Policy Brief

AI-POWERED SCALING OF THE EHDS: From Compliance to Value

Prepared by i~HD and the AIDAVA Consortium, June 2026

Based on four stakeholder roundtables: patients, hospitals, decision-makers, and industry

For the full evidence base see: AIDAVA Evidence and Position Paper, June 2026.

Today's challenge

The EHDS Regulation (EU 2025/327) establishes the governance, citizen rights, and technical baseline for a European health data space. It does not, and cannot, guarantee that the data exchanged will be clinically trustworthy, semantically consistent, or economically usable for research and innovation. **Regulatory compliance and value extraction are therefore two very different things.** Four stakeholder roundtables convened by the AIDAVA consortium in 2026 converged on this finding: Member States will likely meet the 2029 compliance deadlines, but if data quality and semantic interoperability are not addressed at the source, the EHDS risks replicating the existing secondary use costs and bottlenecks at a higher scale.

The cost of the status quo is substantial. European innovators - pharmaceutical companies, medical device developers, academic researchers, and health technology companies - spend billions of euros every year preparing health data for research before any analysis can begin, with the majority of that expenditure absorbed by the process of cleaning, structuring, and enriching raw, messy data rather than generating insights. This structural inefficiency will not change by EHDS compliance alone and it has real consequences: rising prices for innovative medicines, narrower patient access to life-saving treatments, and a near-halving of Europe's share of global commercial clinical trials over the past decade, leaving 60,000 fewer patients with access to trials. Poor data quality is a primary contributor to longer site startup and recruitment times. And the cost does not stop with innovators; it flows through R&D budgets into the price of medical technologies, contributes to suboptimal clinical outcomes, and is ultimately paid by health systems and patients.

A paradigm shift – Curate once, Use many times

The AIDAVA project[1] has demonstrated at TRL 5–6, across four hospitals, in three countries and three languages, that AI-assisted curation can transform heterogeneous hospital records into a high-quality, semantically structured **Personal Health Knowledge Graph (PHKG)**, i.e., a clearly documented semantic foundation from which EEHRxF exports, research datasets and clinical trial data made available through HDABs can be generated on demand. The principle is to **curate once, and use many times** at marginal cost. The AIDAVA cost model estimates that deploying this approach at EU-27 scale would cost approximately **€1.0–1.5 billion over five years**, less than one year of what European innovators currently spend on data preparation alone. The model requires national-level validation to refine its parameters, but the direction of travel is robust:

AI assisted curation at scale costs significantly less than the per study preparation burden it eliminates.

[1] www.aidava.eu. *Horizon Europe GA 101057062, €8.6M, 14 partners, 9 countries, coordinated by Maastricht University, 2022–2026.*

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Calls to Action

These calls reflect the consensus of four stakeholder roundtables and address five interdependent conditions for success.

1. Technology: Test and expand

Support additional clinical use cases and national implementation pilots, involving multiple data holders, real governance frameworks, real data access use cases, in at least 3–5 Member States through dedicated EU funding calls. Recommended priority entry points are electronic health record (EHR)-to-electronic data capture (EDC) clinical trial enablement and patient matching for pharma; federated registry population for clinical research.

2. Governance: A European health data semantic strategy

Establish an EU Health Data Semantic Strategy including: (a) governance and sustainable public funding for a shared Simplified Upper Level Ontology (SULO or equivalent) as an EU public asset; (b) formal engagement of HL7, SNOMED International, CEN/TC 251 and other international Standards Development Organisations to develop mappings based on agreed, shared semantics and to enable cost-effective, AI-powered mapping; and (c) open licensing for all EU-funded semantic assets

3. Preparation: Capacity building and workforce preparation

Invest in tools and the needed set of skills to enable this change; etsablsih an EU open-source ecosystem, ensuring shared tools and semantic assets are accessible to all Member States regardless of their starting point.

4. Infrastructure: Define a Sustainable Data Infrastructure Funding Model

A paradigm shift is needed toward treating health data infrastructure as a pre-competitive national asset — co-funded by public Member States/EU budgets, industry and research bodies. A clear economic model with ROI articulated for each stakeholder group (hospitals, pharma, regulators, patients) must be developed and adopted by decision-makers.

5. Coordination: EU and national action aligned with the regulatory framework

Coordinated EU and national action is needed, in line with the AI Act, MDR, and the Biotech Act's data quality accelerator provisions, with strong involvement of Standards Development Organisations as governance partners. The EHDS Board, eHealth Network, and AI Office should establish a joint regulatory learning mechanism, including AI Act regulatory sandboxes, to resolve open qualification and governance questions for AI-enabled health data infrastructure.

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