We would like to express our appreciation for the opportunity to provide our feedback. We consider that the Guidelines 1/2026 on the processing of personal data for scientific research purposes offer a clear and valuable clarification regarding the application of the GDPR in processing of personal data for scientific research purposes.

Specific comments:

This guidance is a general guidance on data protection principles in scientific research, not specifically focusing on the interface between CTR 536/2014 and the GDPR.

Principles outlining the definition of broad consent in section 4.1.2.1. are endorsed.

Point 136, The definition of controller as the sponsor of the clinical trial, proposed to be defined in the future BTA (footnote 201) is endorsed. In point 139 the example 23 is helpful in characterizing the roles of CROs vs sponsors in data processing in clinical trials. Section 7.3 on the principles of joint contollership is clear.

The guidance does not specify the role of GCP inspectors and CROs in the source data verification process where access to directly identifiable special categories of personal data is mandatory to exercise their legal obligations. Reference is made to the EDPB –EDPS joint opinon 10 th March 2026.

Section 2.1.12 of the six-criteria test in examples: The introduction of the six-criteria test to assess whether an activity qualifies as genuine scientific research is a valuable addition that supports consistent interpretation.

The assessment of Examples 2 (p.12) and 4 (p.13), does not explicitly address criterion (vi), namely *"potential to contribute to existing scientific knowledge or apply existing knowledge in novel ways."* While the fulfilment of this criterion appears evident in the examples, it would nevertheless be beneficial for all six criteria to be explicitly considered in each example, at least briefly.

More generally, where a research activity fulfils all six criteria, it can in principle be regarded as scientific research within the meaning of the GDPR. However, if one or more of the criteria are not met, or their fulfilment is not clearly demonstrated, the controller should provide a justification explaining why the activity may still be considered scientific research.

In line with the above, we recommend that all six criteria are systematically addressed in the example assessments, including in situations where the fulfilment of a criterion appears self-evident. This would improve clarity, facilitate consistent interpretation, and support the practical application of the Guidelines.