Biomedical Alliance in Europe

Need for more clarity for data sharing for health research

Feedback from BioMed Alliance on the EDPB Guidelines 1/2026 on processing of personal data for scientific research purposes

The BioMed Alliance, representing 34 European Medical and Research Societies, welcomes the European Data Protection Board's (EDPB) efforts to provide more clarity on the application of the General Data Protection Regulation (GDPR). While some essential questions are resolved, more guidance is necessary that specifically focuses on sector-specific challenges related to health data sharing for scientific research. The future European Health Data Space might facilitate health data sharing for both primary and secondary use of data, but it is not a one-size-fits-all solution that would govern all aspects related to the collection and sharing of health data.

This reply should be read in conjunction with the replies of BioMed Alliance members, and we thank our data taskforce and particularly EAU for their support in preparing this feedback document.

Background

Medical Societies play a key role in the collection and sharing of data; including through various activities related to research, the development of guidelines, education, and contributions to registries. The healthcare professionals and researchers that they represent also work with health data on a daily basis and continue to face obstacles and barriers. Even though the General Data Protection Regulation (GDPR) has applied since 2018, there are still differences in interpretation and implementation in the health research sector across countries, regions, health institutions, and even within departments of the same organisation. This fragmentation is perhaps greatest in health research as the provisions for scientific research (including but not limited to Art 89) create barriers to data use and sharing in healthcare and research, particularly considering that healthcare institutions often adopt a risk-averse approach. In some cases, they hesitate to share data for research or innovation or are reluctant to approve data-driven research activities, fearing potential legal consequences. Nonetheless, these activities are often permissible under GDPR and could greatly benefit patients, but due to misinterpretation they sometimes do not take place. Sector specific guidance on the implementation of GDPR for health research would help to take away uncertainty and facilitate a more harmonised interoperation across the EU.

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General feedback

While the guidelines on processing of personal data for scientific research purposes provide important information to support researchers, there are still a number of aspects that are not sufficiently covered when applying the guidelines to health research as a very specific, highly regulated field.

We would like to highlight three general gaps in the current guidelines which apply to health research:

1. Lack of clarity on interaction with other horizontal and sector- specific regulations (AI Act, Medical Devices and IVD Regulations, Clinical Trials Regulation, European Health Data Space, for example)

2. Lack of harmonized approaches across the EU to health research. The issue is referred to in paragraph 66 of the current guidelines as an area where Member States have significant possibilities to impose further restrictions and measures for processing health data, genetic or biometric data. The 2021 Study on the Assessment of EU Member States' rules on health data in the light of the GDPR is a clear indication of the scope of the challenge.

3. Acknowledgement of the overlap with ethical requirements in the health research, which have led to ethics committees having a considerable interpretive voice to GDPR requirements.

Definition of Scientific research

The definitions are sound and reasonable, but these will need to be clearly refined to be implementable in a health research setting. Additional clarity and some flexibility are therefore necessary so that it encompasses the broad range of research related activities in the health field.

The one example in the guideline is a clinical trial, which is still the 'gold standard' of clinical research. But what about other studies which include: Prospective disease registries, quality management research in health, real-world evidence to guide clinical practice guidelines, implementation science on health system capacity and feasibility.

We appreciate the case study that a retail sales analysis of online customer data would fall outside of scope of scientific research, but where, for example a health care service or provider is monitoring and analysing health data for quality and effectiveness purposes this leaves a level of uncertainty in interpretation which should be clarified with more specific case studies from the health research sector. Examples of quality improvement related research include: research about improving existing healthcare services, workflows and clinical practice/management; investigating trends and analysis of patient outcomes following a surgical procedure; analysis of medical therapies against surgical procedures; analyses of mortality and comorbidities in response to disease-specific therapies to inform changes in clinical practice.

We would therefore call for the inclusion of quality improvement in the definition, as many important discoveries emerge from real-world service improvement and learning systems and modern health, public-sector and industrial innovation often blends research and improvement.

Scientific research as a purpose in its own right

To avoid unnecessary fragmentation across institutional and EU borders as well as the loss of much data due to unnecessary re-consenting, the EDPB should clarify that “scientific research” constitutes a broad, overarching purpose under the GDPR, where multiple projects, studies and analyses can take place. This interpretation is consistent with Recital 159 GDPR, the presumption of compatibility (Article 5(1)(b) GDPR,) and operational realities for many public health researchers and teams.

Reliance on consent-based models

Consent is implicitly framed as a default expectation, even in settings where the GDPR itself anticipates that public interest or legitimate interests are both viable and appropriate for research purposes.

Dynamic consent is presented as a “solution” but its impracticality at scale is not properly addressed. For large multi-centre studies re-consenting per sub-project is simply not feasible, yet the guidelines offer no proportionate alternative. The guideline does not sufficiently acknowledge the impossibility of re-consent due to many factors in health research: people moving health providers, patients lost to follow-up, death or people purely not interested. Insisting on re-contact can render further research impossible or not feasible.

This happens in parallel to the involvement of ethics committees reviewing research protocols through the lens of informed consent and thus often end up determining the effective legal basis for research as consent, largely because national guidance is limited or absent. This situation creates inconsistency and uncertainty across Member States, with differential implementation. Legal clarity in the health sector is needed to define the boundaries of ethical oversight in defining GDPR provisions.

The Guidelines should affirm that ethical committees are responsible for ethical and scientific oversight, not for determining the GDPR legal basis for processing personal data or other GDPR-specific provisions.

A clear distinction should be made between ethical consent and GDPR consent. One governs the participation in research studies, while the latter is only one possible legal basis for processing personal data. The Guidelines should clarify that re-consent is not required for secondary use when it is impossible or disproportionate, provided that Article 89 safeguards and ethical oversight are in place.

Broad consent area boundaries also remain vague. What constitutes staying "within" a research area versus crossing into a new one requiring fresh consent is never operationally defined. For evolving long-term research this is a real problem with no practical guidance.

Legitimate interest test

Legitimate interest is highlighted as a possible legal basis for scientific research, and the guideline mentions that "significant weight" may be attributed to the processing of personal data for scientific research purposes. However, the guideline falls short of practical implementation guidance on how this may be applied in health research. The Legitimate interest assessment (Purpose – necessity – balancing tests) is a concept that was mainly derived for commercial partners, but the health research landscape is much more complex. Without concrete guidance and with the fragmented legal landscape for health data (outlined above), including conflicting advice from ethical committees, many studies find themselves pushed to consent as the legal basis. This goes against the proportionate advice given in the EPPB opinion in 2019 on the interplay between clinical trials and GDPR.

More practical guidance on which health research studies may fall under 'reasonable expectations' for secondary use will be required. In particular, there is an urgent need for guidance on the secondary use of health system data (where data subjects are individuals receiving healthcare services rather than participants enrolled in studies or trials) including clarification of situations in which legitimate interest may not be appropriate and where public interest or alternative legal bases may be more suitable.

The legitimate interest test becomes prohibitive as full anonymisation often removes the scientific value and analytical abilities for health research, and it also prohibits any chance of reporting significant findings to research participants. This is important because it is a provision of the European Health Data Space.

Pseudonymisation

Further clarification of the concept of pseudonymisation would be valuable, as the term is interpreted differently by different stakeholders in practice. Regarding risk-based pseudonymisation, the guideline references the judgment of 4 September 2025 (C-413/23 P, EDPS v. SRB, EU:C:2025:645) EUR-Lex - 62023CJ0413 - EN - EUR-Lex, but falls short of clarifying how the concept of 'relative identifiability' (data can be personal for one actor but not another) can be reasonably and legally applied in health research settings.

This guidance would be of critical importance to the health sector as a whole but in particular to multi-center health studies, health data access platforms and federated health research models. These studies all fall under ethical scrutiny, with data protection impact assessments performed, and data is generally processed in a secure processing environment.

In addition, there have been situations where pseudonymised datasets are shared with external registries or database services, and the receiving organisation considers the data to be anonymous from its perspective (and therefore outside the scope of the GDPR), while the original data holder continues to regard the same data as personal data because it remains pseudonymised rather than fully anonymised when assessed in the context of the data holder's ability to re-identify individuals.

These differing interpretations can create legal uncertainty and act as a practical barrier to data sharing for scientific research purposes. Data owners may be reluctant to share data where

there is ambiguity over whether the transferred dataset should be treated as anonymous data or as personal data subject to GDPR obligations.

Storage limitation

Storage limitation can be a significant issue for longitudinal studies and prospective registries. This is acknowledged in the guidelines especially in paragraph 27, but the possibility to use data across the lifespan is often critical for health research and not a niche issue. Ethical committees or institutional DPOs will often find longer retention periods of data concerning, forcing shorter retention periods on controllers unless there are statutory or legal requirements to keep data for longer. This is prohibitive for large amounts of longitudinal research using RWE and big data from numerous cohorts. The impact of screening on mortality is an example where long term data is required to map outcomes, as in the recent 23 year follow up of the European Study on Prostate Cancer Screening. European Study of Prostate Cancer Screening — 23-Year Follow-up | New England Journal of Medicine

Legislative complexity

Additional clarity on the application and interaction with other legal frameworks is also key, including sectorial legislation. For instance, the European Health Data Space Regulation (EHDS, adopted 2025) creates a parallel framework for health data access. These guidelines reference the EHDS only in footnotes and do not address how researchers should navigate cases where EHDS access rules and GDPR consent obligations point in different directions. This gap will create confusion in practice very soon

At the same time, the issue of diverging policies and rules at national level is mentioned but not resolved. The guidelines repeatedly acknowledge that national laws may impose additional conditions but offer no mechanism for cross-border research to achieve consistent compliance which is a significant barrier for pan-European studies. This patchwork of approaches might encourage actors to adopt a risk-adverse approach to avoid legal issues, preventing essential health research activities from taking place.