EORTC contribution to the public consultation concerning EDPB Guidelines 1/2026 on processing of personal data for scientific research purposes

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1 Introduction

The European Organisation for Research and Treatment of Cancer (EORTC) welcomes the opportunity to comment on the EDPB Guidelines 1/2026 on processing of personal data for scientific research purposes. As an independent, non-profit cancer research organisation coordinating multinational clinical and translational research, EORTC has a strong interest in guidance that supports responsible scientific research while ensuring a high level of protection for research participants.

The Guidelines provide useful clarification on several issues that are important for clinical research, including further processing for scientific research purposes, safeguards, transparency and long-term retention. However, EORTC is concerned that certain parts of the Guidelines remain too abstract for practical application in multinational biomedical research. In particular, the final Guidelines would benefit from more clinical research examples and clearer operational guidance. Without this, divergent interpretations by Member States, ethics committees, clinical sites and local DPOs may continue to create legal uncertainty and administrative burden. EORTC therefore respectfully invites the EDPB to strengthen the final Guidelines by adding clinical research examples and clarifying the operational points set out below.

This contribution refers to the draft EDPB Guidelines 1/2026 published for public consultation.

2 Summary of key recommendations

EORTC invites the EDPB to consider the following points in the final Guidelines:

1. clarify the expected documentation for assessing whether processing qualifies as scientific research;
2. provide examples for secondary use, retrospective research, real-world data research and model-training research;
3. distinguish the GDPR compatibility assessment from separate ethical, regulatory or participant-choice limitations;
4. clarify the distinction between informed consent, future research choice, broad consent and GDPR consent;

5. clarify whether, and in which circumstances, GDPR consent can validly be used for clinical trial processing;
6. clarify the effect of withdrawal from trial participation, withdrawal of future research choice and withdrawal of GDPR consent;
7. provide oncology-specific examples on freely given consent where trial participation may offer access to otherwise unavailable treatment;
8. provide clearer guidance on reimbursement where reimbursement is required by law, ethics committee practice or standard clinical trial arrangements;
9. clarify layered transparency through patient information sheets, public webpages and contact points;
10. clarify the level of effort expected for consultation with patient representatives or data subject groups;
11. provide practical examples of retention wording and data minimisation for future research;
12. clarify when imaging or molecular-image datasets are anonymous and when they remain pseudonymised personal data;
13. provide examples for research data infrastructures and controlled-access governance;
14. clarify sponsor-site role allocation in clinical research;
15. address Member State divergence, including ethics committee interpretation of future research wording;
16. ensure coherence with EU clinical research and biotechnology policy developments; and
17. consider future guidance on AI in scientific research and adjacent issues such as pharmacovigilance-related transfers.

3 Detailed comments

3.1 Comment 1 — Need for clinical research examples and operational clarity

EORTC welcomes the EDPB's effort to provide guidance on scientific research. The Guidelines are useful, but several points remain abstract for multinational clinical and translational research.

Clinical research involves specific operational features. These include coded data held by sponsors, directly identifiable data held at site level, ethics committee review, clinical trial informed consent, long-term retention, future research choices, health and genetic data, data sharing, and multinational site contracting.

Without clinical research examples, there is a risk that the Guidelines will not reduce divergence in practice. Ethics committees, local DPOs, sponsors, sites and national authorities may continue to apply different interpretations to similar research activities.

Requested clarification

EORTC invites the EDPB to add more clinical research examples throughout the final Guidelines, in particular for:

- Secondary use and future research: including further use beyond the original study objective, the relationship between GDPR compatibility and ethical or participant-choice limitations, and changes of legal basis for later research use. See Comments 3 to 6.

- Consent and withdrawal in clinical trials: including GDPR consent as a legal basis, informed consent to participate, future research choice, freely given consent in oncology trials, withdrawal scenarios, and reimbursement. See Comments 5 to 9.
- Transparency and participant communication: including layered information through patient information sheets, public webpages and contact points, communication where the sponsor holds coded data only, and patient representative involvement. See Comments 10 to 12.
- Long-term research value and future data use: including retention wording, data minimisation for future research, imaging and molecular-image datasets, research identifiers, repository access and controlled-access infrastructures. See Comments 13 to 17.
- Multinational governance: including sponsor-site role allocation, Member State divergence, ethics committee interpretation, and coherence with EU clinical research and biotechnology policy. See Comments 18 to 20.

These examples would help reduce divergent interpretation and make the Guidelines more operational for clinical research.

3.2 Comment 2 — Scientific research qualification and documentation expectations

The Guidelines introduce indicative factors to assess whether an activity qualifies as scientific research. This is helpful. However, the final Guidelines should avoid creating an additional heavy administrative test for research organisations.

In clinical research, scientific validity may already be assessed through existing governance. This may include a protocol, concept review, scientific committee review, ethics review, funding review, statistical review or other equivalent process. In secondary use, retrospective research, real-world data studies and model-training research, the evidence may look different from a prospective clinical trial.

Requested clarification

EORTC invites the EDPB to clarify whether controllers are expected to maintain a specific documented assessment against the indicative factors. If yes, the Guidelines should clarify the expected format and level of detail.

The final Guidelines should confirm that controllers may rely on existing scientific review, protocol review, ethics review, concept review or equivalent governance as evidence that an activity qualifies as scientific research. Controllers should not be required to duplicate scientific review solely for GDPR purposes.

The Guidelines should also include examples showing how the indicative factors apply to:

- secondary use of existing clinical trial data;
- retrospective research;
- registry-based research;
- real-world data research;
- methodological research; and

- development or training of research models.

Relevant part of the Guidelines: Section 2.1, key-indicative factors for determining whether processing is motivated by scientific research purposes.

3.3 Comment 3 — Boundary between further scientific research and non-research use

The Guidelines clearly state that further processing for scientific research purposes benefits from the GDPR compatibility presumption and does not require a separate Article 6(4) compatibility test. EORTC welcomes this clarification.

The remaining practical question is how to determine the boundary between further scientific research and other types of further use, especially in clinical research.

Example

Personal data are collected in a cancer clinical trial. Later, the data are proposed for another activity that does not directly aim to advance treatment of the same cancer. The new activity may concern statistical methodology, software validation, cross-disease comparison, development or training of research models, or broader health research.

Such activities may be scientifically valid and beneficial, but their link with the original disease or treatment purpose may be less direct.

Requested clarification

EORTC invites the EDPB to provide clinical research examples showing when such activities still qualify as further processing for scientific research purposes, and when they should be treated as too remote, generic, or non-research in nature.

Relevant part of the Guidelines: Sections 2.1 and 3.1.1, scientific research qualification and presumption of purpose compatibility.

3.4 Comment 4 — GDPR compatibility versus ethical consent or participant choice for future research

EORTC considers it important that the final Guidelines distinguish the GDPR compatibility question from other legal, ethical or regulatory gateways.

In clinical research, participants may be asked whether they agree to future research use. This agreement may be an ethical safeguard or participant choice. It is not necessarily the GDPR legal basis for processing.

Example

Data are collected in a cancer clinical trial. The participant is informed that data may be used for future cancer-related research. This future research choice is collected as an ethical safeguard or participant preference, not as GDPR consent. Later, the data are proposed for another valid scientific research purpose, such as methodology research, model training or cross-disease analysis.

The new use may qualify as scientific research under the GDPR and may benefit from the compatibility presumption. However, it may still fall outside the participant's original future research choice or the ethics-approved scope.

Requested clarification

EORTC invites the EDPB to clarify that the GDPR presumption of compatibility for further scientific research does not override other applicable conditions. These may include informed consent to participate, future research choices, ethics approvals, protocol limits or Member State research rules.

The Guidelines should include an example where a reuse passes the GDPR compatibility analysis but still cannot proceed unless a new ethics-approved route, re-consent or another appropriate non-GDPR route is available.

This clarification would help avoid misunderstanding by ethics committees, sponsors, sites and participants.

Relevant part of the Guidelines: Sections 3.1.1, 4.1.2.1 and 4.1.3, presumption of compatibility, broad consent, and consent to participate in scientific research under ethical or legal requirements not stemming from the GDPR.

3.5 Comment 5 — Distinction between informed consent, future research choice, broad consent and GDPR consent

In clinical research, the word "consent" is used in several different ways. This creates practical confusion.

A participant may:

- consent to participate in a clinical trial;
- agree to future research use;
- give broad consent as an ethical safeguard or participant choice;
- give consent as a GDPR legal basis under Article 6(1)(a); or
- give explicit consent as an Article 9 condition under Article 9(2)(a).

These are not the same. In particular, when a clinical trial information sheet asks participants to agree to future research, this may be a participant choice or ethical safeguard. It does not necessarily mean that the sponsor relies on GDPR consent as the legal basis for the secondary processing.

This distinction is often misunderstood by ethics committees, sites and local stakeholders. EORTC has encountered practical difficulties in some Member States, including Italy and Germany, where ethics committees may reject future research or broad-consent style wording even where the wording is not intended to function as GDPR consent.

Requested clarification

EORTC invites the EDPB to distinguish more clearly between:

- informed consent to participate in a clinical trial;
- participant choice or agreement for future research use;
- broad consent under Recital 33 GDPR; and

- consent or explicit consent as a GDPR legal basis.

The Guidelines should include a clinical trial example where a sponsor records a participant's future research choice while relying on another GDPR legal basis for processing. This would help reduce confusion in ethics review and participant-facing documentation.

Relevant part of the Guidelines: Sections 4.1.2.1, 4.1.3 and 4.4.1, broad consent, consent to participate in scientific research, and explicit consent under Article 9(2)(a) GDPR.

3.6 Comment 6 — GDPR consent as legal basis for clinical trial processing

EORTC welcomes the Guidelines' discussion of consent as a possible legal basis for scientific research. The Guidelines usefully recall that consent must be freely given, that vulnerability and imbalance of power must be considered, and that consent to participate in research must be distinguished from consent as a GDPR legal basis. EORTC also welcomes the examples already provided in the Guidelines. However, these examples do not fully address a specific difficulty in clinical trials.

In many clinical trials, personal data processing is indispensable. If a patient agrees to participate in the trial but refuses GDPR consent for data processing, the sponsor cannot practically include the patient. This creates a structural difficulty for using GDPR consent as the legal basis for the core clinical trial processing.

EORTC considers that, in such circumstances, GDPR consent will often be an inappropriate legal basis for core clinical trial processing. This is because the processing is a condition of trial participation, and the participant does not have a real possibility to participate without the processing. The issue is particularly important where Member States, ethics committees or local stakeholders continue to expect consent-based GDPR wording for clinical trial processing.

Requested clarification

EORTC invites the EDPB to add clinical trial examples showing when GDPR consent should not be used as the legal basis for core clinical trial processing.

In particular, the Guidelines should clarify whether consent under Article 6(1)(a) and explicit consent under Article 9(2)(a) are appropriate where:

- the clinical trial cannot be conducted without processing the participant's personal data;
- refusal of GDPR consent means that the participant cannot be included in the trial;
- the same form is used for informed consent to participate and GDPR consent; and
- special categories of data are processed as an inherent part of the trial.

The Guidelines should also clarify when another GDPR legal basis should be preferred, where available, and how this interacts with informed consent to participate in a clinical trial under the Clinical Trials Regulation.

Relevant part of the Guidelines: Sections 4.1, 4.1.1 and 4.4.1, consent as legal basis, freely given consent, and explicit consent under Article 9(2)(a) GDPR.

3.7 Comment 7 — Withdrawal from clinical trial participation, future research choice and GDPR consent

In clinical research, different types of withdrawal may occur. They should not be treated as the same event.

A participant may:

- withdraw from participation in the clinical trial;
- withdraw from future research use;
- withdraw GDPR consent, where GDPR consent is used as the legal basis; or
- withdraw all of the above at the same time.

Where processing is based on legitimate interest, public interest or another appropriate basis, withdrawal from trial participation should not automatically require deletion of data already collected. Where processing is based on GDPR consent, withdrawal of trial participation should also not automatically be treated as withdrawal of GDPR consent unless this is clearly the participant's intention.

At the same time, where GDPR consent is withdrawn, the controller needs clear guidance on whether data collected before withdrawal may still be retained and used to protect trial integrity, safety analysis, regulatory documentation, statistical validity and reproducibility.

Requested clarification

EORTC invites the EDPB to provide clinical trial examples covering:

- withdrawal from participation only;
- withdrawal of future research choice only;
- withdrawal of GDPR consent only; and
- simultaneous withdrawal of participation, future research choice and GDPR consent.

The Guidelines should clarify whether data collected before withdrawal may continue to be:

- stored only;
- used in safety analysis;
- used in primary or secondary statistical analysis;
- retained for regulatory documentation;
- used for scientific integrity or reproducibility; and
- used for further scientific research.

The Guidelines should also explain which GDPR basis or exception may justify continued retention or use, where applicable.

Relevant part of the Guidelines: Sections 4.1.3, 6.2 and 6.3, consent to participate in scientific research, right to erasure and right to object.

3.8 Comment 8 — Freely given consent in oncology trials

The Guidelines discuss freely given consent and the need to consider imbalance of power and the condition of the data subject. This is relevant in oncology research.

In oncology trials, participation may provide access to a treatment, treatment combination or clinical pathway that is not otherwise available to the patient. Cancer patients may also be in a vulnerable position because of the seriousness of the disease and the limited treatment options available.

EORTC notes that the upcoming implementation of the European Health Data Space (EHDS) introduces a framework for the secondary use of health data for scientific research (Chapter IV). The foundational pillar of secondary data use under the EHDS is that it serves the public interest, specifically in the realms of scientific research, innovation, and public health.

The EHDS explicitly relies on this public interest framing to bridge the gap with the GDPR. According to the final legislative text (specifically Recital 52), when a researcher or sponsor is granted a permit for secondary use, the EHDS itself serves as the statutory Union law that triggers the GDPR's public interest legal bases.

Because the legal basis shifts to a public interest framework (meaning patients aren't giving explicit GDPR consent for every single secondary research project), the EHDS balances this by granting EU citizens a reversible right to opt-out of secondary use.

Requested clarification

EORTC invites the EDPB to include an oncology clinical trial example where participation may provide access to a treatment or treatment combination not otherwise available to the patient.

We also invite the EDPB to explicitly clarify the relationship between GDPR consent and the EHDS secondary use pathways. The Guidelines should confirm that for secondary/future processing, instead of pushing vulnerable patients to provide GDPR ‘‘broad consent’’ at the time of a critical diagnosis to secure future research utility, controllers should be encouraged to utilize the EHDS secondary use framework, which operates on public interest grounds accompanied by the strict, built-in safeguards of the EHDS (e.g., processing in secure processing environments, data minimization, and oversight by Health Data Access Bodies).

The example should clarify:

- whether this situation creates an imbalance of power;
- whether GDPR consent can still be freely given;
- what safeguards are expected if GDPR consent is used; and
- whether another legal basis should be preferred where available, such as the EHDS secondary use framework.

Relevant part of the Guidelines: Section 4.1.1, freely given consent, including Example 7.

3.9 Comment 9 — Reimbursement and legally required compensation

The Guidelines state that controllers must assess whether reimbursement or other incentives may affect the data subject's choice to agree to the processing of personal data.

In clinical trials, reimbursement may be required by Member State law, ethics committee practice or standard clinical trial arrangements. This may include travel expenses, accommodation, meals, lost income or other reasonable costs.

Sponsors may face situations where reimbursement is legally required or expected, but the sponsor still considers that the amount, context or participant vulnerability may have some impact on free choice.

Requested clarification

EORTC invites the EDPB to clarify what sponsors should do where reimbursement is required or expected under Member State law, ethics committee practice or standard clinical trial arrangements, but may still affect the assessment of freely given consent.

The Guidelines should clarify whether the sponsor should document:

- the legal or ethics-based requirement for reimbursement;
- the proportionality of the reimbursement;
- ethics committee approval;
- the absence of excessive inducement;
- equal treatment of participants;
- the non-commercial or scientific nature of the trial, where relevant; and
- any other safeguards.

The Guidelines should also clarify whether another GDPR legal basis should be preferred where available if reimbursement or participant vulnerability materially affects free choice.

Relevant part of the Guidelines: Section 4.1.1, freely given consent, especially the discussion of reimbursement and incentives.

3.10 Comment 10 — Transparency through patient information sheets, public webpage and contact point

EORTC welcomes the practical approach in the Guidelines allowing clinical trial participants to receive core GDPR information in the clinical trial folder, with more detailed information available through a dedicated webpage or contact point.

This layered approach may be useful. However, it raises practical questions for multinational trials.

If the public webpage forms part of the transparency package, it is unclear:

- whether the webpage text must be submitted to ethics committees or competent authorities;
- whether it must be available in all participant languages;

- how updates to the webpage should be controlled during long-running studies;
- how consistency should be maintained between the patient information sheet and the webpage; and
- whether changes to the webpage require ethics notification or approval.

These questions are operationally important. If the webpage is treated as participant-facing study information, ethics committees may expect to review it. If the webpage is not reviewed, sponsors may be uncertain whether the transparency model is acceptable.

Requested clarification

EORTC invites the EDPB to clarify how layered transparency should work in clinical trials.

The final Guidelines should explain:

- whether detailed GDPR webpages should be submitted to ethics committees or competent authorities;
- whether such webpages must be translated into all participant languages;
- how updates should be controlled;
- whether all changes require ethics review or only material changes;
- how the webpage should be referenced in the patient information sheet; and
- how sponsors should ensure consistency across countries and languages.

Relevant part of the Guidelines: Sections 5.2 and 5.3, including Example 11 on clinical trial information and layered transparency.

3.11 Comment 11 — Transparency where the sponsor receives coded data only

In many clinical trials, the sponsor receives coded data only. Directly identifiable data remain at the clinical site. This is an important safeguard for participants.

At the same time, participants may need to obtain GDPR information or exercise rights. The communication channel should not unnecessarily reveal the participant's direct identity to the sponsor.

Requested clarification

EORTC invites the EDPB to clarify that, where the sponsor holds only coded data and no direct contact details, transparency and rights communication may be organised through the investigator or study site, provided this is effective and properly explained.

The Guidelines should also clarify that public webpages and contact channels should be designed so that participants can obtain general GDPR information without revealing direct identity to the sponsor, unless identification is necessary to handle a specific request.

Relevant part of the Guidelines: Sections 5.2, 5.3 and 5.4, information obligations where the controller has no direct contact or limited contact details.

3.12 Comment 12 — Patient representative or data subject group involvement

The Guidelines refer to consultation with groups representing data subjects in certain contexts, including broad consent and vulnerable populations. They also mention representation by data subjects as a possible safeguard in certain governance structures.

EORTC supports meaningful patient involvement. However, the final Guidelines should clarify the expected level of effort. Otherwise, stakeholders may read the Guidelines as requiring patient representative review of GDPR language or future research wording in every study.

Requested clarification

EORTC invites the EDPB to clarify when sponsors are expected to consult patient representatives or data subject groups on GDPR information, future research expectations or broad consent.

The Guidelines should clarify whether this is expected:

- for every study;
- only for template development;
- for high-risk research;
- for vulnerable populations;
- where broad consent is used;
- where future research expectations are complex; or
- where a study-specific issue makes such consultation proportionate.

Relevant part of the Guidelines: Sections 4.1.2.1 and 8.5, consultation with groups representing data subjects and additional safeguards.

3.13 Comment 13 — Retention wording in clinical research information sheets

The Guidelines support longer storage for scientific research where appropriate, but also require meaningful information about retention periods or criteria. This is helpful, but clinical research needs more practical examples.

In clinical trials, retention may be determined by specific regulatory requirements, such as the Clinical Trials Regulation. In other research contexts, there may be no fixed legal retention period. At the same time, clinical research data may have long-term scientific value, including for long follow-up, rare cancers, reproducibility, meta-analysis, validation studies and future research.

Ethics committees in some Member States may reject wording stating that data may be stored longer for future research if no fixed end date is provided. This can make it difficult to explain long-term scientific retention in a way that is both accurate and accepted.

Requested clarification

EORTC invites the EDPB to provide practical examples of retention wording for clinical research information sheets.

The examples should cover:

- fixed legal retention, such as under the Clinical Trials Regulation;
- non-CTR research where no fixed legal period exists;
- longer retention for future scientific research;
- retention based on criteria rather than a fixed end date;
- retention subject to governance and periodic review; and
- communication of extended retention to participants.

The Guidelines should discourage national or local interpretations that reject longer research retention solely because no fixed end date can be identified at the time of participant information, where the controller provides clear criteria, governance and safeguards.

Relevant part of the Guidelines: Section 3.2, storage limitation, and Section 5, transparency obligations.

3.14 Comment 14 — Data minimisation for future research

The Guidelines require controllers to determine what categories of personal data are necessary for scientific research. EORTC agrees with the principle of data minimisation.

However, in future research, the exact future hypothesis may not yet be known. In biomedical research, the scientific value of a dataset often depends on preserving sufficient richness. This may be particularly important for cancer research, rare cancers, biomarker research, imaging research, omics research, longitudinal analysis and model development.

If minimisation is interpreted too narrowly, valuable datasets may lose their scientific utility before future research questions are known.

Requested clarification

EORTC invites the EDPB to clarify how controllers should apply data minimisation where future research can only be described by research area, disease area, dataset type or scientific field.

The Guidelines should include an example where a cancer clinical trial dataset may be valuable for future biomarker, imaging, survival, quality-of-life, methodology or model-development research, but the exact future hypothesis is not yet known.

The Guidelines should explain how to balance minimisation with the need to preserve scientifically useful datasets under appropriate safeguards.

Relevant part of the Guidelines: Sections 3.2 and 8.3, data minimisation, storage for future research, and anonymisation or pseudonymisation.

3.15 Comment 15 — Imaging, molecular images, sequence identifiers, anonymisation and repository access

Cancer research may involve molecular images, digital pathology images, imaging-derived files, tissue images or omics-linked datasets. These datasets may contain no direct identifiers. However, they may contain a study sequence identifier, study ID or metadata needed to link the image to clinical variables or longitudinal records.

Some repositories ask for "anonymous data". Some journals or funders also expect data availability or repository deposit. In practice, removing the study ID or sequence ID may destroy the scientific value of the image, because the image can no longer be linked to the relevant clinical or research variables.

It is therefore important to distinguish:

- images that are genuinely anonymous;
- images that contain limited metadata but no direct identifiers;
- images that remain pseudonymised personal data because a link to clinical data exists; and
- images that cannot be made public without unacceptable re-identification or linkage risk.

Requested clarification

EORTC invites the EDPB to provide biomedical examples on when imaging or molecular-image datasets can be considered anonymous, and when they remain pseudonymised personal data.

The Guidelines should clarify whether public-access deposit may be acceptable where:

- the image contains no direct identifiers;
- the identifiability risk is limited;
- no accessible key is available to the repository or public users;
- metadata are controlled; and
- the dataset cannot reasonably be linked back to participants.

Conversely, where a sequence ID or study ID is needed to preserve scientific value or link with clinical data, the Guidelines should clarify whether the dataset should be treated as pseudonymised personal data and that controlled access or other safeguards may be required.

The Guidelines should also provide examples of how controllers can balance journal or funder data-sharing expectations with GDPR safeguards where open access is not appropriate.

Relevant part of the Guidelines: Sections 8.3 and 8.5, anonymisation, pseudonymisation and appropriate safeguards.

3.16 Comment 16 — Research data infrastructures and controlled access governance

Scientific research increasingly depends on research data infrastructures. These may be operated by non-profit or academic organisations after the end of a research project. External researchers may request access to coded clinical, imaging, biological or omics-linked datasets.

Access may be restricted by research field, scientific objective, researcher qualification, ethical approval where required, data minimisation, no re-identification obligations, publication rules and access agreements.

The Guidelines recognise access conditions for research data infrastructures, but should clarify how far the infrastructure controller must go in verifying each condition.

Example

A non-profit academic research organisation operates a controlled-access infrastructure containing coded imaging and clinical data for cancer research. External researchers may request access. Access is limited to projects with a scientific objective, ethics approval where required, qualified researchers, data minimisation, no re-identification obligations and publication controls.

Requested clarification

EORTC invites the EDPB to clarify whether documented access criteria, applicant declarations, access committee review, data use agreements, audit rights and enforceable terms may be sufficient, or whether the infrastructure controller must independently verify every researcher's qualification and ethical compliance in each case.

The Guidelines should include examples for controlled-access biomedical research infrastructures, especially for coded health, imaging, genetic and omics-linked datasets.

Relevant part of the Guidelines: Sections 2.2 and 8.5, research data infrastructures and appropriate safeguards.

3.17 Comment 17 — Open science, journal requirements and repository expectations

Journals and funders increasingly require data availability or repository deposit. EORTC supports responsible data sharing and scientific transparency. However, open access is not always appropriate for clinical, genetic, imaging, omics or linked health datasets.

Where journals or funders expect data to be deposited, researchers and sponsors may face tension between scientific publication requirements and GDPR safeguards.

Requested clarification

EORTC invites the EDPB to provide examples on how controllers can balance journal or funder data-sharing expectations with GDPR requirements.

The Guidelines should clarify when controlled access, access committees, data use agreements, no re-identification clauses, secure processing environments, data minimisation and publication controls are appropriate alternatives to open access.

Relevant part of the Guidelines: Sections 2.2, 8.3 and 8.5, research data infrastructures, anonymisation or pseudonymisation, and safeguards for further use.

3.18 Comment 18 — Sponsor-site role allocation in clinical research

Multinational clinical research faces inconsistent interpretations of sponsor-site roles.

Depending on the processing operation, a clinical site may act as:

- an independent controller for healthcare or site obligations;
- a processor for sponsor-controlled database processing;
- a joint controller for certain research processing; or
- another party with specific obligations under national clinical research rules.

In practice, some Member States, sites or local stakeholders may insist on a specific role model. This creates lengthy contract negotiations and legal uncertainty, particularly where the sponsor holds coded data only and the site holds directly identifiable data.

Recent national enforcement concerning a multicentre research database in Spain also illustrates that participating sites may be characterised differently depending on the processing activity and factual governance. This creates uncertainty for sponsors and coordinating research organisations operating across multiple Member States.[1]

Requested clarification

EORTC invites the EDPB to provide more clinical trial examples on sponsor-site role allocation.

The Guidelines should clarify:

- when a site acts as processor for sponsor-controlled database processing;
- when a site acts as independent controller for healthcare, medical records or site-level obligations;
- when joint controllership is appropriate;
- whether an independent controller arrangement requires a dedicated independent controller agreement, or whether role wording in the clinical trial agreement may be sufficient;
- how sponsors should manage divergent national expectations for materially similar clinical research activities.

Where joint controllership applies, the Guidelines should provide examples of Article 26 task allocation, including:

- transparency;
- data subject rights handling;

- breach notification;
- retention;
- site-held directly identifiable data;
- sponsor-held coded data; and
- communication with authorities.

Relevant part of the Guidelines: Section 7, attribution of responsibility between controllers and processors, including controllers, processors and joint controllers.

3.19 Comment 19 — Member State divergence and ethics committee interpretation

The Guidelines acknowledge that Member State law may impose additional conditions for health, genetic and biometric data. This remains one of the main operational barriers for multinational clinical research.

Divergence affects:

- patient information wording;
- future research choice;
- ethics approval;
- use of health and genetic data;
- site contract negotiations;
- use of deceased patients' data in retrospective or secondary research;
- local DPO interpretation; and
- the legal basis expected in a given country.

In some Member States, including Italy and Germany, ethics committees may reject future research or broad-consent style wording even where such wording is intended as participant information, ethical safeguard or participant choice, and not as GDPR consent.

Similar difficulties may arise where research involves data relating to deceased patients. Although the GDPR does not apply to data of deceased persons, Member States may adopt national rules in this area. In practice, national requirements in some countries such as Ireland and Italy, may still create disproportionate obstacles for low-risk retrospective or secondary use on deceased patients' data. Such use is scientifically valuable, involves very limited privacy impact for living individuals, and is subject to appropriate safeguards, thus member states shall provide more flexibility.

Requested clarification

EORTC invites the EDPB to clarify how far Member States may go in imposing additional requirements for scientific research, including where national rules apply to deceased patients' data.

The final Guidelines should identify examples of national or local interpretations that are disproportionate. Additional national requirements should be proportionate and should provide a clear protection benefit.

The Guidelines should also clarify how future research wording can be used as participant information, ethical safeguard or participant choice without necessarily constituting GDPR consent as legal basis.

Relevant part of the Guidelines: Introduction and Section 4.4.3, Member State law and further conditions for special categories of personal data.

3.20 Comment 20 — Coherence with EU policy developments, including the BioTech Act and CTR framework

The final Guidelines will operate alongside broader EU policy initiatives on clinical research, biotechnology, health data, innovation and competitiveness.

EORTC considers that the Guidelines should be coherent with these initiatives. If the Guidelines are interpreted too restrictively, they may unintentionally increase fragmentation and administrative burden in multinational biomedical research.

Requested clarification

EORTC invites the EDPB to ensure that the final Guidelines remain coherent with ongoing EU initiatives aimed at strengthening and simplifying clinical research and biotechnology, including possible future developments affecting the Clinical Trials Regulation framework.

This means ensuring that GDPR interpretation supports responsible, well-governed and socially valuable scientific research.

Relevant part of the Guidelines: Introduction and references in the Guidelines to the proposed European BioTech Act.

3.21 Comment 21 — Future guidance on AI in scientific research and adjacent issues

The Guidelines mention new technologies and AI in the scientific research context, but they do not provide operational guidance on AI use in biomedical research.

Scientific research is increasingly using AI and machine-learning methods for imaging, omics, clinical prediction, methodology research and secondary use of health datasets. This raises practical questions around purpose specification, secondary use, data minimisation, transparency, model training, validation, explainability, safeguards and governance.

The Guidelines also do not address some adjacent research-related issues, such as international transfers in pharmacovigilance or research-related safety reporting.

Requested clarification

EORTC invites the EDPB to consider future guidance on AI use in scientific research, especially for secondary use of health data, imaging, omics and clinical datasets.

EORTC also notes that further guidance would be valuable on adjacent issues not covered by the current Guidelines, including international transfers in pharmacovigilance and research-related safety reporting.

Relevant part of the Guidelines: Section 2.1, including the example on AI research; the pharmacovigilance transfer point is an adjacent issue not covered by the Guidelines.

4. Closing remarks

EORTC appreciates the EDPB's work on these Guidelines. The final Guidelines can play an important role in improving consistency and legal certainty for scientific research under the GDPR.

For multinational cancer research, the most useful improvement would be additional practical examples. These examples should reflect the reality of clinical trials, coded data, secondary use, future research choices, ethics review, long-term retention, imaging and omics datasets, controlled access infrastructures, and sponsor-site role allocation.

EORTC respectfully invites the EDPB to ensure that the final Guidelines support responsible scientific research while maintaining strong protection for participants and data subjects.

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[1] For example, AEPD decision PS-00442-2024 concerning a multicentre research database illustrates practical uncertainty around role allocation between the coordinating entity, participating hospitals and technology provider