Digital Omnibus: Preserving patient agency and rights

22 September 2026

Following the publication on 22 June of the draft report by the European Parliament's Committees[1], EPF notes that several concerns remain unaddressed in the Digital Omnibus proposal. While the legislation covers aspects much broader than healthcare, EPF reiterates the need to carefully assess the proposal's impacts in the field of health. In the field of health, the European Health Data Space (EHDS) offers a well-balanced approach to many of these issues, which should be maintained. We call for the safeguards provided by the General Data Protection Regulation (GDPR) not to be weakened. These protections remain essential to protecting patients' health data and preserving patient agency, while enabling the full potential of health data to be harnessed.

Protecting patients' health data

Redefinition of 'personal data'

The Digital Omnibus proposal introduces the so-called 'relative' approach to the definition of personal data under Article 4. Under this approach, it should be assessed for each entity individually whether that entity has, or may reasonably have, the means to link the data to an identifiable individual[2]. This contrasts with the 'absolute' approach, under which an individual is considered identifiable by all entities if any single entity is capable of linking the data to that individual[3].

In line with the joint opinion of the European Data Protection Board (EDPB) and the European Data Protection Supervisor (EDPS), EPF expresses concerns that the definition of personal data would become narrower and ultimately weaken the fundamental right to data protection. In addition, the changes could introduce legal loopholes for data controllers to circumvent the legal obligations of managing "personal data".

Under this approach, whether a dataset qualifies as personal data depends on the means reasonably likely to be used by each specific entity to re-identify the data subject. For example, the same pseudonymised dataset could therefore fall within the scope of the GDPR for organisations X, Y and Z, which have the technical means and auxiliary information to single out individuals, while being treated as non-personal data for organisation W, which lacks them.

Furthermore, if the definition of personal data is relativised to each actor, organisations may claim that datasets are "non-personal" for them even when those data remain re-linkable elsewhere, fragmenting accountability and complicating risk assessment[4].

The legal uncertainty inherent in the relative approach is disproportionally high, due to the higher risks of re-identification. Conversely, an absolute approach ties the status of the data to its inherent

[1] Industry, Research and Energy (ITRE) and Committee on Civil Liberties, Justice and Home Affairs (LIBE)

[2] "*Information relating to a natural person is not necessarily personal data for every other person or entity, merely because another entity can identify that natural person*"

[3] KU Leuven, Personal data in the Digital Omnibus: where are we going? by Julie Mannekens - 06 January 2026

[4] Russo M, Bignami EG. Smarter rules for digital health: How the digital omnibus can simplify without sacrificing patient rights. Digit Health. 2026 Jul 4;12:20552076261452583. doi: 10.1177/20552076261452583. PMID: 42404599; PMCID: PMC13333043.

identifiability and gives patients a stable, predictable level of protection, which is a precondition for trust in the system.

Pseudonymisation of data

These concerns are further reinforced by the Commission's proposal for a new Article 41a GDPR, which provides that the Commission may adopt implementing acts to specify means and criteria to determine whether data resulting from pseudonymisation no longer constitutes personal data for certain entities.

While we acknowledge that this can foster the sharing of pseudonymised data for health research, this would also give the Commission significant discretion to further specify when pseudonymised data cease to constitute personal data, without the same direct involvement of the co-legislators. Relevant stakeholders, such as patient organisations, should be able to provide input.

Definition of scientific research

Similarly, the new definition in Article 4 of the GDPR, which provides that scientific research does not exclude that the research may also aim to further a commercial interest, broadens the scope of the concept. In this respect, the European Data Protection Board (EDPB) and European Data Protection Supervisor (EDPS) cautioned against conflating research with commercial exploitation[5].

EPF highlights that Article 53 of the EHDS provides a robust framework for defining the scope and purposes of scientific research involving the secondary use of health data.[6]

Preserving patients' agency and human oversight

Under regulations such as Article 22 GDPR, individuals generally have the right not to be subject to fully **automated decisions** (AIDM) that significantly affect them. In healthcare, AIDM ranges from low-risk, routine algorithmic administrative tasks (e.g., automated patient scheduling or preliminary scan sorting) to high-stakes interventions (e.g. influencing diagnosis, treatment and access to services)[7][8].

The text proposed by the European Commission introduces a shift and changes from a 'right not to be subject to' automated decision-making, that is a prohibition in principle unless certain conditions apply, to the situation of being allowed provided that certain conditions apply.

EPF highlights that personal health characteristics should not be used to make automated decisions and profile an individual. Patients with chronic diseases are particularly vulnerable to

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[5] Russo M, Bignami EG. Smarter rules for digital health: How the digital omnibus can simplify without sacrificing patient rights. Digit Health. 2026 Jul 4;12:20552076261452583. doi: 10.1177/20552076261452583. PMID: 42404599; PMCID: PMC13333043.

[6] *"Scientific research related to health or care sectors that contributes to public health or health technology assessments, or ensures high levels of quality and safety of healthcare, of medicinal products or of medical devices, with the aim of benefiting end-users, such as patients, health professionals and health administrators"*

[7] From triage scoring to diagnostic support

[8] Russo M, Bignami EG. Smarter rules for digital health: How the digital omnibus can simplify without sacrificing patient rights. Digit Health. 2026 Jul 4;12:20552076261452583. doi: 10.1177/20552076261452583. PMID: 42404599; PMCID: PMC13333043.

automated individual decision-making and profiling, as their chronic condition could be used to make decisions against them or categorise them and lead to discrimination based on predictive and not factual health data.

Furthermore, chronic, fluctuating and largely 'invisible' symptoms (e.g. fatigue, dryness, pain, etc.) are poorly captured by structured clinical data. This creates a real risk that automated triage/scheduling or eligibility tools systematically under-prioritise these patients precisely because their disease burden is harder to quantify.

Meaningful human oversight, context-sensitive assessments and a practical ability for patients to contest outcomes remain central for trustworthy digital health AI[9]. It is also a matter of patient information: patients should know when an automated system has materially influenced a decision about their care or access to services, receive a clear and understandable explanation, and have a clear route to request meaningful human review.

Finally, EPF underlines the absence of provisions on **digital literacy** in the Digital Omnibus proposal. The successful adoption of digital technologies is not driven by technical performance alone, but by building patients' trust in the tools - including older patients – and by building patient organisations capacities.

Recognising the particular sensitivity of health data

EPF regrets that the Digital Omnibus proposal does not take a proportionate and sector-specific approach that adequately accounts for the particular sensitivity of health data. Foundational legislation such as the **European Health Data Space (EHDS)** rely directly on the GDPR's definitions, notably the definition of personal data[10]. It remains unclear whether changes to the GDPR's definitions could affect the interpretation of certain provisions of the EHDS.

This also applies to other health dossiers such as the **Medical Devices Regulation / In Vitro Diagnostic Medical Devices Regulation revision**. The simplification of the EU regulatory framework should not result in regulatory gaps for AI-enabled medical devices, which bring many opportunities to support better healthcare but also pose specific challenges and risks for patient safety. This is particularly important for lifecycle oversight, including continuous monitoring of safety and performance, risk management, transparency, cybersecurity, human oversight and the protection of health data.

EPF is concerned that the pace of the Digital Omnibus process limits the ability of civil society - and patient organisations in particular - to contribute meaningfully. This is even more true in smaller Member States, where limited capacity to engage with accelerated and highly technical legislative processes can itself constitute a significant barrier to meaningful participation. We call on the co-legislators to carefully consider these proposals and take the time needed to assess their impacts on patients and on sensitive sectors such as healthcare.

[9] Russo M, Bignami EG. Smarter rules for digital health: How the digital omnibus can simplify without sacrificing patient rights. Digit Health. 2026 Jul 4;12:20552076261452583. doi: 10.1177/20552076261452583. PMID: 42404599; PMCID: PMC13333043.

[10] Article 2 of the EHDS Regulation.

About EPF

The European Patients' Forum (EPF) is an umbrella organisation of patient organisations across Europe and across disease areas. Our 82 members include disease-specific patient groups active at the EU level and national coalitions of patients representing 24 countries across Europe. www.eu-patient.eu