Novo Nordisk's response related to EDPB's Guidelines 1/2026 on processing of personal data for scientific research purposes

Novo Nordisk welcomes the EDPB's effort to clarify the GDPR framework for scientific research. Novo Nordisk is a global pharmaceutical company with headquarters in Denmark.

Novo Nordisk supports the Guidelines' recognition that scientific research may take many forms, including commercial and privately funded life-sciences research, and that such research can serve important societal interests by enabling responsible reuse of health data, strengthening evidence-based healthcare across the EU, and ultimately improving patient outcomes. We also welcome the Guidelines' acknowledgement that Article 89 safeguards such as pseudonymisation and appropriate governance can enable rather than restrict valuable research.

At the same time, the final Guidelines would benefit from further clarification to ensure that the practical obligations placed on researchers and research organisations are proportionate to the risks and to the additional protection achieved for individual research participants. In particular, the Guidelines should clarify that regulated clinical research and other research conducted under established scientific, ethical and regulatory frameworks can be assessed as proportionate research, that the compatibility presumption applies to all further processing for scientific research, and that transparency obligations must be applied consistently with Article 11, data minimisation, Art 89, blinding and the practical realities of health research, including clinical research and sponsor-site responsibility splits. Without these clarifications, the Guidelines risk increasing fragmentation across Member States and undermine the ethical obligation to make the fullest possible use of data already collected in clinical trials and other scientific research to reduce patient burden and avoid unnecessary interventions to generate new data where data already exists.

Novo Nordisk has identified five areas where we would recommend additional clarification in the EDPB's Guidelines in order to foster innovation and ensure a competitive research environment in Europe. These are covered in detail below.

1. Definition and scope of "scientific research"

Novo Nordisk welcomes the EDPB's effort to clarify the concept of scientific research and supports the introduction of six assessment factors as a useful contribution to legal certainty in this area. However, the final Guidelines should make clear that these factors are indicative and not exhaustive, and that they should not operate as a cumulative test or a mandatory project-by-project documentation requirement. This is particularly important for research activities already governed by established scientific, ethical and regulatory frameworks, such as clinical trials and other regulated research, where existing documentation will often demonstrate the scientific purpose, methodology, governance and oversight of the activity.

Therefore, we recommend that the EDPB further refine the drafting to ensure that the factors may be applied proportionately, including at activity or programme level where appropriate, rather than as a mandatory project-by-project documentation requirement, in particular for activities already governed by established scientific and regulatory frameworks such as the CTR, GCP, MDR or other relevant regulatory scientific guidance e.g. from competent authorities such as EMA.

Further, the Guidelines should explain how the autonomy and independence factor is to be assessed where research is conducted by multidisciplinary teams that include e.g. nurses, laboratory technicians, statisticians, data scientists and industry researchers, rather than only academically qualified researchers.

Finally, we invite the EDPB to broaden the examples included in the Guidelines to avoid unintentionally excluding legitimate forms of applied life-sciences research.

Specific input to the Guidelines

- Novo Nordisk supports a principled definition of scientific research. While assessment factors may be helpful as informative criteria, the final Guidelines should further enhance clarity and predictability by confirming that the factors are indicative, non-exhaustive and to be assessed holistically. They should not introduce a new authorisation test for research activities or create uncertainty through inconsistent case-by-case interpretation.

- Activities carried out under recognised scientific and regulatory frameworks such as CTR, GCP, MDR, and relevant regulatory scientific guidance are already subject to extensive scientific, ethical, and regulatory oversight. Therefore, we recommend that the Guidelines confirm that such frameworks may provide strong evidence that an activity qualifies as scientific research, without requiring a separate "six-factor" assessments for each individual project. Requiring duplicative documentation in such cases would create additional operational complexity and reduce innovation without a corresponding increase in protection for data subjects.

- The Guidelines should make clear that scientific research is not limited to academically led researchers or to research conducted only by persons with specific academic credentials. In modern life-sciences research, scientific research is often carried out by multidisciplinary teams, including clinical, technical, statistical, data science and industry specialists. The relevant consideration should be whether the activity follows recognised scientific methods and appropriate ethical governance safeguards, rather than whether each contributor has a particular academic qualification or whether the research has a commercial objective or not.

- We recommend that the Guidelines expressly cover industry-led research, Health Economic Outcome Research (HEOR), market access research, Health Technology Assessments (HTA), research that support reimbursement of medicines, post-authorisation studies and local observational research where these activities apply recognised scientific methods and safeguards.

2. Compatibility and further processing

Novo Nordisk welcomes the Guidelines' clarification that further processing for scientific research purposes under GDPR benefits from the compatibility presumption under Article 5(1)(b) GDPR and does not require a separate compatibility assessment under Article 6(4) GDPR. This clarification is important for responsible secondary use of health data, including clinical trial data, real-world evidence generation, post-authorisation research, longitudinal analyses and collaborative research.

At the same time, the final Guidelines would benefit from further clarification to ensure that the compatibility presumption has practical effect in regulated and collaborative research settings. In particular, the drafting should avoid any implication that the presumption applies only where the original processing was for a non-research purpose and not where data collected for one scientific research purpose is further processed for another genuine scientific research purpose. Article 5(1)(b) GDPR does not distinguish between non-scientific-to-scientific or scientific-to-scientific further processing, provided the further processing is for scientific research purposes and is subject to appropriate safeguards.

We also recommend that the EDPB clarify how the compatibility presumption interacts with Article 6 legal bases and Article 9 conditions. Where further processing is compatible under Article 5(1)(b) GDPR, the Guidelines should avoid suggesting that controllers must identify a new legal basis in all cases. In particular, further clarification would be valuable for regulated clinical research where the original processing was carried out under Union or Member State law, including the Clinical Trials Regulation, or where research participation consent and GDPR consent may coexist but serve different legal functions. Without this clarification, controllers may be driven towards legal bases such as legitimate interests primarily to manage uncertainty, rather than because this is necessarily the most appropriate or protective basis in the specific research context.

Specific input to the Guidelines

- The final Guidelines should confirm that the compatibility presumption applies to all further processing for scientific research purposes, including further processing of data originally collected for another scientific research purpose. The current drafting could be read as distinguishing between non-scientific-to-scientific further processing and scientific-to-scientific reuse. This distinction risks narrowing Article 5(1)(b) GDPR in practice and may create uncertainty for common research scenarios, including secondary analyses, exploratory analyses, post-authorisation studies and reuse of clinical trial data for related exploratory or future research questions.

- The Guidelines should further clarify the relationship between purpose compatibility, Article 6 legal bases and Article 9 conditions. If controllers must identify a new Article 6 legal basis and reassess the relevant Article 9 condition for each further research use, the practical value of the compatibility presumption may be significantly reduced. The Guidelines should therefore explain when the original legal basis and Article 9 condition may continue to support compatible further processing for scientific research, and when and why a separate assessment is required.

- The Guidelines should clarify that the presumption of compatibility extends to situations where personal data is shared with new collaborators or controllers for genuine scientific research purposes. This would support established collaborative research practices e.g. public-private-partnerships,

while maintaining alignment with the purpose limitation principle. The Guidelines should avoid creating uncertainty that would discourage responsible data sharing or incentivise unnecessary recollection of data, duplicate studies or lead to a loss of gaining further evidence and understanding from existing datasets due to legal uncertainty.

- Where personal data are shared between independent controllers for further scientific research, the Guidelines should provide a clearer allocation of responsibilities. In particular, the Guidelines should confirm that the disclosing controller is among other responsible for assessing compatibility with the original purpose, while the receiving controller being able to rely on this assessment. Clear guidance on this point would support consistent governance without imposing disproportionate duplication of assessments.

3. Lawfulness, consent, legitimate interests, and Member State law

Novo Nordisk welcomes the Guidelines' effort to clarify the lawfulness requirements applicable to processing of sensitive personal data (health data) for scientific research. This is an important area where further guidance can support more consistent application across Member States and reduce uncertainty for cross-border research.

However, the final Guidelines would benefit from more practical clarification on the respective roles of consent, public interest, legitimate interests and Member State law in regulated and collaborative life-sciences research. In particular, the Guidelines should avoid any implication that consent is the default or preferred legal basis for clinical research or secondary research involving health data. Further clarification would also be valuable on how controllers should assess the impact of withdrawal where consent is relied upon, including where data have already been included in analyses, regulatory submissions, publications, safety documentation or shared with research collaborators under appropriate safeguards. Without such clarification, the use of GDPR consent may create operational and legal uncertainty, particularly in longitudinal, multi-country and regulated research. Lastly, further clarification would also be valuable on the scope and limits of broad consent, including whether such a consent can support disclosure of personal data to previously unidentified controllers and whether its scope can be expanded through subsequent notifications as the Guidelines currently seem to suggest.

Novo Nordisk also recommends that the EDPB provide clearer guidance on the role of Member State law under Article 9(2)(j) GDPR and related research provisions. Open-ended references to national law may be unavoidable under the GDPR, but the Guidelines should aim to reduce, rather than perpetuate, divergent interpretation by ethics committees, IRBs, supervisory authorities and other national or local bodies. This is particularly important for multinational studies, where inconsistent national expectations may lead to different legal bases, consent models or Article 9 conditions for the same research activity, which increase complexity for research conducted in the EU and leads to longer research timelines. To support practical implementation, the Guidelines should include or coordinate a structured appendix identifying relevant Member State research laws and conditions for the processing of health, genetic and biometric data for scientific research purposes. Even if such an appendix cannot be exhaustive, it would materially improve usability and reduce fragmentation for controllers conducting cross Member State research.

Further guidance would also be helpful on the relationship between Article 6(1)(e) and Article 6(1)(f) GDPR in life-sciences research, particularly where private-sector organisations conduct research that serves public-health, regulatory, scientific or societal objectives such as development of new medicines. The Guidelines should clarify when public-interest legal bases established in Union or Member State law may be available to private entities, and when legitimate interests may instead be the more appropriate route. Clear examples would reduce inconsistent national practice and avoid unnecessary uncertainty for commercial sponsors conducting research under regulatory or public-health frameworks in the EU.

Specific input to the Guidelines

- Where Article 6(1)(f) GDPR is relied upon, the Guidelines should allow legitimate-interest assessments to be conducted at activity, programme or category level where the processing activities, safeguards and data-subject expectations are materially similar, e.g. clinical trial conduct. Requiring a separate balancing test for each individual research project would create significant operational complexity without necessarily improving protection for data subjects.

- The Guidelines should provide clearer examples of when Article 6(1)(e) or Article 6(1)(f) may be appropriate for private-sector organisations conducting scientific research. Clarifying expectations, including the role of balancing tests and the impact of national laws, would support more consistent and predictable implementation. This harmonisation effort should be further enhanced by mapping of Member State requirements relevant to Article 9(2)(j) and additional clarification on how researchers should resolve cross-border inconsistent interpretations.

- The final Guidelines should make explicitly clear that consent is one possible legal basis for scientific research, but not the required, default or preferred basis in all clinical or health-data research. In regulated clinical research, GDPR consent should be distinguished from informed consent to participate in the research. The Guidelines should also explain how withdrawal should be handled where consent is relied upon, particularly where data have already been analysed, included in regulatory documentation, published, or shared with third parties under appropriate safeguards.

- The Guidelines should explain whether and how the scope of broad consent may be operationalised through layered transparency or subsequent updates, without requiring re-consent for every new project, partner or methodology within the originally described research area. This would be particularly important for biobanking, platform studies, long-term research infrastructures and multi-country research programmes. Furthermore, the Guidelines should clarify the conditions under which broad consent may support future research, including where the specific future research partners or controllers cannot be individually identified at the time of collection. Where participants are informed of the categories of future research, categories of potential recipients or collaborators, governance arrangements, safeguards, withdrawal mechanisms and transparency channels, broad consent should remain available as a practical and protective mechanism for future research.

4. Transparency, re-notification, and Article 11 of the GDPR

Novo Nordisk supports meaningful transparency for research participants and data subjects. Transparency is an important safeguard in scientific research and can help maintain trust in the responsible use and reuse of health data for research. At the same time, transparency obligations must be applied in a way that is consistent with the GDPR's other principles, including data minimisation, storage limitation, Article 11 GDPR and the safeguards required under Article 89(1) GDPR and not impose an unproportional burden on researchers that could potentially limit research activities in Europe due to administrative requirements.

In regulated clinical research and other health-data research, sponsors will often receive only coded or pseudonymised data and will not hold names, contact details or other direct identifiers. This separation between sites and sponsors is a core privacy, ethical and research-governance safeguard. Therefore, the final Guidelines should avoid any implication that controllers are expected to retain, obtain or recreate contact details solely to provide future GDPR notices, where such identification is not otherwise necessary for the research. Such an approach could increase privacy risk, undermine pseudonymisation or blinded research, and conflict with the principle of data minimisation.

The Guidelines would benefit from further clarification on how transparency obligations should be fulfilled where individual notification is not feasible, proportionate or consistent with research safeguards. In such cases, layered transparency, study websites, registries, public notices, investigator-site communication, participant portals or other appropriate channels may be suitable depending on the context. These mechanisms should be recognised as risk-based options, rather than default operational requirements for every secondary use or material change.

Specific input to the Guidelines

- The current drafting risks introducing disproportionate administrative complexity, particularly for large-scale, longitudinal and multi-phase research. Requirements such as repeated individual notifications or maintaining communication channels over several years may be impractical in many research contexts and could unintentionally discourage responsible secondary use of data for scientific purposes (which sometime occur 10-15 years after data was originally collected). In particular, the Guidelines should avoid any implication that controllers are expected to collect, retain or refrain from deleting contact details solely to enable potential future GDPR notices. Where contact details are not necessary for the research itself, requiring their retention would be difficult to reconcile with data minimisation and may increase privacy risk. This is especially relevant where Article 89 safeguards, such as pseudonymisation and separation of identifying information from research data, have been implemented. Therefore, we recommend that the EDPB clarify that controllers are not expected to retain or obtain identifying data beyond what is necessary for the initial research purpose. The Guidelines should also explain how transparency for secondary use can be provided where individual notification is not feasible or would undermine Article 89 safeguards, including through proportionate layered or public transparency mechanisms where these are appropriate.

- Novo Nordisk recommends that the Guidelines include a dedicated explanation of Article 11 GDPR in research settings, including clinical trials, registries, biobanks and other research where the controller does not hold direct identifiers. This clarification will also be relevant in the context of the

EHDS. The Guideline should explain how Article 11 interacts with Article 14(5)(b) and should not imply that a controller must obtain identifiers merely because another party may hold them.

- Individual re-notification should be limited to genuinely new purposes or material changes that fall outside the original information scope. The Guidelines should distinguish genuinely new research purposes from extensions or secondary analyses within the same research scope or therapeutic area. Routine protocol amendments, additional analyses within the same research scope, new partners already covered by layered transparency, or changes in methodology should not automatically trigger individual re-notification.

- Transparency requirements should not be calibrated in a way that makes responsible secondary use of existing health data more burdensome than collecting new data or conducting new interventions. Where existing data can be reused under appropriate safeguards, this may reduce participant burden, be safer e.g. not require new interventions and support more efficient, ethical generation of scientific evidence.

- The Guidelines should avoid creating a general expectation that pseudonymised participants must be informed of subject IDs or similar identifiers. In clinical trials, this may burden sites, undermine blinding, potentially influence research results or conflict with established role separation. Participants should instead be informed of practical channels for exercising rights and raising questions related to their participation in research and data protection rights.

5. Safeguards, anonymisation, pseudonymisation, and genetic data

Novo Nordisk encourages the EDPB to clarify how the Guidelines' expectations on pseudonymisation relate to coded clinical trial data and established sponsor-site separation models in regulated clinical research. In clinical trials, sponsors receive coded/pseudonymised data, while directly identifying information remains with the investigator site under strict controls. This separation is an established research-governance and privacy safeguard under CTR and GCP.

The Guidelines should also clarify the legal basis expectations for anonymisation. Anonymisation is a privacy-enhancing and risk-reducing operation, and the final Guidelines should avoid suggesting that controllers must identify a separate legal basis for a distinct "anonymisation purpose" where personal data are already being lawfully processed. Requiring a separate legal basis for anonymisation could create unnecessary uncertainty around a privacy-enhancing operation. Where personal data are already being lawfully processed, anonymisation should be treated as a risk-reducing safeguard, not as a separate purpose requiring a new legal basis. This approach is consistent with data minimisation, storage limitation and Article 89(1), which support safeguards that limit or remove identifiability where the research purpose can still be fulfilled, as would be the case for many secondary uses of health data.

Regarding genetic data, Novo Nordisk agrees that genomic data can be highly sensitive and require strong safeguards. However, the Guidelines should avoid treating all genetic or genomic-derived data as having the same identifiability and privacy-risk profile. The statement that genetic data can only be

anonymous in "exceptional circumstances" should therefore be qualified, with anonymisation assessed case by case based on data granularity, linkability, access conditions and safeguards.

Specific input to the Guidelines

- Article 89 safeguards must remain risk-based and context-specific. The Guidelines should expressly recognise that GCP-coded clinical trial data, sponsor-site separation, secure processing environments, role-based access, contractual restrictions, professional confidentiality and governance controls may all form part of a risk-based Article 89 safeguard assessment. These should not be converted into a mandatory checklist but should be recognised as established safeguards that can support proportionate Article 89 assessments.

- The Guidelines should clarify that, where personal data are already lawfully processed, anonymisation may be performed as a privacy-enhancing operation without requiring controllers to identify a distinct legal basis for an independent "anonymisation purpose". A contrary interpretation would risk discouraging anonymisation and could create a counterproductive incentive to retain personal data rather than reduce identifiability.

- The Guideline should avoid treating all genetic or genomic-derived data as having the same identifiability and privacy-risk profile. Whole genome sequencing data or similarly rich genomic datasets may carry a particularly high re-identification risk, whereas limited genetic variants, targeted genetic snippets, derived biomarkers, aggregated outputs or data processed in controlled access environments may present a lower risk, depending on the context and safeguards. The Guideline should therefore assess identifiability of genetic data by reference to data granularity, linkability, access conditions, reasonable means of re-identification and the technical and organisational safeguards applied.