vfa. Die forschenden Pharma-Unternehmen

vfa Position on EDPB Guidelines 02/2026 on Anonymisation

General comments

The German Association of Research-Based Pharmaceutical Companies (vfa) welcomes the EDPB initiative to clarify the assessment of anonymisation under the GDPR. Clinical trials produce detailed health data that must be protected while remaining suitable for the reliable assessment of medicines and, where appropriate, further scientific research.

The vfa supports the contextual assessment of identifiability, including the perspective of the relevant recipient and the means reasonably likely to be used. A theoretical possibility of identification should not be treated as equivalent to a realistic identification pathway. The legal assessment should reflect the combined effect of technical, organisational and enforceable contractual safeguards.

The vfa broadly supports the recommendations made in EFPIA's response dated October 27th, 2026, particularly its call for consistent application of the contextual approach and practical examples for controlled health research. The following comments complement this response by focusing on regulatory obligations and data flows specific to clinical trials.

1. Distinguish the actors and data flows in clinical trials

Clinical trial sites, sponsors, contract research organisations and independent researchers have different roles, access rights and means of identification. Sites generally retain the link to the identity of trial participants, while sponsors usually process only coded records. Yet sponsors may retain obligations concerning safety reporting, source-data verification, data correction and inspections. The absence of direct identifiers alone therefore does not establish that sponsor-held data are automatically anonymous.

Three settings should be distinguished: (i) ongoing trial conduct, including processing by service providers on the sponsor's behalf; (ii) transfer of suitably prepared data to an independent recipient for secondary research; and (iii) public disclosure of clinical trial information under regulatory transparency rules. The identity and legal role of the recipient, the actual access conditions and any realistic re-identification pathway differ substantially between these settings.

Recommendation: Add concrete clinical-trial examples to the text illustrating these three settings and explaining when a dataset may be anonymous for an independent recipient although the originating controller retains identifying information. Clarify the relevance of funding, scientific collaboration and return of

aggregate results without presuming that these relationships necessarily confer identifying capabilities.

2. Apply proportionate, evidence-based criteria to research datasets

Clinical research data may contain longitudinal observations, rare disease characteristics, genomic information and small patient populations. Such features can increase the risk of re-identification, but record uniqueness or theoretical linkage does not automatically demonstrate that a person is identifiable. The assessment should consider whether additional information can realistically be accessed and combined, by whom, and with what prospect of successful identification.

The criteria of record isolation, linkage and inference should be applied as part of an overall contextual legal assessment, not as automatic exclusion tests. Excessive suppression or generalisation can undermine the scientific validity of datasets and thereby reduce the value of trial participants' contributions.

Recommendation: Clarify that the simplified technical approach is voluntary and does not become a de facto mandatory threshold. Provide examples of proportionate, targeted measures for higher-risk records, including access restrictions and selective suppression, rather than assuming that an entire dataset must be discarded or extensively transformed.

3. Give effective contractual and organisational safeguards appropriate weight

Controlled research access often combines data minimisation and technical safeguards with binding data-use agreements, prohibitions on re-identification, role-based permissions, separation of duties, audit rights and sanctions for misuse. Contractual restrictions are not equivalent to statutory prohibitions and cannot establish anonymity on their own. Nevertheless, enforceable and operationally effective controls can materially affect whether access to additional identifying information is reasonably likely.

Recommendation: Explicitly recognise the combined effect of enforceable contractual, technical and organisational controls in the contextual assessment, including controlled-access research environments. Assess credible access pathways rather than requiring organisations to exclude every hypothetical unauthorised disclosure.

4. Recognise the indispensable role of pseudonymisation during clinical trials

Anonymisation and pseudonymisation serve different purposes. During clinical trial conduct, the ability to link records back to individual participants under

controlled conditions may be necessary for pharmacovigilance, follow-up, data verification and regulatory inspection. The EU Clinical Trials Regulation (Regulation (EU) No 536/2014) and good clinical practice requirements must be considered alongside data-protection obligations.

It would therefore be inappropriate to suggest that irreversible anonymisation is generally preferable at every stage of a clinical trial. Pseudonymisation remains a central protective measure where continued traceability is necessary. Under established clinical trial procedures, the subject identification key is generally maintained securely at the clinical trial site and is not routinely accessible to the sponsor.

Conversely, subsequent disclosure to an independent research recipient may allow a different assessment once the data and access conditions have changed.

Recommendation: Include a clinical-trial-specific clarification that anonymisation is not a universal substitute for pseudonymisation and that the chosen safeguard must remain compatible with safety, data-integrity and regulatory retention obligations. Clarify that, under established clinical trial procedures, the subject identification key is generally maintained securely at the clinical trial and that re-identification of individual trial participants through the subject identification code is only possible at the clinical trial site, where the corresponding identification key is securely maintained.

5. Ensure legal certainty for anonymisation and secondary research

Preparing data for anonymisation is itself processing of personal data until anonymity has been achieved. It is important to distinguish that protective operation from the subsequent use of genuinely anonymous information. Where anonymisation forms part of an already lawful processing activity for the same or compatible scientific purposes, the Guidelines should clarify the applicable GDPR legal basis and Article 9 condition without implying that a new basis is invariably required solely because a protective transformation is performed.

Once information is genuinely anonymous for the relevant recipient, subsequent processing of that information falls outside the GDPR. Where it remains personal or pseudonymised, the lawfulness of further processing must continue to be assessed under the GDPR. This distinction is essential for secondary analyses and responsible data sharing following completion of a clinical trial.

The vfa also supports proportionate reassessment where material changes affect the original conclusion on anonymity. Fixed periodic reassessments of all archived datasets should not be presumed necessary, particularly given the long retention periods associated with clinical trials.

Recommendation: Clarify the relationship between lawful initial processing, anonymisation as a safeguard and subsequent research use; and favour risk-triggered reassessment over an undifferentiated periodic review requirement.

6. Ensure consistency with the EHDS and clinical trial rules

The European Health Data Space is intended to support responsible secondary use of health data under appropriate safeguards. Guidance on anonymisation should be coherent with that framework and with the requirements governing clinical trials and regulatory transparency. Otherwise, divergent interpretations across Member States could create uncertainty for cross-border research and controlled data sharing.

Recommendation: Provide practical examples for clinical-trial datasets in secure research environments and explain how the contextual approach can be applied consistently alongside the EHDS and applicable clinical trial obligations.

Conclusion

The vfa encourages the EDPB to preserve the contextual, evidence-based approach to anonymity and to clarify its application to the distinct actors and purposes involved in clinical trials. The final Guidelines should recognise effective safeguards, maintain the scientific utility of research data and accommodate the continued need for pseudonymisation where regulatory duties require traceability. Specific clinical-trial examples would help translate the legal principles into predictable practice.