

The European Health Data Space: why even the newest EU data law knows no owner

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The European Health Data Space (EHDS) is often presented as a breakthrough for the citizen: at last control over your own health data, available throughout Europe, to be shared or shielded at the touch of a button. In that enthusiasm an old idea resounds: that the patient will now be "in charge" of his data, as if they were a possession he manages, takes with him or, at the extreme, turns into money. Whoever reads the Regulation will not find that picture in it. The EHDS offers no foothold for a property right in health data. It regulates something else: regulated access to and use of health data, through rights, obligations, permits and infrastructure, embedded in the fundamental-rights framework of the GDPR.

What the EHDS is

The EHDS Regulation, Regulation (EU) 2025/327 of 11 February 2025, was published in the Official Journal of the EU on 5 March 2025. It is the most far-reaching component of a broader European data strategy, which also includes the Data Governance Act (Regulation (EU) 2022/868) and the Data Act (Regulation (EU) 2023/2854). Its general application date is 26 March 2027, but many substantive duties are deferred. Primary-use rights and infrastructure apply to the first priority categories from 26 March 2029 and to further categories from 26 March 2031; Chapter IV on secondary use applies largely from 26 March 2029. A limited number of elements follow in 2035 (Article 105 EHDS). Saying simply that "the EHDS applies from 2027" is therefore legally correct but too coarse for implementation planning.

The Regulation governs two things at once. *Primary use* concerns the processing of electronic health data for the provision of care to the natural person to whom they relate, including related administrative and reimbursement processes. *Secondary use* concerns making health data available for purposes outside care: scientific research, policy-making, public health monitoring. For both tracks the EHDS consistently chooses the language of access, sharing, opt-out and permit. The word "owner" does not appear in it.

Primary use: access and restriction, no power of disposal

For primary use the EHDS introduces, among other things, a common European format for electronic health records, requirements on interoperability, logging and the security of EHR systems, and rights for the patient to access his data and to restrict that access for specific data.

These are rights of control, not rights of ownership. The patient can exercise access and indicate which data he does not wish to share, or wishes to share only restrictedly, with healthcare providers, but he acquires no exclusive power of disposal over a delimited object.

The Regulation contains no directly applicable, uniform opt-out regime for primary use; it does contain rights to restrict access, and the possibility for Member States to introduce such an opt-out nationally (Article 10 EHDS), provided it is reversible and access remains possible where vital interests so require. The Dutch legislature has announced its intention to make use of that possibility; for secondary use the Regulation itself provides for a right to

object (Article 71 EHDS), the modalities of which are elaborated nationally (Letter to Parliament on the implementation of the EHDS, 20 January 2026; see also *P&I* 2025/3).

Telling, moreover, is that the rights of control know exceptions for the protection of vital interests. Think of a patient who has requested shielding but ends up in a life-threatening situation in which the care provider nevertheless needs access. The patient thus receives no exclusive power of disposal, but a bounded right to restrict access, embedded in patient safety, continuity of care, logging and national implementing rules (*P&I* 2024/5). Control within conditions is something essentially different from the free power of disposal associated with ownership.

On one point the EHDS goes even further than Article 20 GDPR. Where the GDPR portability right is limited to data the data subject has *provided* (WP242 rev.01; Bijvoets, 2026b), Article 7 EHDS creates a distinct portability right for electronic health data. Article 15 governs the common European EHR exchange format. Recital 15 indicates that the regime may also encompass electronic health data obtained through inference, such as a diagnosis. The fact that this broader mobility right is framed as regulated transfer within healthcare infrastructure, not ownership, underlines the legislative choice: greater mobility does not mean greater possession.

Secondary use: governance through permits, no consent market

For secondary use the EHDS opts for a system that does not primarily rest on individual consent, nor on sale or proprietary transfer, but on permits and statutory safeguards. Health data are in principle made available in anonymised form; only where the user's purpose demonstrably so requires are they made available in pseudonymised form (Article 66 EHDS), within a secure processing environment, and always only after a national *Health Data Access Body* (HDAB) has issued a permit. That permit may moreover be issued only for exhaustively defined purposes: public health, policy, statistics, education, scientific research, innovation and the improvement of care. Use for marketing, for harmful or discriminatory decisions and for adverse insurance or credit decisions is expressly prohibited.

In addition, the Regulation itself gives data subjects a right to object to secondary use of their health data; national legislation elaborates its modalities.

Within this system the patient cannot "sell" his data to a research institution, and the research institution cannot "buy" them. Any fees within the system are likewise no purchase price for the data, but cost compensations for making them available, which must be proportionate to those costs. What comes into being is not a transaction between owner and buyer, but permitted, conditional access under public supervision. Additional safeguards may apply to particularly sensitive categories, such as genetic data or data from wellness apps. The picture is that of a regulated chain, not of a market.

Three roles, no owner

The choice of the EU legislature emerges most sharply from the concepts the Regulation does employ. The EHDS knows a *health data holder*: the party which, under EU or national law, is entitled or obliged to process electronic health data or make them available, in practice usually the healthcare provider. Next to it a *health data user*: the research institution or policy-maker granted access for secondary use on the basis of a permit (*data permit*). And finally the *data subject*: the natural person to whom the data relate. None of these roles comprises ownership.

The term "holder" must not be read in a proprietary sense. It is not about possession or ownership in civil-law terms, but about a functional role within the EHDS: the party that manages the data and must be able to make them available under conditions.

That is no accidental choice of words. An explicit ownership model would have required the Regulation to designate who acts as rightholder and which exclusive powers attach to that position; such a designation is absent. The EU legislature instead distributes rights and obligations across the links of a chain and leaves the civil-law question "whose data are these?" unanswered, because the answer is not needed for the functioning of the system. The same pattern is visible in the Data Act, which regulates access to data from smart devices with concepts such as "user", "data holder" and "recipient", and expressly creates no property regime over the data. Instead of property rights, the legislature opts for public-law rules of access and use.

The EHDS does not set the GDPR aside

A persistent misunderstanding is that the EHDS replaces the GDPR, or that an HDAB permit by itself supplies the complete legal basis for every actor. Neither is correct. The GDPR continues to apply, while the EHDS itself creates statutory obligations, public-interest tasks and safeguards. The health data holder's duty to make data available may correspond to Article 6(1)(c) GDPR, while the HDAB's task may rest on Article 6(1)(e) (see recital 52 EHDS). The user must still demonstrate the applicable Article 6 basis in the application. Depending on purpose and the EU or national legal framework, special-category data also require an exception under Article 9(2)(g), (h), (i) or (j). A data permit is therefore a necessary EHDS access condition, but not automatically the user's complete GDPR basis.

The GDPR rights of data subjects therefore also remain relevant, in so far as they apply in the concrete processing context: access (Article 15), rectification (Article 16), erasure (Article 17) and objection (Article 21 GDPR), in healthcare often bounded by statutory retention duties and research regimes. Alongside these stand the specific rights under the EHDS and, in the Netherlands, the patient rights under the WGBO (Bijvoets, 2026d). The EHDS, in short, introduces additional rules alongside the GDPR, without replacing it.

Why this confirms the ownership thesis

In earlier blogs in this knowledge base the same line ran throughout: personal data are not property but control (Bijvoets, 2026a), data portability is a bounded mobility right and no transfer of possession (Bijvoets, 2026b), personal data do not lend themselves to a commodity approach (Bijvoets, 2026c), and the medical record is kept by the physician within a relationship of trust, not possessed by the patient (Bijvoets, 2026d).

The EHDS is the heaviest test of that thesis, and confirms it. Precisely now that the EU legislature is redesigning the entire infrastructure around health data, with all the economic interests involved, an ownership approach lies rhetorically within easy reach. "Give citizens their data back" translates readily into a title of ownership. The legislature did not take that step. It chose access, opt-out, permit and supervision, the same approach the GDPR chose in 2016. That is no shortcoming of the Regulation. It is a choice that fits the nature of health data: relational, layered and deeply personal. Such data are better governed through trust and regulated access than through possession and transfer.

Conclusion

The European Health Data Space makes health data more widely accessible than ever, for care and for research alike. But nowhere does it make the patient an owner. It gives him rights of control (access, restriction, objection) and places his data in a chain of holders, users and supervisors, governed by the GDPR and, in the Netherlands, by the WGBO and professional secrecy. Whoever looks for an owner in the most far-reaching European regulation of health data will find none. And that is precisely the confirmation towards which this series has been working: in the era of European data spaces, too, the protection of health data remains a matter not of possession, but of fundamental rights, trust and regulated access.

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- 1 *P&I* 2025/3 'Actualiteiten' [Current developments] (on the Dutch opt-out choice and the positioning of the HDAB).
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