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EANM Reply to the Digital Omnibus Regulation Proposal

March 2026

The European Association of Nuclear Medicine (EANM) represents a medical specialty where clinical outcomes are inseparable from high-fidelity data. We welcome the European Commission's move to streamline the Union's digital regulatory framework through the Digital Omnibus. The European Commission's Digital Omnibus proposal (COM(2025) 837, November 2025) represents the first systematic "stress-test" of the EU's digital regulatory framework. While it delivers useful consolidation and simplification across the data acquis, it treats healthcare and health-related research as peripheral concerns — deferring almost entirely to the European Health Data Space (EHDS, Regulation (EU) 2025/327) while leaving a series of structural gaps that will materially impede cross-border health research and secondary use of health data in the EU.

In nuclear medicine, evidence generation depends on the ability to securely exchange and pool imaging and outcome data across centres. Without predictable, harmonised rules for multi-centre data sharing, Europe cannot scale quantitative imaging, robust assessment of therapeutic effectiveness and safety, or AI evaluation and deployment.

However, for this framework to be operationally viable, it must move beyond high-level definitions and address the technical realities of molecular imaging and radiopharmaceutical therapies.

This reply identifies 7 specific gaps and proposes targeted legislative amendments:

The 7 issues addressed are:

- EHDS / general data framework interoperability for cross-border research
- Secondary use of health data (Art. 9 GDPR) beyond AI training
- Clinical trial data and the relationship with the Clinical Trials Regulation
- The role of scientific and medical societies as data actors
- Consent-free secondary use pathways for non-profit health research
- Ethics committee approval as a harmonised safeguard
- Broad and dynamic consent models for data altruism in health

Issue 1
EHDS and General Data Framework: Missing Interoperability
Cross-border research mixing health and non-health data

What the Omnibus says

The EHDS (Regulation (EU) 2025/327, adopted February 2025) is referenced in the Omnibus only once — in a footnote (fn. 35) — as a pre-existing instrument. The Omnibus makes no attempt to articulate how the EHDS secondary use framework (Chapter IV of EHDS) interacts with the general data sharing rules being consolidated into the Data Act, nor with the amended GDPR provisions.

The gap

In practice, cross-border health research projects routinely combine data governed by different regimes: patient records (EHDS), wearable device data (Data Act IoT provisions), genomic data (GDPR Art. 9), and administrative data (Open Data rules, now merged into the Data Act). The Omnibus creates a single consolidated framework for the latter three but never addresses the seam with EHDS. Research teams running pan-European registries or multi-centre cohort studies will face:

- Different access procedures depending on whether data originated in an EHDS-governed health data access body or a general public sector body
- No clear rule on which framework governs mixed datasets (e.g., a dataset combining EHR data with IoT sensor data from wearables)
- No harmonised interoperability standards between EHDS data permits and Data Act re-use licences
- Uncertainty on which supervisory authority has jurisdiction over a processing operation that spans both frameworks

✦ PROPOSED AMENDMENT

Insert a new Recital and Article into the amended Data Act (Regulation (EU) 2023/2854) establishing a 'health research bridge clause': where a data processing activity for scientific research purposes involves data governed both by this Regulation and by Regulation (EU) 2025/327 (EHDS), the competent health data access body and the relevant data re-use authority shall coordinate access procedures. A single access point for cross-framework research applications shall be designated.

Issue 2

Secondary Use of Health Data (Art. 9 GDPR)

Beyond AI training — pharmacovigilance, rare disease, public health surveillance

What the Omnibus says

The Omnibus amends Article 9 GDPR in two respects only: (1) it adds a derogation for biometric data used for identity verification under sole user control; and (2) it adds a derogation for residual processing of special categories of personal data in AI system development, subject to strict technical measures (para. 300, 462 of the Omnibus). Both amendments are explicitly and narrowly scoped to AI. The broader Article 9(2)(j) exception — processing for scientific research purposes under Union or Member State law with appropriate safeguards — is left entirely unchanged and unharmonised.

The gap

Health data is by definition special category data under Art. 9(1) GDPR. This means the general 'research as legitimate interest' recognition introduced by the Omnibus into Art. 6 GDPR does not, on its own, authorise processing health data for research. Researchers still need to rely on Art. 9(2)(j), which requires a basis in national law — creating 27 divergent national regimes for pan-European studies. The Omnibus explicitly acknowledges the fragmentation problem in data law generally but treats health data as out of scope. Activities specifically affected include:

- Pharmacovigilance studies requiring secondary analysis of prescription and adverse event data
- Rare disease patient registries that collect longitudinal clinical data across Member States
- Public health surveillance using hospital discharge data
- Comparative effectiveness research on treatment outcomes

✦ PROPOSED AMENDMENT

Amend Article 9(2) GDPR to add a new point (l): 'the processing is necessary for scientific research purposes by a non-profit research organisation, research performing organisation, or recognised data altruism organisation within the meaning of [amended Data Act], and is subject to: (i) a Data Protection Impact Assessment; (ii) approval by a recognised ethics committee; (iii) appropriate technical and organisational measures including pseudonymisation where possible; and (iv) public registration of the research protocol.' This creates a harmonised EU-level pathway for health research processing, reducing dependence on divergent national laws while maintaining a robust safeguard structure.

Issue 3
Clinical Trial Data and the Clinical Trials Regulation
A complete regulatory blind spot

What the Omnibus says

The Omnibus does not mention clinical trials, clinical trial data, the Clinical Trials Regulation (Regulation (EU) 536/2014), or the EU Clinical Trials Information System (CTIS) at any point. The research data provisions in the new Art. 32t of the Data Act address publicly funded research data under open-access policies, but clinical trial data — which has its own complex ownership, confidentiality, and disclosure regime — is not referenced.

The gap

Clinical trial data sits at the intersection of multiple overlapping frameworks none of which are harmonised in the Omnibus:

- Regulation (EU) 536/2014 requires disclosure of clinical trial results via CTIS but contains no data re-use provisions
- GDPR governs trial participant personal data but the research exemptions are, as noted above, fragmented across Member States
- The EHDS secondary use framework potentially covers health data generated in trials but only where it flows through national electronic health record systems
- The Data Act's research data open-access rules (new Art. 32t) apply to publicly funded research data — but most Phase II/III trials are commercially funded
- EMA transparency policies create partial disclosure obligations, but access to underlying individual patient data (IPD) for re-analysis remains legally uncertain under the new consolidated framework

The practical consequence is that secondary use of clinical trial data for meta-analyses, comparative effectiveness research, or safety signal detection — activities of enormous public health value — has no clear legal basis in the consolidated digital framework.

✦ PROPOSED AMENDMENT

Insert a new Article into the amended Data Act creating a 'clinical research data' category, distinct from general research data, providing that: (1) anonymised or pseudonymised summary-level clinical trial data lodged with CTIS shall be treated as open government data and re-usable under the conditions of the open data section of this Regulation; (2) individual patient data from publicly funded clinical trials shall be accessible to recognised research organisations through a secure access mechanism to be established jointly by EMA, national medicines agencies, and the European Health Data Innovation Board.

Issue 4
Scientific and Medical Societies as Data Actors
An entirely absent category in the framework

What the Omnibus says

The Omnibus defines 'research performing organisations' and 'research funding organisations' as eligible actors for research data open-access purposes (Art. 32t), but provides no definition of either term. The implicit reference is to universities and public research institutes. 'Data altruism organisations' must operate on a not-for-profit basis and be registered in the EU public register (Art. 32d, para. 833). Scientific societies are not mentioned anywhere in the 153-page regulation.

The gap

In European healthcare, scientific and medical societies play roles that are structurally distinct from universities, public health bodies, and commercial entities, and that are not captured by any existing category in the Omnibus:

- Disease-specific registries: Many of the most important European patient registries (cardiovascular, oncological, neurological) are owned and operated by specialty societies, not by universities or governments
- Clinical quality databases: Societies run mandatory or voluntary quality databases used for post-market surveillance, guideline development, and comparative audit — none of which fit neatly into the 'scientific research' definition as clarified by the Omnibus
- Cross-border guideline development: European specialty societies routinely pool data across Member States to develop clinical practice guidelines — a key public health function with no clear data re-use pathway
- Biobank networks: Societies operate and govern biobank networks that collect biological samples and linked clinical data under broad consent frameworks incompatible with the current data altruism model

✦ **PROPOSED AMENDMENT**

Amend the research data provisions to: (1) define 'research performing organisation' explicitly to include 'scientific and medical societies registered as non-profit legal entities, where they conduct, fund, or coordinate scientific research activities'; (2) allow societies to apply for recognition as 'research-grade data altruism organisations' under a simplified registration procedure acknowledging their existing governance structures and ethical oversight mechanisms.

Issue 5
Consent-Free Secondary Use for Non-Profit Health Research
The altruism model requires consent; research needs more flexibility

What the Omnibus says

The Omnibus preserves and streamlines the 'data altruism organisation' model from the Data Governance Act into the Data Act. These organisations collect data voluntarily shared by individuals, with healthcare explicitly listed as a qualifying general-interest objective. Critically, recognised data altruism organisations are required to 'provide electronic means for obtaining consent from data subjects... as well as for their withdrawal'. The consent requirement is absolute and structural — no provision allows an altruism organisation to process data without active, granular, revocable consent.

The gap

Health research practice has evolved well beyond simple consent/no-consent binaries. The requirement for per-use revocable consent is incompatible with how legitimate health research actually operates, particularly for:

- Longitudinal studies: A patient enrolled in a 20-year follow-up study cannot practicably re-consent to every downstream analysis. Requiring this would either destroy the study or reduce it to a population skewed towards highly engaged, digitally literate participants
- Secondary analyses and meta-analyses: Large-scale reuse of existing cohort data — the engine of evidence-based medicine — is structurally incompatible with individual re-consent for each new research question
- Decedent data: A significant portion of long-term health research involves data from deceased individuals, for whom consent withdrawal is impossible and re-consent irrelevant

✦ **PROPOSED AMENDMENT**

Amend the data altruism provisions to introduce a 'research altruism' sub-category for recognised organisations conducting or supporting scientific research in health. Within this sub-category: (1) broad consent (covering a defined scope of future research uses) shall be accepted as equivalent to specific consent, provided the scope is described with sufficient clarity; (2) dynamic consent mechanisms (allowing data subjects to adjust their consent preferences over time via a digital interface) shall be explicitly recognised; (3) processing of pseudonymised health data for approved research purposes by the altruism organisation shall be permitted to continue after a data subject's withdrawal of consent, where re-identification risk is demonstrably low and immediate cessation would disproportionately harm research integrity. These modifications require corresponding safeguards: mandatory ethics committee approval and annual transparency reporting to the competent authority.

Issue 6
Ethics Committee Approval as a Harmonised Safeguard
27 national regimes where one EU standard should exist

What the Omnibus says

Article 89(1) GDPR — which governs processing for scientific research purposes — requires 'appropriate safeguards' for the rights and freedoms of data subjects. The Omnibus introduces scientific research as a defined concept and as a recognised legitimate interest for non-health data processing, but says nothing about what constitutes 'appropriate safeguards' under Art. 89(1). This is left to Member State law, creating the 27-jurisdiction fragmentation problem described above. Ethics committees are not mentioned anywhere in the Omnibus.

The gap

In every EU Member State, ethics committee (or Institutional Review Board) approval is the standard institutional mechanism for validating that a research project meets ethical and data protection standards. Ethics committees assess: scientific validity, necessity and proportionality of data collection, adequacy of consent procedures or justification for consent waiver, data security measures, and safeguards for vulnerable populations. This is precisely the 'appropriate safeguards' assessment that Art. 89(1) GDPR requires — yet the two frameworks are not connected. The result is:

- Controllers must separately satisfy ethics committee requirements (under national research law) and data protection requirements (under GDPR as implemented nationally), often with different national standards
- Cross-border research requires ethics approvals from multiple Member States — a process that can take years and creates incompatible conditions

- There is no mechanism for ethics committee approval to serve as a structured safeguard satisfying GDPR Art. 89(1), even where the ethics committee specifically reviewed data protection aspects

✦ PROPOSED AMENDMENT

Amend Article 89(1) GDPR to add an explicit provision that: 'For the purposes of this Article, approval by a recognised ethics committee — including approval granted under Regulation (EU) 536/2014 on clinical trials, or by a national ethics committee operating under equivalent standards — shall constitute a presumption that appropriate safeguards are in place, subject to the controller implementing the specific measures mandated by that approval. The Commission shall adopt implementing acts establishing minimum standards for ethics committee review that satisfy this presumption across all Member States, thereby enabling mutual recognition of ethics approvals for multi-centre and cross-border health research.'

Issue 7
Broad and Dynamic Consent for Health Data Altruism
Technical recognition of established research practice

What the Omnibus says

The Omnibus retains the data altruism consent model without modification beyond removing some transparency reporting obligations. It requires electronic means for obtaining and withdrawing consent (para. 858) and registering which data uses are consented to. There is no provision for consent layering, pre-specified scope-based consent, or digital tools that allow data subjects to update their preferences over time for ongoing data use.

The gap

Broad consent — where a patient agrees to future research uses within a defined scope (e.g., 'cardiovascular disease research') — is the standard model used by biobanks, disease registries, and large cohort studies across Europe. It is ethically accepted under international standards (Declaration of Helsinki, CIOMS guidelines) and is functionally indispensable for long-running health research. Dynamic consent — an evolution of broad consent using digital platforms where participants can adjust their preferences over time — has been implemented in major European research infrastructures (UK Biobank, BBMRI-ERIC).

Neither model is currently referenced in EU law. The Omnibus's consent framework, by treating consent as a binary on/off switch for each specific use, is incompatible with the operational reality of health research. This is not a privacy weakening — broad and dynamic consent are more transparent, more engaging, and more respectful of autonomy than one-time blanket consent. The issue is purely one of legal recognition.

✦ PROPOSED AMENDMENT

Amend the data altruism consent provisions to: (1) explicitly recognise 'scope-based consent' as a valid consent mechanism for health research altruism, where a data subject consents to a defined category of research uses described with sufficient specificity; (2) recognise 'dynamic consent' — implemented via a certified digital interface — as satisfying the consent requirements of this Chapter; (3) require the European Data Innovation Board (EDIB), in coordination with BBMRI-ERIC and relevant health research infrastructure bodies, to develop technical standards for dynamic consent platforms; and (4) provide that scope-based consent, once given, remains valid for the defined research category unless explicitly withdrawn, without requiring re-consent for individual studies within that scope.

EANM remains committed to supporting the European Commission in refining the Digital Omnibus proposal to ensure that the EU's digital regulatory framework enables responsible and effective health research. Addressing the gaps identified in this reply will be essential to facilitate secure cross-border data sharing, strengthen the secondary use of health data, and support innovation in data-driven and personalised medicine.

EANM also endorses the response submitted by the Biomedical Alliance in Europe, whose recommendations complement the considerations presented in this document. EANM stands ready to continue engaging constructively with the Commission and other stakeholders throughout the legislative process.