# MedTech Europe response to the EDPB public consultation on Guidelines 1/2026 on processing of personal data for scientific research purposes

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## Executive summary


MedTech Europe welcomes the EDPB's draft Guidelines 1/2026 on processing of personal data for scientific research purposes as a significant and timely step towards clarifying the application of the GDPR to scientific research, including for private-sector actors. The Guidelines provide valuable guidance on key concepts such as the definition of scientific research, the presumption of compatibility for further processing, the use of broad consent, and the role of safeguards under Article 89 GDPR.

At the same time, the medical technology sector has identified a number of practical and sector-specific challenges that may limit the effective application of the Guidelines in practice, particularly in highly regulated, innovation-driven environments.

In particular, further clarification is needed regarding:

- the application of the six key indicative factors to industry-led and early-stage research activities;
- the interaction between the GDPR and sector-specific regulatory frameworks;
- the need to distinguish ethical informed consent from consent as a GDPR legal basis, and to recognise alternative legal bases for regulated research;
- the practical implementation of anonymisation, especially for health data and biological material;
- the secondary use of legacy datasets and leftover biological samples, particularly in low-risk scenarios;
- the balance between data subject rights and scientific validity;
- the proportional application of transparency obligations, including the notion of *disproportionate effort*;
- the management of data minimisation and retention in long-term research contexts;
- the challenges arising from Member State fragmentation for cross-border research;
- the need to reconcile transparency with the protection of intellectual property and trade secrets; and
- the absence of guidance on AI and machine learning in scientific research, despite their growing relevance for innovation in the medical technology sector.

MedTech Europe therefore encourages the EDPB to further refine the Guidelines by providing additional practical guidance, sector-specific examples, and a stronger risk-based approach. In particular, the Guidelines should better reflect the realities of regulated clinical research, the role of safeguards under the Medical Devices Regulation and the In Vitro Diagnostic Medical Devices Regulation, the practical limits of anonymisation and transparency obligations, and the need to support responsible secondary use of data and AI-enabled research.

With these clarifications, the Guidelines can provide a more coherent and workable framework for responsible data use, while supporting innovation, competitiveness and better patient outcomes across Europe.

## Introduction

MedTech Europe welcomes the opportunity to comment on the European Data Protection Board's (EDPB) draft Guidelines 1/2026 on the processing of personal data for scientific research purposes.

**As a European trade association representing the medical technology sector, we welcome the development of these Guidelines, which constitute a significant and timely step towards clarifying the application of the General Data Protection Regulation (GDPR)[1] to scientific research**. Scientific research in the medical technology sector plays a critical role in driving innovation, improving patient outcomes, and supporting resilient and sustainable healthcare systems in Europe.[2]

Given that key aspects of the GDPR framework for research — including the concept of scientific research, the conditions for further processing for scientific research purposes, and the role of safeguards under Article 89 GDPR — have remained subject to divergent interpretations, additional guidance at EU level is both necessary and valuable.

We particularly welcome the clarification that:

- scientific research may be conducted by private, for-profit entities;
- further processing for scientific research purposes benefits from a presumption of compatibility;
- broad consent may be used in appropriate circumstances; and
- safeguards under Article 89 GDPR play a central role in ensuring compliance.

At the same time, while the Guidelines represent a long-awaited step towards greater legal clarity and a harmonised interpretation of the GDPR, certain aspects may still give rise to uncertainty in practice, including the operational application of the presumption of compatibility for further processing. **More broadly, a number of practical and sector-specific challenges remain, particularly for industry-led research in highly regulated environments such as medical technology.** Addressing these challenges will be essential to ensure that the Guidelines are fully operational and effectively support data-driven innovation in healthcare.

## From principles to practice: observations from the medical technology sector

The following sections highlight key areas where further clarification would improve the operational application of the Guidelines in practice. MedTech Europe complements its analysis with illustrative examples drawn from real-world research scenarios. These observations aim to support a proportionate and practical application of the GDPR framework, while maintaining a high level of protection for individuals.

### i. Scope of scientific research and applicability to industry-led R&D

The introduction of six key indicative factors provides useful structure for assessing whether an activity qualifies as scientific research. We appreciate the EDPB's effort to clarify the concept of scientific research and to enhance legal certainty while safeguarding fundamental rights.

That said, we would respectfully encourage reconsideration of the practical effect of the six key indicative factors in Section 2.1. While described as *indicative*, their presentation may in practice be interpreted as cumulative conditions. **Moreover, where not all factors are met, controllers must justify why the activity still qualifies as scientific research, effectively creating a higher burden of proof.** This approach risks:

- creating undue rigidity in interpreting scientific research;
- reducing legal certainty; and
- discouraging innovative or early-stage research, in particular industry-led research.

[1] Regulation 2016/679, available here.
[2] See e.g. Global Medical Technology Alliance (GMTA), *Considerations for Privacy Laws Involving Health Data*, available here.

This is difficult to reconcile with the GDPR's requirement that scientific research be interpreted broadly. 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.** This may create legal uncertainty in practice and shift the assessment from a purpose-based evaluation towards a compliance-driven threshold.

For example, early-stage and exploratory R&D activities, such as feasibility testing, technical validation, and non-clinical performance verification, may not always meet criteria such as full verifiability and public transparency, the publication or dissemination of results, or independence as interpreted in an academic sense.

These activities are nonetheless methodical, ethically conducted, and aimed at generating knowledge and innovation, often as precursors to regulated clinical investigations. **Without further clarification, there is a risk that such activities may be interpreted as falling outside the scope of *scientific research* under the GDPR, leading to legal uncertainty and inconsistent application across Member States**.

**Use case 1: Early-stage feasibility testing**

A medical device manufacturer may conduct early-stage feasibility testing using clinical material to validate whether a concept is viable before initiating formal clinical investigations. These activities follow structured protocols and ethical standards, but do not always result in publication or external dissemination. A strict application of the six key criteria (in particular regarding verifiability and transparency) may create uncertainty as to whether such activities qualify as *scientific research*, despite being an essential precursor to innovation and future patient benefit.

This example also highlights that certain criteria, such as *independence*, should not be interpreted in a way that inadvertently exclude industry-led research conducted by qualified and experienced professionals. In industry-led research, *independence* should not be understood as the absence of any link to commercial objectives. Rather, *independence* relates to the absence of undue bias in the design, conduct, analysis and interpretation of research activities. While commercial considerations may play a role in initiating research, these subsequent stages must remain under the control of qualified researchers operating within appropriate internal governance frameworks, quality systems, and regulatory oversight.

We recommend a **more flexible, principle-based approach** that would:

- clarify that the factors are non-cumulative and non-determinative;
- avoid a binary *presumption vs. justification* dynamic, in favour of a holistic, case-by-case assessment;
- emphasise that the absence of some factors should not trigger a higher evidentiary burden; and
- clarify that the factors themselves should not be interpreted narrowly in practice. For example, *independence* should not exclude research conducted by qualified researchers employed by industry, and *verifiability and transparency* should not necessarily require immediate publication of results, but may be satisfied through sharing methodologies with the scientific community or through a later intention to disseminate results (including via intellectual property protection, such as patents).

### ii. Unclarity about the need for consent under Article 9(2) GDPR

The Guidelines risk creating the impression that consent is the default legal basis for scientific research, whereas the GDPR establishes a neutral framework in which consent is only one option among several, and may often be less appropriate than alternatives such as public interest, legal obligation, or legitimate interests.

**In this context, it is essential to clearly distinguish between ethical informed consent to participate in research and consent as a legal basis for the processing of personal data under the GDPR.** In clinical investigations, informed consent ensures that participation is voluntary and informed, while the GDPR determines the legal conditions under which personal data may be processed. These frameworks operate in parallel but should be assessed separately. Using consent as the legal basis for processing in regulated clinical investigations is often difficult to reconcile with the realities of clinical research. Sponsors and investigators are subject to extensive obligations relating to participant safety, vigilance reporting, scientific validity, record retention, inspections and regulatory oversight, many of which continue to apply even after a participant withdraws from the study.

**As a result, certain processing activities must continue after withdrawal in order to preserve the integrity and reliability of study results and to comply with applicable legal requirements. This creates tension with consent as a legal basis, which must be freely given and capable of being withdrawn at any time, and may create a misleading perception that participants can determine whether their data continue to be processed.**

This is also consistent with previous EDPB guidance in Opinion 3/2019 on the interplay between the Clinical Trials Regulation and the GDPR,[3] which emphasised that consent may not always be an appropriate legal basis in research contexts. The structure of the GDPR itself supports this approach. Through Article 9(2)(j) GDPR, the legislator has expressly recognised scientific research as a legitimate ground for processing special categories of personal data, subject to appropriate safeguards under Article 89 GDPR. Its practical relevance would be limited if regulated research were expected to rely primarily on consent.

Further clarification would also be beneficial regarding the statement that Article 9(2)(j) GDPR may only be relied upon where a Union or Member State law specifically permits the processing for scientific research purposes. In practice, this interpretation contributes to fragmentation across Member States, with some jurisdictions considering that the GDPR itself provides the necessary Union law, while others require an additional national legal provision. As a result, sponsors of multinational clinical investigations may need to rely on different legal bases for the same study, creating legal uncertainty and operational complexity.

From a policy perspective, **it would be preferable to recognise that the GDPR itself can provide the necessary Union law framework for processing personal data for scientific research under Article 9(2)(j) GDPR, subject to appropriate safeguards under Article 89 GDPR.** At a minimum, the Guidelines could usefully acknowledge that EU regulatory frameworks governing clinical research — such as the Clinical Trials Regulation, the Medical Devices Regulation (MDR)[4] and the In Vitro Diagnostic Medical Devices Regulation (IVDR)[5] — provide the necessary safeguards and oversight to support reliance on Article 9(2)(j) GDPR.

[3] Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection regulation (GDPR), available here.
[4] Regulation (EU) 2017/745, available here.
[5] Regulation (EU) 2017/746, available here.

In addition, the Guidelines should avoid suggesting that explicit consent is the default option in the absence of specific national legislation. Instead, they should reflect the approach outlined in Opinion 3/2019, recognising that alternative legal bases, such as public interest or legitimate interests, in combination with Article 9(2)(j) GDPR, may constitute appropriate and proportionate grounds for processing in regulated clinical research environments.

In practice, participation in a clinical investigation may be based on informed consent under clinical research legislation, while the associated processing of personal data relies on alternative legal bases under the GDPR. This distinction also reflects practical realities in clinical research settings, where sponsors are typically not in direct contact with participants and data are processed in coded form, with re-identification managed at site level.

A clearer and more transparent framework would therefore distinguish between:

- ethical informed consent, which authorises participation in the clinical investigation; and
- the legal basis for data processing under the GDPR.

This concern is particularly relevant in health research, where patients may face limitations in their ability to provide fully free and informed consent. Over-reliance on consent may therefore risk excluding important patient populations. Moreover, health research data are typically processed in pseudonymised form, subject to strict technical and organisational safeguards. **Where residual risks to individuals are low and the societal interest in improving patient outcomes is high, the Guidelines should more clearly acknowledge the role of alternative legal bases — such as public interest or legitimate interests — as appropriate and proportionate foundations for research activities.**

**Use case 2: Limitations of consent in clinical research contexts**

In clinical research settings, patients may be in situations of dependency or vulnerability, such as during acute care or complex treatment pathways. In such circumstances, obtaining freely given and fully informed consent may be challenging in practice. At the same time, the use of pseudonymised data for research purposes may present minimal risks to individuals while generating significant public health benefits. This highlights the importance of enabling alternative legal bases where appropriate.

### iii. Alignment with medical device regulatory frameworks

The Guidelines do not sufficiently reflect the existing regulatory environment governing medical technology research, notably under the MDR and IVDR.

These frameworks impose:

- strict requirements on clinical evidence generation;
- comprehensive technical documentation and traceability;
- oversight by notified bodies and competent authorities; and
- structured clinical investigation and performance study regimes with proportionate transparency requirements.

These mechanisms already ensure high levels of scientific validity, accountability, transparency and oversight, and should be explicitly recognised as fulfilling key elements such as verifiability and transparency. At present, the lack of such recognition results in fragmented interpretation across Member States, driving divergent GDPR interpretations and requiring medtech companies to navigate inconsistent legal bases for comparable or even identical activities.

### iv. Anonymisation and practical implementation challenges

The strong emphasis on anonymisation as a preferred safeguard is understood. However, in practice, its application raises significant challenges in the medical technology context.

In many cases:

- identifiable or pseudonymised data must be retained to comply with regulatory requirements;
- irreversible anonymisation may compromise scientific validity or traceability; and
- genetic data derived from biological material (e.g. blood samples) remains, in theory, inherently identifiable over time due to technological developments.

More generally, anonymisation in the medical technology sector is typically implemented through iterative, risk-based processes combining data transformations and organisational controls, rather than as a one-step operation.

**Use case 3: Post-market surveillance and traceability obligations**

Medical device manufacturers are subject to strict obligations under the MDR and IVDR to monitor device safety and performance, including investigating adverse events and long-term safety signals. This requires the ability to trace data back to patients, procedures or device identifiers for follow-up analyses and regulatory reporting.

Irreversible anonymisation at an early stage would prevent compliance with these obligations and may compromise patient safety. As a result, data often needs to remain identifiable or pseudonymised for extended periods. This illustrates that anonymisation cannot always be fully implemented without undermining regulatory compliance and public health objectives, and that a flexible, risk-based approach is necessary.

In addition, clarification would be beneficial regarding the statement in the Guidelines that "*the anonymisation process itself […] is a processing operation under the GDPR that must comply with the provisions of the GDPR, including the requirements of lawfulness.*" While it is understood that anonymisation involves operations on personal data, it would be helpful to clarify that not every individual processing step requires a standalone legal basis. Rather, under the GDPR framework, it is the overall processing purpose that must be grounded in a legal basis, with specific operations — such as anonymisation, deletion or other data minimisation measures — forming part of that broader lawful processing lifecycle.

In practice, anonymisation in the medical technology sector is typically performed as part of a broader processing activity and serves as a safeguard or outcome of that processing, rather than constituting a separate purpose in itself. Treating anonymisation as requiring a standalone legal basis may therefore create unnecessary legal uncertainty and could inadvertently discourage the adoption of privacy-enhancing practices. This interpretation would also be difficult to reconcile with existing legal and regulatory references that treat anonymisation alongside deletion, suggesting that such operations are part of the lifecycle of processing rather than distinct purposes requiring an independent legal basis.

**A more nuanced interpretation, recognising anonymisation as an integral component of lawful processing operations and risk mitigation strategies, would better reflect operational realities.** This is particularly important in contexts where data must remain identifiable or pseudonymised for extended periods to meet regulatory requirements under the MDR and IVDR, ensure traceability, and protect patient safety.

### v. Secondary use of data and low-risk research scenarios

From an ethical perspective, the secondary use of existing data may in certain cases be preferable to the collection of new data. It can reduce unnecessary patient burden and limit additional processing of sensitive

health data, in line with the GDPR principles of data minimisation and proportionality, while enabling faster generation of clinically relevant evidence and supporting innovation for public health benefit.

The confirmation of the presumption of compatibility for further processing for scientific research purposes is welcomed. However, important uncertainties remain in relation to its practical application.

Examples of further processing for scientific research purposes in the medtech sector include:

- reuse of legacy datasets, collected for non-research-related purposes, by the original controller;
- reuse of clinical investigation data, collected for scientific research, by the same data controller; and
- reuse of discarded or leftover blood samples for technical validation of contemplated changes to devices in the context of early feasibility studies (where the blood shows certain pathologies required for such testing, and the leftovers would otherwise be discarded).

In addition to the barrier created by the expected cumulative application of the six key indicative factors for further use to qualify as scientific research, the expected guardrails for *compatibility* may create disproportionate burdens, particularly where risks to data subjects are minimal. This applies in particular to the combined application of:

- transparency obligations;
- consent requirements, guarantees to data subjects and an unconditional right to object to the processing of personal data;
- anonymisation expectations.

A particularly relevant example concerns feasibility testing using leftover biological material (that would otherwise be discarded). Such material is often:

- originally collected in a routine clinical context and deemed valuable due to specific blood pathologies required for effective research;
- de-linked from direct identifiers before reuse, although in theory the genetic data in the material could link back to the donor; and
- used in low-risk, non-interventional settings.

However, the Guidelines do not provide clear, operational guidance on how anonymisation expectations should be satisfied in such scenarios, nor how responsibilities should be shared between controllers (e.g. hospitals) and downstream users (e.g. manufacturers receiving the leftover samples for technical testing of innovative changes to devices).

**Use case 4: Reuse of leftover biological samples**

Feasibility testing often relies on leftover biological samples collected during routine clinical care that would otherwise be discarded. The availability of such samples is time-sensitive, as biological material may degrade or be disposed of before any additional procedural steps can be implemented. These samples may be de-linked from direct identifiers by the healthcare provider prior to use and are used in low-risk, non-interventional research activities. In many cases, the healthcare provider remains the data controller and performs the de-identification step before transferring the material to a downstream user, such as a manufacturer.

While biological material may theoretically be considered potentially identifiable depending on context and available means, in practice the samples are used exclusively for the intended scientific purpose and fully consumed during testing, leaving no material available for any attempt at re-identification.

In this context, while full anonymisation in a strict or irreversible sense may not be achieved, the residual risk to individuals is effectively negligible. However, the current lack of clear and operational guidance on how

anonymisation expectations should be applied in such scenarios creates legal uncertainty. In addition, the allocation of responsibilities between actors involved in the reuse of such material, including healthcare providers and downstream users, remains unclear under the Guidelines.

### vi. Data subject rights and scientific validity

The Guidelines acknowledge that certain rights, such as the right to erasure or right to object, may be limited where their exercise would render research impossible or seriously impair it. However, in practice, scientific integrity may be affected at a very early stage. Even limited data removal can introduce bias, affect datasets' representativeness, and undermine statistical conclusions.

The absence of more granular guidance on how to assess these situations creates legal uncertainty and operational risk for controllers. Additional guidance would also be beneficial on the operational management of withdrawal of consent in ongoing research activities.

**Use case 5: Impact of data erasure on research validity**

In a clinical dataset used for research, the removal of even a limited number of records following an erasure request may introduce statistical bias or affect the robustness of results. While this may not render the research "impossible", it may nonetheless affect its validity and reliability. The absence of practical guidance on how to assess this threshold creates uncertainty for controllers.

### vii. Transparency requirements and proportionality

The Guidelines set out extensive expectations regarding transparency, including indirect notification, public information measures, and ongoing updates. While these objectives are understood, their practical application may be disproportionate in specific scenarios, including:

- legacy datasets where providing additional individual-level information or engaging in follow-up communication with data subjects may not be feasible;
- closed clinical studies where clinical investigation sites are no longer active; and
- low-risk research using non-identifiable or weakly identifiable data.

At the same time, the Guidelines provide useful clarification on the application of transparency obligations in complex research settings. In particular, paragraphs 86-89 of the Guidelines suggest that, where data is pseudonymised and identifiers are not accessible to the controller, a regime comparable to the Article 14(5)(b) exemption may be available, even in situations of direct data collection, while still encouraging appropriate safeguards, such as forward-looking notification mechanisms where further research is envisaged.

In clinical research settings, sponsors are most often not in direct contact with patients. Case report forms (CRFs) and other data transferred to the sponsor use a participant code rather than names or direct identifiers. The clinical site retains the code-breaking key, known as the subject identification log. Any situation requiring re-identification, such as a serious adverse event requiring follow-up, goes through the investigator, not the sponsor directly. This makes re-notification to clinical trial participants very difficult and would require the involvement of different investigator sites, creating a significant burden on the healthcare system.

The Guidelines already recognise, including through the examples provided in paragraph 100 (e.g. patient registries), that fulfilling transparency obligations may in practice involve disproportionate effort in certain contexts. However, further clarification on how to operationalise the assessment of *disproportionate effort* under Article 14 GDPR would still be beneficial. In this respect, paragraph 101's risk-based approach is particularly welcome.

Building on this, it would be helpful to clarify that the assessment of disproportionate effort may explicitly take into account factors such as the level of risk to individuals, the degree of identifiability of the data, the practical feasibility of contacting individuals, the use of public health resources, and the broader societal benefits of research. Such clarification would support a proportionate application of transparency obligations, while preserving a high level of protection for data subjects.

**Use case 6: Legacy datasets and disproportionate effort**

Medical research frequently relies on historical datasets, including data from previously completed clinical investigations. In such cases, providing additional individual-level information or engaging in follow-up communication with data subjects may not be feasible.

The Guidelines provide helpful elements, particularly regarding pseudonymisation, limited accessibility of identifiers, and examples of disproportionate effort. However, some uncertainty may remain in practice as to how transparency obligations should be fulfilled in these complex scenarios. Further alignment with the risk-based approach outlined in paragraph 101 would therefore be valuable to ensure consistent and proportionate implementation.

### viii. Data minimisation, retention, and research lifecycle

The Guidelines reaffirm core GDPR principles such as data minimisation and storage limitation but provide limited practical guidance on their application in research contexts. In practice, there is an inherent tension between:

- limiting data collection and retention, and
- ensuring long-term usability for ongoing or future research, including regulatory requirements.

This tension is particularly pronounced where regulatory frameworks impose extended retention periods (e.g. clinical investigation data under MDR/IVDR), which may not easily align with GDPR expectations. This is especially relevant for long-term clinical evidence generation, research data infrastructures, and post-market and real-world evidence activities.

### ix. Fragmentation and cross-border research challenges

Despite the objective of promoting harmonised interpretation and consistency, key elements of the framework remain subject to Member State laws, particularly regarding:

- processing of special categories of data;
- legal bases; and
- retention practices and access conditions.

For multi-country clinical studies and research activities, this results in significant operational complexity and compliance burden, which is not sufficiently addressed in the Guidelines.

Additional practical guidance would be particularly beneficial in areas where divergence is most pronounced in practice, including the interpretation of controller/processor roles, the involvement of ethics committees, and the application of national requirements to clinical studies. In some national frameworks, exemptions from ethical consent may be available under specific conditions. In practice, however, ethics committees may be inclined to reassess such situations through a data protection lens and reintroduce consent expectations, rather than recognising alternative lawful bases under the GDPR. Without greater harmonisation, there is a risk that further national guidance may develop, leading to additional fragmentation and reduced legal certainty.

### x. Innovation, intellectual property, and transparency

Finally, the Guidelines do not sufficiently address the balance between transparency requirements and the protection of intellectual property and trade secrets. In the medical technology sector research results cannot always be fully disclosed, publication is not always feasible, and innovation depends on protecting proprietary information.

Overall, while the Guidelines provide useful clarification in several areas, they represent a missed opportunity to address key operational challenges and, in certain respects, may create new areas of legal uncertainty for organisations conducting scientific research. **Greater clarity is needed to ensure that transparency obligations remain compatible with legitimate commercial and innovation interests.**

A further area where the Guidelines could further benefit from additional clarification concerns the use of artificial intelligence (AI) and machine learning in scientific research. AI-driven research methods — including the training and validation of algorithms on health data, AI-assisted diagnostics, predictive modelling, and federated learning approaches — have become central to innovation in the medical technology sector and are increasingly integral to the scientific research lifecycle. Despite this, the Guidelines are silent on the specific data protection challenges arising from the use of AI in research contexts. **Given the pace of technological development and the growing regulatory landscape, the absence of any guidance on the processing of personal data for AI-related purposes in the context of scientific research creates a significant gap.** MedTech Europe strongly encourages the EDPB to address this gap, either within these Guidelines or through dedicated supplementary guidance, to provide the legal certainty that is essential for responsible AI-driven innovation in healthcare.

## Our recommendations

The above observations are intended to support a proportionate and practical application of the GDPR framework, while maintaining a high level of protection for individuals. Based on them, MedTech Europe therefore recommends that the EDPB:

**Clarify scope and applicability**

- Provide additional guidance on the application of the six key indicative factors, including examples covering industry-led and early-stage research;
- Confirm that exploratory and feasibility-stage research can qualify as scientific research where appropriate safeguards are in place;

**Ensure alignment with sectoral frameworks**

- Explicitly recognise MDR/IVDR and related guidance frameworks as providing robust safeguards relevant to GDPR compliance;

**Provide practical guidance on data use and legal bases**

- Re-emphasise that consent is only one of several legal bases under the GDPR and provide clearer guidance on the use of alternative legal bases for scientific research, particularly in regulated clinical contexts;
- Develop clearer guidance on anonymisation in practice, including where full anonymisation is not feasible;
- Clarify the management of identifiable and anonymised datasets within the same research lifecycle;

**Support data reuse and low-risk research**

- Provide specific guidance on the secondary use of data and biological material, including leftover samples and legacy datasets;
- Introduce a stronger risk-based approach, allowing flexibility where risks to data subjects are minimal;

**Clarify rights and transparency obligations**

- Provide more operational guidance on the application of data subject rights limitations;
- Clarify thresholds for *disproportionate effort* and ensure proportionate transparency obligations;
- Address practical constraints in clinical trial communication structures, including by providing specific guidance for cross-border clinical studies;

**Address fragmentation and coherence**

- Provide guidance to support organisations managing cross-border research activities;

- Clarify interactions between GDPR and sector-specific legislation;

**Support innovation and competitiveness**

- Clarify how to balance transparency with IP and trade secret protection;
- Consider developing sector-specific examples for the use of health-related data in scientific research;
- Address AI and emerging technologies, for example by providing guidance on the data protection implications of using AI and machine learning techniques in scientific research, including in relation to legal bases, data minimisation and purpose limitation.

## Conclusion

MedTech Europe strongly supports the EDPB's objective of facilitating responsible and effective scientific research under the GDPR and considers the Guidelines an important step towards greater clarity and consistency at EU level. To fully achieve this objective, it is essential that the Guidelines are further refined to ensure that they are operationally workable, proportionate, and aligned with sector-specific realities, particularly in highly regulated and innovation-driven sectors such as medical technology.

We therefore encourage the EDPB to build on the current draft by providing additional practical guidance and clarifications, including through sector-specific examples and a more explicit risk-based approach. This will help ensure that the framework remains both robust and adaptable to real-world research environments. A balanced and workable approach is essential not only to ensure effective data protection, but also to support Europe's competitiveness in global research and innovation, the development of safe and effective medical technologies, and ultimately better outcomes for patients.

## About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.
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