such as healthcare.

Under the phrasing of paragraph 29, it is unclear to what extent controllers are expected to define future research uses in advance, and how narrowly or broadly such foreseeability must be framed. This uncertainty is particularly notable in data lake or research infrastructure scenarios, including those envisaged under the EHDS. In these contexts, the requirement that future uses must be "reasonably foreseeable" at the time of storage raises fundamental questions:

- How can foreseeability be assessed where the specific research questions and users are not yet known (such as in Example 22)?

- Does foreseeability need to be determined at the level of:
    - Individual research projects;
    - Categories of users; or
    - Broad research domains (e.g. medical technology, public health, AI)?

Without clarification, paragraph 29 risks being interpreted in a manner that is incompatible with large-scale, reusable research datasets, effectively discouraging the creation and use of such infrastructures.

Request for clarification:

- Review and clarify the concept of “reasonable foreseeability” in the context of EHDS-like infrastructures.
- Explicitly recognise the compatibility of data lake and research infrastructure models (as allowed and supported under EHDS) with Article 5(1)(e) GDPR, including:
    - Storage of data for future research under robust governance frameworks;
    - Reuse of data for multiple and evolving research purposes, subject to Article 89(1) safeguards.

3. Conclusion

Mölnlycke appreciates the EDPB’s work in developing these Guidelines and recognises their importance in supporting a consistent and practical application of the GDPR in the field of scientific research. We submit the above comments with the aim of further strengthening the clarity and usability of the Guidelines.

Mölnlycke remains at the EDPB’s disposal for any further engagement or clarification.

Yours faithfully,

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