In this submission, three concerns are addressed with the Draft Guidelines 1/2026 on processing of personal data for scientific research purposes ("**Draft Guidelines**"):

1. **Position on further processing of special categories of data ("SCD") is unnecessarily strict and inconsistent with GDPR.** The GDPR's presumption of compatibility under Article 5(1)(b) applies to all personal data, including SCD, and Recital 50 GDPR confirms that no separate legal basis is required for compatible further processing. The Draft Guidelines should not require controllers to determine a separate legal basis under Article 6(1) GDPR and a derogation under Article 9(2) GDPR when further processing SCD for scientific research purposes; only specific national requirements under Article 9(4) GDPR should be taken into account.
2. **Autonomy should not be considered a separate key indicator of scientific research.** The European Code of Conduct for Research Integrity ("**ECCRI**"), to which the Draft Guidelines refer, includes a requirement for **independence** (of which autonomy is an integral part) and does not refer to autonomy as a separate key indicator. The addition of autonomy as a distinct concept risks implying that the EDPB's key indicators of scientific research exceed the requirements set out in the ECCRI.
3. **Clarify acceptable limitations on freedom to disseminate and publish research results**. The Draft Guidelines include an incomplete citation of the European Charter for Researchers ("**ECR**") which omits the ECR's express recognition that researchers should acknowledge limitations to publication freedom arising from, inter alia, intellectual property rights and other legal or operational constraints. This omission can be read as the Draft Guidelines imposing stricter requirements than the ECR, on which the Draft Guidelines on this point are based.

We address these three points in more detail below.

1. FURTHER PROCESSING OF SPECIAL CATEGORY DATA

The Draft Guidelines take as a starting point that if SCD are further processed for scientific research purposes, the controller may rely on the presumption of compatibility of purposes pursuant to Article 5(1)(b), but nevertheless must still determine an appropriate legal basis under Article 6(1) GDPR and, when applicable, a derogation under Article 9(2) GDPR that it can rely on to process SCD. The Draft Guidelines further indicate that additional conditions or limitations pursuant to Article 9(4) GDPR may apply. See specifically paragraphs 24-26 (and in particular footnotes 39 and 40) and paragraph 33 of the Draft Guidelines:

> "*24. If a controller further processes special categories of personal data, pursuant to Article 9(1) GDPR, for scientific research purposes, it may also rely on the presumption of compatibility of purposes, pursuant to Article 5(1)(b). Nevertheless, the controller must still assess which derogation to the prohibition to process special categories of personal data, pursuant to Article*

9(2) GDPR, that applies when further processing such data for scientific research purposes.[38] *Accordingly, if the controller intends to rely on the same derogation, pursuant to Article 9(2) GDPR, that it relied on for the initial processing operation, then the controller must assess whether that derogation is also suitable for the further processing of personal data for scientific research purposes.*[39]

25. When the controller further processes personal data concerning health, genetic or biometric data, it should also consider that there may be additional conditions or limitations imposed by MS law on the processing, pursuant to Article 9(4) of GDPR, also in cases of further processing for scientific research purposes.

26. If a controller (controller A) wishes to, or is obliged by Union or MS law, to provide personal data to another controller (controller B), and controller B intends to process the data for its own scientific research purposes, the provision of personal data by controller A will be considered further processing if it was not one of the primary processing purposes when the personal data was collected. When providing personal data to another controller for scientific research purposes, neither the providing (controller A) nor receiving controller (controller B) needs to undertake a compatibility assessment, pursuant to Article 6(4) GDPR.[40]

[…]

33. If a controller intends to process special categories of personal data for scientific research purposes, then it needs to determine which derogation under Article 9(2) GDPR applies. Similarly, if a controller processes personal data relating to criminal convictions and offences for scientific research purposes, it has to ensure that it can do so under the control of official authority or authorisation by Union or MS Law."

Footnote 39 (see above) refers to para. 22 of the EDPB Document responding to the request from the European Commission for clarifications on the consistent application of the GDPR, focusing on health research dated 2 February 2021 (the "**EDPB Document**"), where a similar position is expressed:

"***Q7. If a health care provider collected health data from patients and wishes to use those data for a scientific research project, to what extent would this be considered compatible further processing?***

22. When further processing of health data for scientific research purposes relies on the presumption of compatible use (Article 5(1)(b) GDPR), the controller will have to take Article 9 GDPR into account as well. It could very well be that the exemption to the prohibition on the processing of health data the health care provider relied on for the original purpose does not extend to or does not cover the processing of health data for scientific research purposes. For instance, if the exemption in MS law only allows for the processing of health data by the health care provider in order to provide health care or medical treatments (Article 9(2)(h) GDPR), the

[38] See further in section 4.4.

[39] EDPB Document on response to the request from the European Commission for clarifications on the consistent application of the GDPR, focusing on health research (2.2.2021) para. 22.

[40] Both controllers must still comply with all relevant obligations of the GDPR including, inter alia, determining an appropriate legal basis under Article 6(1) GDPR and, when applicable, which derogation under Article 9(2) GDPR that it can rely on to process special categories of personal data, as well as if any additional conditions or limitations pursuant to Article 9(4) GDPR apply.

health care provider would still need to rely on an exemption based on Union or MS law as required in Article 9(2) GDPR for the processing of health data for scientific research purposes."

In para. 20 – 21 of the same Document, the EDPB, however, indicates that Article 5(1)(b) GDPR applies in case SCD is processed for a specific research project and may be further processed for another research project and the EDPB indicates that it "will provide further clarification on the requirement of a legal basis for further processing for scientific research purposes by the original or a subsequent controller, **also taking into account Recital 50 and Article 6(4) GDPR**, in its Guidelines on processing personal data for scientific research purposes (presently under preparation, due in 2021

See para. 20-21 of the EDPB Document:

"*3 FURTHER PROCESSING OF PREVIOUSLY COLLECTED HEALTH DATA*

Q5. To what extent could health data collected for one specific research project with the consent of the data subjects be re-used in different research projects of the same nature by another controller without the consent of data subjects?

Q6. What are the requirements for the lawfulness and transparency of processing of special categories of data in cases where the compatibility presumption in Article 5(1)(b) would apply? Furthermore to what extent can the initial legal basis be relied upon for the further processing in such cases?

20. When relying on the presumption of compatibility stipulated in Article 5(1)(b) GDPR for further processing personal data for scientific research purposes in different research projects, it should be taken into account that the presumption of compatibility can only be used under the condition that in such further processing for scientific research purposes adequate safeguards as required by Article 89(1) GDPR are respected. Therefore the application of this exception is dependent on a further clarification of what such safeguards should entail.

21. The EDPB will provide further clarification on the requirement of a legal basis for further processing for scientific research purposes by the original or a subsequent controller, also taking into account Recital 50 and Article 6(4) GDPR, in its Guidelines on processing personal data for scientific research purposes (presently under preparation, due in 2021)."

Note: it appears that the above-mentioned guidance due in 2021 never materialized, until the Draft Guidelines.

In an earlier opinion adopted on 23 January 2019 (Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection regulation (GDPR) (the "**CTR Opinion**"), the EDPB took a similar position as in para. 20-21 of the EDPB Document cited above, clarifying the specific situation where consent for participation in clinical trial compares to consent under GDPR. The EDPB confirms that, even in the case of processing of personal data in clinical trials for processing outside the Clinical Trial Protocol (for which consent is required under the Clinical Trial Regulation), consent is not

automatically also required under the GDPR. According to the Opinion this concerns further processing that meets the compatibility requirement for further processing under Art. 5(1)(b) GDPR in conjunction with Art. 89 GDPR. The EDPB starts with discussing the question posed by the European Commission to the EDPB:

> "*Therefore, as the European Commission points out in its Q&A, namely in question 7, if a sponsor or an investigator would like to further use the personal data gathered for any other scientific purposes, other than the ones defined by the clinical trial protocol,* ***it would require another specific legal ground than the one used for the primary purpose****. The chosen legal basis may or may not differ from the legal basis of the primary use.*"

In reply the EDPB states:

> "*However, the EDPB* ***considers that this approach excludes****, in all circumstances, the applicability of the so-called presumption of compatibility provided under Article 5(1)(b) GDPR. This Article provides that where data is further processed for archiving purposes in the public interest, scientific, historical research or statistical purposes, these shall a priori not be considered as incompatible with the initial purpose, provided that it occurs in accordance with the provisions of Article 89, which foresees specific adequate safeguards and derogations in these cases.* ***Where that is the case, the controller could be able, under certain conditions, to further process the data without the need for a new legal basis [13] [footnote 13: refers to Recital 50 GDPR].*** *These conditions, due to their horizontal and complex nature, will require specific attention and guidance from the EDPB in the future. For the time being, the presumption of compatibility, subject to the conditions set forth in Article 89,* ***should not be excluded, in all circumstances, for the secondary use of clinical trial data outside the clinical trial protocol for other scientific purposes****."*
>
> *In any event, even when the presumption of compatibility will find to apply, the scientific research making use of the data outside the protocol of the clinical trial must be conducted in compliance with all other relevant applicable provisions of data protection as stated under Article 28(2) CTR. Therefore, the controller shall not be deemed exempt from the other obligations under data protection law, for example with regard to fairness, lawfulness (i.e. in accordance with applicable EU and national law), necessity and proportionality, as well as data quality.*"

<u>Assessment of EDPB Position</u>

The position of the EDPB is:

1. Unnecessarily strict and in contradiction with the GDPR; and also
2. More strict than in its previous guidance, where the EDPB recognizes that also for SCD the further processing is allowed for scientific research provided this research meets the conditions set out in article 89 GDPR.

It is not under discussion that Article 5(1)(b) GDPR on purpose limitation applies to <u>all personal data</u>, including SCD. The provision in paragraph 1(b) that further processing for scientific purposes is not considered incompatible on the basis of Article 89 of the GDPR therefore also applies to SCD.

This is also reflected in Article 6(4) GDPR where the criteria on the basis of which "compatibility" must be tested include:

> "***Criterion (c)*** *the* ***nature of the personal data****, in particular whether special personal data are processed, in accordance with Article 9 and whether the personal data relating to criminal convictions and offences are processed in accordance with Article 10.*"

Recital 50 GDPR clarifies that no legal basis separate from the original legal basis is required in case of a compatible further processing:

> "*The processing of personal data for purposes other than those for which the personal data were initially collected should be allowed only where the processing is compatible with the purposes for which the personal data were initially collected.* ***In such a case, no legal basis separate from that which allowed the collection of the personal data is required****. If the processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller, Union or Member State law may determine and specify the tasks and purposes for which the further processing should be regarded as compatible and lawful.* ***Further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes should be considered to be compatible lawful processing operations. The legal basis provided by Union or Member State law for the processing of personal data may also provide a legal basis for further processing.***"

Article 89(1) GDPR provides for the safeguards that must be provided for processing personal data for scientific research (and other) purposes. According to Article 89(2) union law and member state law may provide for derogations to the rights in article 15, 16, 18, 19, 20 and 21 GDPR. This therefore does not allow Member States to restrict the right to processing of personal data for purposes of scientific research.

The only relevant provision here is Article 9(4) GDPR which provides that Member States may maintain or introduce further conditions, including limitations, with regard to the exemptions provided in Article 9(2) GDPR as to processing of genetic data, biometric data or data concerning health.

Article 9(2)(j) provides an exemption for processing necessary for scientific research purposes in accordance with Article 89(1) based on union or member state law. Most member states have included this exemption in their GDPR implementation law and in some cases provided stricter requirements.

Based on the above, the conclusion is that any further processing of health data for purposes of scientific research is allowed based on Article 5(1)(b) GDPR provided that the requirements of art. 89 are met as well as any specific national requirements related to processing of health data for scientific research purposes.

The position in the Draft Guidelines is therefore too limiting where it requires that the controller must still **determine an appropriate legal basis under Article 6(1) GDPR and, when applicable, which derogation under Article 9(2) GDPR that it can rely on to process SCD**. Only specific national requirements under Article 9(4) GDPR as to processing of genetic data, biometric data or data concerning health may be taken into account.

2. AUTONOMY AS A SEPARATE KEY INDICATOR OF SCIENTIFIC RESEARCH

Par. 11(iv) of the Draft Guidelines indicate that "autonomy and independence" are key indicators of scientific research. The Draft Guidelines refer here to The European Code of Conduct for Research Integrity ("**ECCRI**"), but the ECCRI includes a requirement for independence only (of which autonomy forms an integral part). The Draft Guidelines do not explain how the reference to also autonomy differs to the references to independence in the ECCRI. We suggest removing in the Draft Guidelines references to autonomy, to prevent the implication that the EDPB's key indicators of scientific research exceed the requirements set out in the ECCRI.

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The ECCRI provides that a **good** research practice is "*Research institutions and organisations create an environment free from undue pressures on researchers that allows them to work independently and according to the principles of good research practice*" (ECCRI, par. 2.1) and that "*Allowing funders, sponsors, or others to jeopardise independence and impartiality in the research process or unbiased reporting of the results*" constitutes an unacceptable practice (ECCRI, par. 3.1). The ECCRI does not at any point refer separately to researchers' autonomy, as this is encompassed by the requirement of independence.

The Draft Guidelines provide that "*The research activities are conducted **autonomously and** independently in relation to the prejudices of the scientific community and other external parties, as well as the researcher's own prejudices, in an environment free from undue pressures.*" The Draft Guidelines do not define this concept of autonomy. The Draft Guidelines in this context refer the reader to paragraph 2.1 of the ECCRI, which includes a reference to independence only, and not autonomy (see above). Examples 1, 2, 3, and 4 included in the Draft Guidelines all refer to researchers' autonomy, but the examples all relate to the requirements of independence and freedom from undue influence as set out in the ECCRI. We therefore suggest removing the references to researchers' autonomy from the Draft Guidelines, to align with the ECCRI requirements and prevent the implication that the EDPB's key indicators of scientific research exceed the requirements set out in the ECCRI.

3. CLARIFY ACCEPTABLE LIMITATIONS ON THE FREEDOM TO DISSEMINATE AND PUBLISH RESEARCH RESULTS

Par. 11(iv) of the Draft Guidelines provide that conducting research activities autonomously and independently means that the research team has the freedom to disseminate and publish the results of their research, implying that legal constraints (e.g., intellectual property rights) may affect researchers' autonomy and independence.

The Draft Guidelines set out that autonomy and independence entail that "*the research team has* […] *the freedom to disseminate and publish the results of their research*." At the end of this sentence, the Draft Guidelines include footnote 19 which refers cites the following sentence of the European Charter for Researchers ("**ECR**"): "*limitations*

to this freedom can arise because of particular research circumstances – including supervision/guidance/management – or legal or operational constraints, e.g. intellectual property rights, budgetary or infrastructural reasons." [*note: This citation is not entirely correct, as it replaces "that could arise" with "can arise"*].

More importantly, the citation misses the first part of the sentence and the context in which the ECR includes this sentence. This makes it seem as if legal constraints are an **impermissible limitation** to the freedom to publish research results, while the ECR provides these examples as limitations that the researcher should comply with:

> "*Researchers should have the right to disseminate and publish the results of their research including through training and teaching. Researchers should, however,* ***recognise the limitations to this freedom*** *that could arise because of particular research circumstances – including supervision/guidance/management – or legal or operational constraints, e.g. intellectual property rights, budgetary or infrastructural reasons.*" (ECR, Pillar 1, Section 2).

We suggest including the full and correct citation in footnote 19 of the Draft Guidelines and including in the text of Par. 11(iv) of the Draft Guidelines that limitations to this freedom to publish should be recognised.

In footnote 19, the EDPB refers to the European Charter for Researchers ("**ECR**"). The EDPB includes here only a part of the statement in the ECR, implying that legal constraints (e.g., intellectual property rights) may impact a researchers' autonomy and independence. This is not the case, as the ECR specifically calls out that researchers should recognize limitations to publication, such as, intellectual property rights.