European Association of Urology

European Association of Urology Response to Anonymisation Guidelines

The European Association of Urology (EAU) welcomes the European Data Protection Board's draft Guidelines on Anonymisation. The guidelines provide important clarification regarding the interpretation of the GDPR, including relevant principles established through case law. We also strongly support the objective of ensuring robust protection of personal data, particularly health data, given its sensitive nature and the potential impact that misuse may have on individuals and their fundamental rights.

We recognise the risks associated with data linkage, re-identification and inference. In particular, health-related information or inferred health characteristics may be used in ways that adversely affect individuals, even where no formal diagnosis exists. On top of this, different anonymisation considerations must also be considered when dealing with health data pertaining to a small number of people, such as with rare diseases. Such risks justify strong safeguards and careful assessment of anonymisation measures.

The comments below reflect the perspective of the urological medical and clinical research community, particularly investigator-led and non-commercial research conducted within established legal, ethical and professional governance frameworks. Health research is typically subject to professional duties of confidentiality, ethics review, institutional oversight, and legal restrictions on data access and use. While these safeguards do not themselves render data anonymous, they are important contextual factors that may influence whether identification is reasonably likely in a particular setting.

Our principal recommendation is that the final guidelines should provide greater contextualisation for health research and be complemented by sector-specific guidance and practical examples relevant to clinical and medical research environments.

1. Technical Analysis of Anonymisation: Is There a Middle Ground for Health Research?

We acknowledge the distinction drawn in the guidelines between simplified and contextual approaches to anonymisation. Historically, many organisations involved in health research have adopted a cautious approach, treating datasets as potentially identifiable even where direct identifiers have been removed and extensive safeguards are in place. As a result, researchers often face significant administrative, legal and ethical barriers when seeking to access pseudonymised data, particularly across institutional and national boundaries.

At the same time, differences in the implementation and interpretation of GDPR provisions relating to research have created a complex and fragmented compliance landscape across Member States. This has led many research collaborations to prioritise the use of anonymised datasets in order to facilitate lawful and efficient data sharing. While this objective is understandable, the pursuit of anonymisation can in some cases reduce the scientific utility of data and limit the ability to conduct more granular analyses that are necessary for personalised medicine, risk stratification and the development of innovative healthcare interventions.

For example, a clinical registry may contain information on a rare biomarker that is highly informative for research purposes but may also increase the possibility of singling out a small group of individuals. The response may be to suppress or remove such information to reduce disclosure risk. However, doing so may significantly diminish the scientific value of the dataset. We would therefore welcome further guidance on how controllers can appropriately balance disclosure risk mitigation with preservation of scientific utility.

While the contextual approach outlined in the guidelines appears promising, additional practical examples will be essential to support consistent implementation within the health research sector. In particular, examples involving multinational research consortia, clinical registries, longitudinal cohort studies, and rare disease research would help researchers understand how contextual factors should be assessed in practice and how different actors and safeguards should be taken into account.

2. Application of the Anonymisation Criteria: Clarifying Risk Thresholds

The guidelines emphasise protection against singling out, linkability and inference. We agree that these represent important considerations when assessing whether a dataset can reasonably be considered anonymous.

However, in health research settings, the practical application of these criteria may come at the expense of advancing public health and at the expense of generating evidence that supports regulatory decision making. Certain forms of inference are intrinsic to the scientific purpose of health research. Researchers routinely seek to identify correlations between biomarkers, clinical characteristics, disease progression and health outcomes. Additional clarification would therefore be valuable regarding how the criteria should be applied in circumstances where some degree of inference is both expected and scientifically necessary.

Importantly, the GDPR does not require absolute impossibility of re-identification. Rather, Recital 26 requires an assessment of whether identification is reasonably likely, taking account of objective factors such as available technology, costs, time required and the means reasonably likely to be used. In practice, health research often takes place within highly regulated environments, characterised by restricted access, contractual controls, professional duties of confidentiality, ethics approvals and institutional oversight.

The EAU therefore encourages the EDPB to provide further guidance on how such legal, ethical and organisational safeguards may be considered within a contextual analysis of anonymisation. Although these safeguards cannot transform personal data into anonymous data, they may be highly relevant when assessing whether identification or misuse is reasonably likely in a particular research environment.

A more practical and risk-based framework would assist researchers, institutions and regulators in distinguishing theoretical possibilities of identification from realistic risks that could result in harm to individuals. This would improve legal certainty while maintaining a high level of protection for data subjects.

Conclusion

The EAU strongly supports the objective of protecting individuals against singling out, linkability and inappropriate inference. At the same time, health research presents unique challenges because the generation of clinically meaningful knowledge often depends upon the analysis of detailed and highly informative datasets.

We therefore encourage the EDPB to supplement the final guidelines with additional guidance specifically addressing health research. Such guidance should include worked examples covering clinical registries, rare disease research, academic research collaborations and longitudinal health studies. It should also provide further clarification on how the "reasonably likely" standard should be applied in environments characterised by strong legal, ethical and professional governance mechanisms.

Greater clarity in this area would improve consistency across Member States, strengthen legal certainty for researchers and institutions, and support the responsible use of data for scientific advancement, public health and improved patient outcomes, while continuing to safeguard the fundamental rights and interests of individuals.