Essays

The New Frontiers of Socialised Medicine: AI, Bio-Legal and Clinical-Legal Liability Between EU Law and the Italian Legal System

Ionut Virgil Serban, Adrian Nicolae Dan*

ABSTRACT: Socialised medicine in Europe is entering an algorithmic era. The Artificial Intelligence (AI) Act (Regulation (EU) 2024/1689) introduces horizontal, risk-based rules that coexist with sectoral regimes for medical devices-Medical Device Regulation (MDR) / In Vitro Diagnostic Medical Device Regulation (IVDR). In Italy, Law 24/2017 (Gelli Bianco) structures professional and organisational liability. We examined how these regimes interact in clinical practice and which governance, auditing and insurance tools make AI both safe and equitable. We conducted a multidisciplinary doctrinal and policy analysis of EU instruments (AI Act, MDR/IVDR, Medical Device Coordination Group-MDCG 2019 11 rev.1 and MDCG 2025 6), European Medicines Agency (EMA)'s 2024 Reflection Paper on the medicinal product lifecycle, World Health Organization (WHO) ethics guidance and Organisation for Economic Co-operation and Development (OECD) reports, complemented by a focused scoping of peer reviewed literature on algorithmic auditing, fairness and medico legal accountability. We mapped obligations along the AI lifecycle, built role responsibility matrices and derived an operational co regulation cycle. We identify a dual track compliance architecture: MDR/IVDR ensure clinical safety and performance; the AI Act adds data governance, logging, human oversight, fairness and post market monitoring, with staged application (2025-2027). We specify responsibilities for manufacturers, physicians and facilities and formalise algorithmic audits (pre market/post market/extraordinary) with transparent reporting. We link these to adaptive Health Technology Assessment (HTA) and product liability reform (Directive (EU) 2024/2853). We conclude that dynamic co regulation-living guidelines, lifecycle auditing, transparent logs and risk-based insurance-can align innovation with equity, safety and accountability.

KEYWORDS: Artificial Intelligence; social medicine; medical liability; digital therapeutics; bioethics

SUMMARY: 1. Introduction – 2. Materials and Methods – 3. Results – 3.1. Risk-Based Regulation and the Dual-Track AI Act/MDR Model – 3.2. Professional and Organisational Responsibility – 3.3. Algorithmic Audit – 3.4. Insurance, Risk Pooling and Adaptive HTA – 3.5. Bioethical Profiles and Equitable Access – 3.6. General-Purpose and Genera-

* *Ionut Virgil Serban: Professor PhD, University of Craiova, Romania. Mail: serban.ionut@ucv.ro; Adrian Nicolae Dan: Professor PhD, University of Bucharest, Romania. Mail: adrian.dan@sas.unibuc.ro.* *This article was subject to a blind peer review process.*

tive AI (GPAI/LLMs) in Care – 3.7. Data Governance, Privacy and Documentation – 3.8. Italy Operationalisation under Law 24/2017 – 4. Discussion – 5. Conclusion.

1. Introduction

Artificial intelligence (AI) is reshaping European health systems across prevention, diagnosis, treatment and rehabilitation. It also tests the normative foundations of socialised medicine—equity, safety, accountability and distributive justice by demanding that technical reliability be translated into social reliability. Foundational bio-ethical debates on autonomy, non-maleficence, justice and accountability are now expressed as operational requirements for data governance, measurable fairness and explainability in clinical workflows.[1] As evidence of this clinical footprint across specialties, AI is increasingly used in gastrointestinal oncology, ophthalmology and urology, illustrating the breadth of high-stakes applications that socialised systems must govern.[2]

Within the European multilevel legal order, the Artificial Intelligence Act (AI Act) establishes horizontal, risk-based rules for AI, including definitions, prohibited practices and obligations for high-risk systems. Health software that qualifies as medical device software (MDSW) will typically be high risk and must comply both with the sectoral Medical Device Regulation (MDR, Regulation (EU) 2017/745) or the In Vitro Diagnostic Medical Device Regulation (IVDR, Regulation (EU) 2017/746), and with the AI Act's additional lifecycle duties.[3] Application is phased: prohibitions and general provisions begin in 2025, general application in 2026, and certain classification-linked duties in 2027 (see §3.1).[4]

At national level, Italy's Law 24/2017 ("Gelli-Bianco") centres patient safety and risk management, promoting guideline-concordant practice and organisational learning. Integrating AI reframes duties for

[1] L. Floridi, J. Cowls, M. Beltrametti, *et al.*, *AI4People—An ethical framework for a good AI society: opportunities, risks, principles and recommendations,* in *Minds Mach*, 28, 2018, 689–707; B. Mittelstadt, *Principles alone cannot guarantee ethical AI*, in *Nature Machine Intelligence*, 1, 11, 2019, 501-507; W. Nicholson Price II, S. Gerke, I. G. Cohen, *Liability for Use of Artificial Intelligence in Medicine*, in B. Solaiman, I.G. Cohen (eds.), *Research Handbook on Health, AI and the Law*, 2024; 123-140; World Health Organization, *Ethics and governance of artificial intelligence for health*, Geneva, 2021; High Level Expert Group on Artificial Intelligence, *Ethics guidelines for trustworthy AI*, Brussels, European Commission, 2019.

[2] A. Fulga, D. Iancu, O. M. Dragostin, *et al.*, *Artificial Intelligence Revolutionizes Oesophageal Squamous-Cell Carcinoma Management*, in *BRAIN – Broad Research in Artificial Intelligence and Neuroscience*, 15, 3, 2024, 135-144; A. C. Rusu, R. O. Chistol, *et al.*, *Potential Screening, Grading and Follow-Up of Diabetic Retinopathy in Primary Care Using Artificial Intelligence—How Hard Would It Be to Implement? An Ophthalmologist's Perspective*, in *BRAIN – Broad Research in Artificial Intelligence and Neuroscience,* 15, 2, 2024; B. Novac, R. Zara, A. Ciobica, *Artificial Intelligence in Urology: New Technologies with Major Potential*, in *BRAIN – Broad Research in Artificial Intelligence and Neuroscience,* 15, 4, 2024.

[3] European Parliament and Council, *Regulation (EU) 2024/1689 (Artificial Intelligence Act)*, in *Official Journal of the European Union*, 2024, 1-120; Id, *Regulation (EU) 2017/745 on medical devices (MDR)*, cit., 2017, 1-175; Id, *Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR)*, cit., 2017; 176-332; Medical Device Coordination Group (MDCG), AI Board, *MDCG 2025-6 / AIB 2025-1: Interplay between MDR/IVDR and the AI Act*. 19 June 2025; European Medicines Agency (EMA). *Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle*, Amsterdam, 30 September 2024.

[4] European Parliament and Council, *Regulation (EU) 2024/1689 (Artificial Intelligence Act)*, cit., 2024, 1-120.

physicians and facilities from selection and validation of tools, to documentation of AI-assisted decisions and justification when overriding algorithmic outputs.[5]

Two aims guide this article. First, to map dual-track obligations when AI is deployed in clinical devices, showing how the AI Act and MDR/IVDR converge and where they diverge. Second, to translate those obligations into an implementable co-regulatory cycle linking living clinical guidelines, algorithmic audits and adaptive insurance/HTA capable of sustaining equity and accountability at scale. We test the hypothesis that harmonising AI Act lifecycle controls with MDR/IVDR processes reduces medico-legal ambiguity and improves insurability and sustainability of digital therapeutics without undermining professional autonomy, while supporting distributive justice.[6]

AI promises earlier diagnoses, personalised decisions and less administrative burden, but it reconfigures epistemic authority in the clinic. Decision support may appear precise even under high uncertainty, driving automation bias; conversely, blanket rejection forfeits benefits. Without documentation of model scope, training-data limits and intended populations, neither equity nor safety can be guaranteed. A solidarity-driven system must ask not whether AI beats a benchmark, but whether it improves outcomes fairly across diverse populations and care settings, consistent with WHO's rights-based approach.[7]

Regulatory fragmentation has impeded adoption. MDR/IVDR require clinical evidence, risk management, cybersecurity and post-market surveillance. The AI Act adds horizontal controls dataset governance, traceability (logs), robustness, human oversight across sectors. Coordination is now supported by guidance clarifying interplay, encouraging a single integrated technical file covering both clinical evidence and AI governance.[8]

The conceptual framing adopted in this study reflects how legal, clinical and ethical dimensions intersect across the AI lifecycle. Each element analyzed in the results section—regulatory architecture, professional responsibility, auditing, insurance, equity and governance—was therefore selected to illustrate a continuous operational chain from legal norm to clinical practice, allowing the mapping of AI's transformation from a technical artefact into a socially accountable system.

---

[5] Italian Parliament, *Legge 8 marzo 2017, n. 24 (Gelli-Bianco): Disposizioni in materia di sicurezza delle cure e responsabilità professionale*, in *Gazzetta Ufficiale della Repubblica Italiana*, 64, 17 March 2017.

[6] L. Floridi, J. Cowls, M. Beltrametti, *et al., op.cit.,* 689–707; B. Mittelstadt, *op.cit.,* 501-507; W. Nicholson Price Ii, S. Gerke, I. G. Cohen, *op.cit.*, in B. Solaiman And I. G. Cohen (eds.), *op.cit.*, 123-140; World Health Organization, *Ethics and governance of artificial intelligence for health*, Geneva, 2021; High Level Expert Group on Artificial Intelligence, *Ethics guidelines for trustworthy AI*, Brussels, European Commission, 2019; Organisation for Economic Co-operation and Development (OECD), *AI in Health: Huge potential, huge risks*, Paris, 2024; M. Ebers, *AI robotics in healthcare between the EU MDR and the AI Act*, in *Oslo Law Rev*, 11, 1, 2024, 1–12; E. Biasin, E. Kamenjasević, *Regulatory Approaches Towards AI-Based Medical Device Cybersecurity: A Transatlantic Perspective*, in *European Journal of Risk Regulation*, 15, 4, 2024; M. Veale, F. Zuiderveen Borgesius, *Demystifying the Draft EU Artificial Intelligence Act*. Computer Law Review International, 22, 4, 2021.

[7] World Health Organization, *Ethics and governance of artificial intelligence for health*, Geneva, 2021; High Level Expert Group on Artificial Intelligence, *Ethics guidelines for trustworthy AI*, Brussels, European Commission, 2019; Organisation for Economic Co-operation and Development (OECD), *AI in Health: Huge potential, huge risks*, Paris, 2024.

[8] Medical Device Coordination Group (MDCG), *Guidance on Qualification and Classification of Software under MDR/IVDR*, Brussels, European Commission, June 2025; Medical Device Coordination Group (MDCG), AI Board, *MDCG 2025-6 / AIB 2025-1: Interplay between MDR/IVDR and the AI Act*, 19 June 2025; European Medicines Agency (EMA), *Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle*, Amsterdam, 30 September 2024.

2. Materials and Methods

We designed a multidisciplinary, comparative analysis at the intersection of European public law, medical device regulation, bioethics and health policy.

Primary legal sources. We analysed the AI Act (Regulation (EU) 2024/1689), focusing on definitions, classification, governance and obligations (Chs. III–V), market surveillance (Ch. VII), governance (Ch. XII) and staged application dates. Sectoral instruments included MDR and IVDR. We used MDCG software qualification/classification guidance (MDCG 2019-11 rev.1, June 2025) and the 2025 interplay Q&A (MDCG 2025-6/AIB (Artificial Intelligence Board) 2025-1).[9]

Medicines guidance. Because many products bridge medicines, devices and data, we examined the EMA 2024 Reflection Paper on AI in the medicinal product lifecycle to align lifecycle controls (data integrity, validation, monitoring, documentation).[10]

Ethics and policy frameworks. We drew on WHO's 2021 guidance on ethics and governance of AI for health, the European Commission's High-Level Expert Group on Artificial Intelligence (HLEG) Ethics Guidelines for Trustworthy AI (2019), and OECD's 2024 report AI in Health to ground equity, transparency and accountability requirements.[11]

Focused literature scoping. We surveyed peer-reviewed work on algorithmic auditing and fairness in healthcare, medico-legal accountability and risk pooling for digital therapeutics. Inclusion criteria privileged conceptual clarity and operationalisable methods; purely technical articles without governance implications were excluded.[12]

---

[9] European Parliament and Council, *Regulation (EU) 2024/1689 (Artificial Intelligence Act)*, in *Official Journal of the European Union*, 2024, 1725-2555; Id, *Regulation (EU) 2017/745 on medical devices (MDR)*, cit., 2017, 1-175; Id, *Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR)*, cit., 2017, 176-332; Medical Device Coordination Group (MDCG), *MDCG 2019-11 rev.1: Guidance on Qualification and Classification of Software under MDR/IVDR*, Brussels, European Commission, June 2025; Medical Device Coordination Group (MDCG), AI Board, *MDCG 2025-6 / AIB 2025-1: Interplay between MDR/IVDR and the AI Act*. 19 June 2025; European Medicines Agency (EMA). *Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle*. Amsterdam: EMA, 30 September 2024.

[10] European Medicines Agency (EMA), *Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle*, Amsterdam, 30 September 2024.

[11] World Health Organization, *Ethics and governance of artificial intelligence for health*, Geneva, 2021; High Level Expert Group on Artificial Intelligence, *Ethics guidelines for trustworthy AI*, Brussels, European Commission, 2019; Organisation for Economic Co-operation and Development (OECD), *AI in Health: Huge potential, huge risks*, Paris, 2024.

[12] M. Ebers, *op.cit*, 1–12; E. Biasin, E. Kamenjasević, *op.cit.,* 876-886; M. Veale, F. Zuiderveen Borgesius, *op.cit.,* 97-112; N.A. Smuha, *The EU Approach to Ethics Guidelines for Trustworthy Artificial Intelligence*, in *Computer Law Review International*, 2019; 20, 4, 97-106; N.A.K. Lekadir, A.F. Frangi, A.R. Porras, B. Glocker, C. Cintas, C.P. Langlotz, *et al*., *FUTURE-AI: international consensus guideline for trustworthy and deployable artificial intelligence* in *Healthcare BMJ*, 388, 2025; E. Topol, *Deep Medicine: How Artificial Intelligence Can Make Healthcare Human Again*, PSNet Book/Report Classic, 2019; L. Gondara, J. Simkin, *A clinical-trial design approach to auditing language models in healthcare settings*. arXiv preprint, 2024; X. Liu, B. Glocker, M.M. Mccradden, M. Ghassemi, A.K. Denniston, L. Oakden-Rayner, *The medical algorithmic audit*, in *The Lancet Digital Health*, 4, 5, 2022, e384–e397; X.J.L. Cross, M. A. Choma, J.A. Onofrey, *Bias in medical AI: Implications for clinical decision-making*, in *PLOS Digital Health*, 3, 11, 2024; S.C. Nouis, V. Uren, S. Jariwala, *Evaluating accountability, transparency, and bias in AI-assisted healthcare decision-making: A qualitative study of healthcare professionals' perspectives in the UK*, in *BMC Medical Ethics*, 26, 89, 2025; Z. Obermeyer, E.J. Topol, *Artificial intelligence, bias, and patients' perspectives*, in *The Lancet*, 397, 10289,

Analytic strategy. We (a) constructed a matrix aligning AI Act lifecycle duties with MDR/IVDR processes; (b) mapped role responsibility across manufacturers, physicians, facilities and insurers; (c) specified an audit taxonomy (pre-market, post-market, extraordinary) with traceable KPIs and fairness metrics; and (d) derived clauses for adaptive HTA and insurance reflective of model updates, drift and bias.[13]
Search/synthesis and reproducibility. Sources were identified on EUR-Lex, Commission/MDCG and EMA sites, and international bodies (WHO/OECD). We independently extracted duties, dates and definitions, mapped them to lifecycle phases and actors, and iteratively refined tables/checklists with legal and clinical reviewers for implementability.

3. Results

The results are organised to reflect the logical progression from regulatory structure to operational implementation. Starting from the dual-track regulatory model, the analysis moves through the redefinition of professional and organisational responsibilities, the function of algorithmic auditing, and the integration of these mechanisms into insurance, health technology assessment and equity frameworks.

3.1. Risk-Based Regulation and the Dual-Track AI Act/MDR Model

The AI Act introduces lifecycle controls-risk management, data governance, technical documentation, logging, robustness, accuracy, resilience, human oversight and transparency-for high-risk systems. AI medical software typically falls in scope as high risk and must satisfy this horizontal layer while conforming to MDR/IVDR. The result is a dual track: clinical safety/performance (MDR/IVDR) plus algorithmic governance (AI Act).[14] In practice, representative high-risk deployments include endoscopic decision

2021, 2038; J. Zhang, Z. Zhang, *Ethics and governance of trustworthy medical artificial intelligence*, in *BMC Medical Informatics and Decision Making*, 23, 7, 2023.

[13] European Parliament and Council, *Regulation (EU) 2024/1689 (Artificial Intelligence Act)*, in *Official Journal of the European Union,* 2024, 1-120. Id, *Regulation (EU) 2017/745 on medical devices (MDR)*, cit., 2017, 1-175; Id*, Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR)*, cit., 2017; L 117, 176-332; Medical Device Coordination Group (MDCG), *MDCG 2019-11 rev.1: Guidance on Qualification and Classification of Software under MDR/IVDR*, Brussels, European Commission, June 2025; Medical Device Coordination Group (MDCG), AI Board, *MDCG 2025-6 / AIB 2025-1: Interplay between MDR/IVDR and the AI Act*. 19 June 2025; European Medicines Agency (EMA), *Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle*, Amsterdam, 30 September 2024; World Health Organization, *Ethics and governance of artificial intelligence for health*, Geneva, 2021; High Level Expert Group on Artificial Intelligence, *Ethics guidelines for trustworthy AI*, Brussels, European Commission, 2019; Organisation for Economic Co-operation and Development (OECD), *AI in Health: Huge potential, huge risks*, Paris, 2024; European Parliament and Council, *Directive (EU) 2024/2853 on liability for defective products (revised Product Liability Directive)*, in *Official Journal of the European Union*, 2024, 1-41; Euractiv, *Commission withdraws AI liability directive*, 2025, available at: https://www.euractiv.com.

[14] European Parliament and Council, *Regulation (EU) 2024/1689 (Artificial Intelligence Act)*, cit., 2024, 1-120; Id, *Regulation (EU) 2017/745 on medical devices (MDR)*, cit., 2017; 1-175; Id, *Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR)*, cit., 2017, 176-332; Medical Device Coordination Group (MDCG), AI Board, *MDCG 2025-6 / AIB 2025-1: Interplay between MDR/IVDR and the AI Act*, 19 June 2025; European Medicines Agency (EMA), *Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle*, Amsterdam, 30 September 2024.

support in oesophageal squamous-cell carcinoma, AI-assisted diabetic-retinopathy screening and urologic decision support.[15]

Application timeline (AI Act). Prohibitions and general provisions apply from 2 Feb 2025; selected governance provisions from 2 Aug 2025; general application from 2 Aug 2026; and certain classification-linked obligations from 2 Aug 2027. Transitional arrangements address systems already on the market and general-purpose models.[16]

Table 1. Dual-track compliance for AI-enabled clinical software

Lifecycle phase	AI Act (examples)	MDR/IVDR (examples)
Scoping & intended use	Risk management; data governance; human oversight; transparency	Classification; intended purpose; CE marking; Unique Device Identification (UDI)
Validation & performance	Accuracy; robustness; bias/fairness analysis; logging for auditability	Clinical evaluation; usability; cybersecurity/safety
Post-market	Drift monitoring; periodic audit; Corrective and Preventive Action (CAPA); incident reporting; logs	Post-Market Surveillance/ Post-Market Clinical Follow-up (PMS/PMCF); vigilance; documented Corrective and Preventive Action (CAPA)

Coordination note: Interplay guidance clarifies that sectoral conformity procedures are not duplicated but coordinated via the device route. Manufacturers should build a single integrated technical file covering MDR/IVDR clinical evidence and AI Act data/logging/fairness controls.[17]

This dual-track model reveals a persistent tension between regulatory completeness and practical coherence: while the AI Act expands accountability through lifecycle governance, aligning its risk logic with the clinically grounded MDR/IVDR framework remains a delicate exercise in legal and technical synchronization.

3.2. Professional and Organisational Responsibility

Italian liability remains anchored in clinicians' fault (negligence, imprudence, inexperience) and the facility's contractual responsibility, with guideline-informed practice central. With AI, duties evolve: appropriate tool selection; competence and training; awareness of model limitations and indications; recording AI outputs in the patient record; justification of divergences; and participation in post-market monitoring. Facilities bear organisational duties: procurement and ex-ante compliance assessment; integra-

[15] A. Fulga, D. Iancu, O.M. Dragostin, *et al*., *op.cit.,* 135-144; B. Novac, R. Zara, A. Ciobica, *op.cit.,* 319-324; A.C. Rusu, R.O. Chistol, *et al*., *op.cit.,* 280-303; M. Veale, F. Zuiderveen Borgesius, *op.cit.,* 97-112.

[16] European Parliament and Council, *Regulation (EU) 2024/1689 (Artificial Intelligence Act)*, in *Official Journal of the European Union*, 2024, 1-120.

[17] Medical Device Coordination Group (MDCG), *MDCG 2019-11 rev.1: Guidance on Qualification and Classification of Software under MDR/IVDR*, Brussels, European Commission, June 2025; Medical Device Coordination Group (MDCG), AI Board, *MDCG 2025-6 / AIB 2025-1: Interplay between MDR/IVDR and the AI Act*, 19 June 2025; European Medicines Agency (EMA), *Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle*, Amsterdam, 30 September 2024.

tion into care pathways; incident handling; and periodic audits.[18] The rapid integration of collaborative/robotic AI into clinical environments underscores these redistributed duties for human oversight and organisational governance.[19]

The redistribution of duties between physicians and facilities strengthens accountability but also exposes unresolved ambiguities regarding the threshold of human oversight and the limits of deference to algorithmic recommendations.

Table 2. Accountability across the digital-health chain

Actor	Primary responsibility	Key notes
Manufacturer	Technical compliance; updates; risk management; reporting; logs	Strict/product liability for defects and updates; duties under Product Liability Directive (PLD) 2024/2853.
Physician	Appropriate use; human oversight; documentation; rationale for divergence	Training/continuing education; chart annotation of AI use.
Healthcare facility	Protocols; team qualification; risk management; incident response	Organisational/contractual liability; governance and PMS interfaces.
Insurer	AI-specific cover; claims monitoring; retroactivity for updates	Incentives tied to audit KPIs; exclusions for lack of vigilance.

3.3. Algorithmic Audit

Auditing connects lifecycle controls with accountability. We distinguish pre-market audits (dataset review, representativeness and bias testing, stress tests, generalisation checks), post-market audits (real-world performance, drift monitoring, incident linkage) and extraordinary audits (triggered by anomalies, updates or incidents). Reports should publish abstracts and selected KPIs/fairness metrics to enable contestability without disclosing trade secrets.[20] Concrete examples reinforce why audits must document data provenance/augmentation and robustness/generalisation testing: data-augmentation pipelines (e.g., Conditional Generative Adversarial Network (CGAN) for early Parkinson's voice signals) raise traceability and bias questions, while Brain–Computer Interface/ Magnetoencephalography (BCI/MEG) pipelines illustrate robustness and interference-handling challenges in safety-critical contexts.[21]

---

[18] W. Nicholson Price Ii, S. Gerke, I.G. Cohen, *op. cit.*, in B. Solaiman, I.G. Cohen (eds.), *op.cit.*, 123-140; Italian Parliament, *Legge 8 marzo 2017, n. 24 (Gelli-Bianco): Disposizioni in materia di sicurezza delle cure e responsabilità professionale*, in *Gazzetta Ufficiale della Repubblica Italiana*, 64, 17 March 2017; M. Ebers, *op.cit*, 1–12; E. Biasin, E. Kamenjasević, *op.cit.,* 876-886.

[19] I. Ienina, O. Ovcharenko, N. Opushko, M. Chumak, T. Zahorodnia, O. Dorofieiev, *Major trends in today's intelligent robotics in light of the creation of collaborative artificial intelligence*, in *BRAIN – Broad Research in Artificial Intelligence and Neuroscience*, 14, 3, 314–329, 2023.

[20] European Medicines Agency (EMA), *Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle*, Amsterdam, 30 September 2024; Organisation for Economic Co-operation and Development (OECD), *AI in Health: Huge potential, huge risks*, Paris, 2024; A.J.L. Cross, M.A. Choma, J.A. Onofrey, *op.cit*., 1-19; X. Liu, B. Glocker, M. M. Mccradden, M. Ghassemi, A. K. Denniston, L. Oakden-Rayner, *op.cit.*, e384–e397; S.C. Nouis, V. Uren, S. Jariwala, *op.cit*.

[21] S. Chandrabhanu, S. Hemalatha, *CGAN-Facilitated Data Augmentation of Voice and Speech Parameters for Detecting Parkinson's Disease in the Prodromal Phase*, in *BRAIN – Broad Research in Artificial Intelligence and Neurosci-*

Algorithmic auditing enhances transparency and learning, yet it also confronts the structural dilemma of reconciling openness with intellectual-property protection and the operational burden of continuous verification.

Table 3. Key elements of algorithmic auditing

Phase	Main activities	Objectives
Pre-market	Dataset evaluation; simulation; robustness stress tests	Identify risk, bias, failure modes before release
Post-market	Drift monitoring; real-world KPIs; user feedback	Ensure stability and safety over time
Extraordinary	Root-cause analysis after anomalies/incidents/major updates	Prevent recurrence; improve model and process
Reporting	Summaries with KPIs and fairness metrics	Transparency and multi-actor learning

3.4. Insurance, Risk Pooling and Adaptive HTA

The revised Product Liability Directive (EU) 2024/2853 modernises strict liability, expressly covering software and updates and introducing disclosure/burden-of-proof presumptions relevant to AI-related harm; transposition is due by 9 December 2026.[22] Insurance contracts should recognise software-specific risks: versioning/updates, model drift, data-quality defects and latent bias. Clauses can align premiums to evidence of lifecycle controls—presence of logs, third-party audits, documented datasets and CAPA plans. Adaptive HTA for digital therapeutics should combine pre-market evidence and real-world outcomes, with registry-based agreements and periodic reassessment triggered by substantial updates.[23] Health-system efficiency and sustainability levers include AI-supported simulations for patient flow/cost optimisation and evaluable, outcomes-based digital therapy models (e.g., VR-assisted rehabilitation Randomised Controlled Trial (RCTs), both of which dovetail with risk-based insurance incentives.[24]

Integrating insurance and adaptive HTA introduces economic accountability into the governance chain, but the proportional calibration of premiums and evidentiary thresholds for software risk remains an open challenge for both regulators and markets.

---

ence, 15, 3, 2024; B.S. Philip, D.A. Iordan, *et al.*, *Estimation of Interferences in Magnetoencephalography (MEG) Brain Data Using Intelligent Methods for BCI-Based Neurorehabilitation Applications*, in BRAIN. Broad Research in Artificial Intelligence and Neuroscience, 15, 3, 2024.

[22] European Parliament And Council, *Directive (EU) 2024/2853 on liability for defective products (revised Product Liability Directive)*, in *Official Journal of the European Union*, 2024, 1-41.

[23] W. Nicholson Price Ii, S. Gerke, I.G. Cohen, *op.cit.*, in B. Solaiman, I.G. Cohen (eds.), *op.cit.*, 123-140; Organisation for Economic Co-operation and Development (OECD), *AI in Health: Huge potential, huge risks*, Paris, 2024; L. Gondara, J. Simkin, *A clinical-trial design approach to auditing language models in healthcare settings*, 2024.

[24] K. Cincar, A.A. Minda, M. Varga, *A Simulation-Based Analysis Using Machine-Learning Models to Optimise Patient Flow and Treatment Costs*, in *BRAIN – Broad Research in Artificial Intelligence and Neuroscience*, 15, 3, 2024; R. Dumitrescu, *Medical liability between clinical practice and litigation: a bibliometric thematic analysis*, in *Romanian Journal of Legal Medicine*, 33, 2, 2025, 171-178.

3.5. Bioethical Profiles and Equitable Access

Socialised medicine requires that AI improve safety and dignity without entrenching disadvantage. This implies context-appropriate transparency, meaningful informed consent (including the role of AI in decisions), and user/patient participation in evaluation. Distributional metrics subgroup performance, calibration, error balance-should be part of routine evaluation and reported in plain language. WHO and HLEG guidance reinforce continuous governance as model capabilities evolve.[25] Related literatures on autism spectrum disorders, maternal health in autistic women, dementia, very-early developmental risk, and patient-centred lifestyle approaches highlight consent, communication and equity needs in vulnerable groups that digital tools must respect.[26] Complementary evidence on exercise and occupational/environmental determinants further underlines the importance of proportionate safeguards and accessible explanations when deploying digital health technologies.[27]

Ethical safeguards ensure legitimacy and fairness, yet operationalising equity metrics and meaningful consent across diverse populations requires sustained institutional commitment beyond regulatory compliance.

3.6. General-Purpose and Generative AI (GPAI/LLMs) in Care

Clinicians increasingly interact with general-purpose AI (GPAI) and large language models (LLMs) to draft notes, summarise literature or assist triage. Under the AI Act, GPAI model providers have duties (technical documentation and, for systemic-risk models, model evaluation/reporting). Deployers remain re-

---

[25] World Health Organization, *Ethics and governance of artificial intelligence for health*, Geneva, 2021. High Level Expert Group on Artificial Intelligence, *Ethics guidelines for trustworthy AI*, Brussels, European Commission, 2019; Organisation for Economic Co-operation and Development (OECD), *AI in Health: Huge potential, huge risks*, Paris, 2024; X. Liu, B. Glocker, M.M. Mccradden, M. Ghassemi, A. K. Denniston, L. Oakden-Rayner, *op.cit.*, e384–e397; Z. Obermeyer, E.J. Topol, *op.cit.*, 2038; J. Zhang, Z. Zhang, *op.cit*.

[26] R. Ferrara, R. Nappo, F. Ansermet, P. Ricci, F. Massoni, G. Carbone, A. Sparaci, E. Nonnis, L. Ricci, S. Ricci, *The impact of DSM-5 on the diagnosis of autism spectrum disorder*, in *Psychiatric Annals*, 51, 1, 2020, 38-46; G.M. Troili, R. Businaro, F. Massoni, L. Ricci, L. Petrone, P. Ricci, *et al*., *Investigation on a group of autistic children: Risk factors and medical-social considerations*, in *Clinica Terapeutica*, 164, 4, 2013, e273-e278; P. Ricci, F. Massoni, L. Ricci, E. Onofri, G. Donato, S. Ricci, *Quality of life in dementia sufferers: The role of diet and exercise*, in *Current Alzheimer Research*, 15, 5, 2018, 400-407; R. Ferrara, L. Ricci, P. Ricci, L. Iovino, S. Ricci, F.M. Damato, G. Cicinelli, R. Keller, *How autistic women are aware of their body and take care of their health? Focus on menstruation cycles and gynaecological care*, in *Clinica Terapeutica*, 175, 3, 2024, 168-175; F.M. Damato, P. Ricci, R. Rinaldi, *Informed consent and compulsory treatment on individuals with severe eating disorders: a bio-ethical and juridical problem*, in *Clinica Terapeutica*, 174, 4, 2023, 365-369; R. Ferrara, L. Iovino, R. Latina, A. Avallone, E. Greco, G. Montanari Vergallo, M. Caldararo, P. Ricci, *Adolescent mothers and postpartum depression: a possible connection? A Scoping review*, in *Clinica Terapeutica*, 176, 1, 2025, 81-90; R. Ferrara, L. Iovino, M. Di Renzo, P. Ricci, *Babies under 1 year with atypical development: perspectives for preventive individuation and treatment*, in *Frontiers in Psychology*, 13, 2022; M. V. Rosati, C. Sacco, A. Mastrantonio, G. Giammichele, G. Buonprisco, P. Ricci, G. F. Tomei, F. Tomei, S. Ricci, *Prevalence of chronic venous pathology in healthcare workers and the role of upright standing*, in *International Angiology*, 38, 3, 2019, 201-210; P. Ricci, M. Pallocci, M. Treglia, S. Ricci, R. Ferrara, C. Zanovello, P. L. Passalacqua, F. M. Damato, *The Effect of Physical Exercise during COVID-19 Lockdown*, in *Healthcare*, 11, 11, 2023, 1618.

[27] T. Archer, S. Ricci, F. Massoni, L. Ricci, M. Rapp-Ricciardi, *Cognitive benefits of exercise intervention*, in *Clinica Terapeutica*, 167, 6, 2016, 180-185; M. V. Rosati, A. Sancini, F. Tomei, C. Sacco, V. Traversini, A. De Vita, D. P. De Cesare, G. Giammichele, F. De Marco, F. Pagliara, F. Massoni, L. Ricci, G. Tomei, S. Ricci, *Correlazione tra benzene e testosterone nei lavoratori esposti ad inquinamento urbano*, in *Clinica Terapeutica*, 168, 6, 2017.

sponsible for context-appropriate use in healthcare. Codes of practice are envisaged to operationalise these duties. In clinical settings, deployers should add domain-specific guardrails: constrain prompts to verified sources; require human sign-off; prohibit unsupervised diagnostic/therapeutic recommendations; log prompts/outputs; disclose use to patients in plain language; and route hallucination/unsafe-advice incidents to audit channels. When an LLM is embedded within a device/Clinical Decision Support (CDS), the integrated product must satisfy MDR/IVDR and AI Act logging/oversight duties. Contemporary governance debates around GPAI and superintelligence provide useful risk framings for clinical adoption.[28] WHO guidance on large multimodal models adds safeguards relevant to clinical contexts.[29]

The emergence of general-purpose and generative models blurs the traditional boundaries of medical liability, raising unresolved questions about attribution of error, data provenance and the enforceability of human oversight in hybrid decision processes.

3.7. Data Governance, Privacy and Documentation

Data governance is central to both regimes. Manufacturers and deployers should document provenance, curation, label quality and representativeness of training/validation/test sets; rationales for inclusion/exclusion; handling of missing data and augmentation; and link each dataset to intended use and clinical claims, with subgroup analyses where bias is plausible. Logs should capture inputs, salient context and outputs to enable traceability, incident reconstruction and learning. AI Act obligations complement, not replace, data-protection law; deployers must ensure a lawful basis, purpose limitation, minimisation and security by design.[30]

Despite robust documentation frameworks, the reconciliation of data minimisation, transparency and reproducibility continues to expose friction points between privacy law and the evidentiary needs of clinical AI auditing.

Table 4. Documentation essentials for auditability

Item	Purpose
Data sheet per dataset (provenance, demographics, labelling)	Assess bias/representativeness; support reproducibility
Model card (intended use, performance, limits)	Align expectations; support clinical governance
Change log and versioning	Link updates to evidence and risk assessments

[28] I. Susnea, E. Pecheanu, A. Cocu, S. M. Susnea, *Superintelligence Revisited in Times of ChatGPT*, in *BRAIN – Broad Research in Artificial Intelligence and Neuroscience*, 15, 2, 2024, 344-362.

[29] World Health Organization, *Ethics and governance of AI for health: Guidance on large multimodal models*, Geneva, 2025.

[30] European Parliament and Council, *Regulation (EU) 2024/1689 (Artificial Intelligence Act)*, in *Official Journal of the European Union*, 2024; Id, *Regulation (EU) 2017/745 on medical devices (MDR)*, cit., 2017, 1-175; Id, *Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR)*, cit., 2017, 176-332; European Medicines Agency (EMA), *Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle*, Amsterdam, 30 September 2024; World Health Organization, *Ethics and governance of artificial intelligence for health*, Geneva, 2021; High Level Expert Group on Artificial Intelligence, *Ethics guidelines for trustworthy AI*, Brussels, European Commission, 2019; Organisation for Economic Co-operation and Development (OECD), *AI in Health: Huge potential, huge risks*, Paris, 2024.

Item	Purpose
Post-market monitoring plan with KPIs	Detect drift; trigger CAPA and updates
Incident reporting workflow	Ensure learning and accountability

3.8. Italy Operationalisation under Law 24/2017

Facilities can adopt a three-layer governance model to integrate AI within the Italian liability framework: (i) Clinical governance approves use cases, integrates AI into care pathways and ensures training; (ii) Risk management monitors incidents, oversees audits, liaises with manufacturers/insurers and channels documentation into quality systems; (iii) Ethics/data oversight reviews fairness metrics, consent language and patient communications. Physicians should document the role of AI and justify deviations from AI suggestions. Manufacturers should provide Italian-language Instructions for Use (IFU), performance summaries and known limitations; distributors should assist with updates/vigilance.[31]
The Italian implementation illustrates how national frameworks can translate EU principles into practice, yet its success depends on maintaining flexibility to adapt living guidelines and audit cycles to the rapid evolution of AI technologies.

Table 5. Mapping L. 24/2017 duties to AI governance actions

Legal duty (illustrative)	AI-aligned operational action
Guideline-concordant practice	Adopt living guidelines with AI-specific update triggers
Organisational responsibility	Establish a multidisciplinary audit committee; integrate logs into quality systems
Professional diligence	Train on model scope/limits; document rationale for divergence
Learning from adverse events	Link incident system to AI logs; conduct extraordinary audits and CAPA

4. Discussion

This structure was designed not merely to juxtapose legal and clinical requirements but to show how they co-evolve within a single co-regulatory ecosystem. By tracing the continuity from statutory norms to clinical governance tools, the discussion highlights how abstract principles of fairness, safety and accountability can be operationalised through measurable compliance and audit mechanisms. The analysis also underscores the bidirectional dialogue between academic theorisation and regulatory evolution: scholarly debates on fairness, autonomy and accountability actively inform the design of EU instruments, while emerging legal norms reshape the ethical vocabulary and operational standards of AI governance in medicine.
The AI Act and MDR/IVDR are complementary layers that, if implemented coherently, reduce ambiguity and strengthen safety. MDR/IVDR deliver the clinical safety/performance backbone (classification, clinical evaluation, PMS/PMCF, vigilance), while the AI Act supplies data-governance, logging, human-

[31] W. Nicholson Price Ii, S. Gerke, I. G. Cohen., *op.cit.,* 123-140; Italian Parliament, *Legge 8 marzo 2017, n. 24 (Gelli-Bianco): Disposizioni in materia di sicurezza delle cure e responsabilità professionale*. Gazzetta Ufficiale della Repubblica Italiana, 64, 17 March 2017.

oversight and fairness controls across the lifecycle. Interplay guidance encourages a single, integrated technical file encompassing both.[32]

Three implications follow:

Living guidelines. Static protocols cannot keep pace with adaptive software. Living guidelines should integrate audit outputs and real-world evidence, with explicit triggers for update when performance drifts or the patient mix shifts. EMA's reflection paper points to analogous lifecycle controls in medicines (validation, documentation, monitoring) that can be aligned with device-side governance.[33]

Auditability and contestability. Logs, versioning and declared intended uses are clinical-safety tools. Published summaries of fairness/performance metrics enable scrutiny and patient understanding without compromising trade secrets. Embedded in incident-learning systems, audits drive risk-proportionate CAPA and equitable outcomes.[34]

Liability and insurance. The revised PLD aligns strict liability with software and improves disclosure presumptions. Insurers can accelerate safe adoption by linking cover to demonstrable conformance (external audits; drift monitoring; data governance). This aligns with Italy's risk-management emphasis under Law 24/2017 and supports provider confidence.[35]

Fairness and equity. The moral case for AI in socialised medicine rests on measurable improvements for the least advantage. Unexamined proxies and non-representative data can degrade subgroup performance. Routine subgroup reporting (sensitivity/specificity, calibration error, false-negative gaps) and stakeholder participation must be hard-wired into evaluation and surveillance, as WHO/HLEG/OECD emphasise.[36]

---

[32] European Parliament and Council, *Regulation (EU) 2024/1689 (Artificial Intelligence Act)*, in *Official Journal of the European Union*, 2024, 1-120; Id, *Regulation (EU) 2017/745 on medical devices (MDR)*, cit., 2017, 1-175; Id, *Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR)*, cit., 2017, 176-332; Medical Device Coordination Group (MDCG), *MDCG 2019-11 rev.1: Guidance on Qualification and Classification of Software under MDR/IVDR*, Brussels, European Commission, June 2025; Medical Device Coordination Group (MDCG), AI Board, *MDCG 2025-6 / AIB 2025-1: Interplay between MDR/IVDR and the AI Act*, 19 June 2025; European Medicines Agency (EMA), *Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle*, Amsterdam, 30 September 2024; M. Veale, F. Zuiderveen Borgesius. *op.cit.,* 97-112.

[33] European Medicines Agency (EMA), *Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle*, Amsterdam, 30 September 2024.

[34] Organization for Economic Co-operation and Development (OECD), *AI in Health: Huge potential, huge risks*, Paris, 2024; European Medicines Agency (EMA), *Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle*, Amsterdam, 30 September 2024; X. Liu, B. Glocker, M.M. Mccradden, M. Ghassemi, A.K. Denniston, L. Oakden-Rayner, *op.cit.*, e384–e397; A.J.L. Cross, M.A. Choma, And J.A. Onofrey, *op.cit*., 1-19; S. C. Nouis, V. Uren, S. Jariwala, *op.cit*.

[35] Italian Parliament, *Legge 8 marzo 2017, n. 24 (Gelli-Bianco): Disposizioni in materia di sicurezza delle cure e responsabilità professionale*, in *Gazzetta Ufficiale della Repubblica Italiana*, 64, 17 March 2017; European Parliament and Council, *Directive (EU) 2024/2853 on liability for defective products (revised Product Liability Directive)*, in *Official Journal of the European Union*, 2024, 1-41.

[36] World Health Organization, *Ethics and governance of artificial intelligence for health*, Geneva, 2021; High Level Expert Group on Artificial Intelligence, *Ethics guidelines for trustworthy AI*, Brussels, European Commission, 2019; Organization for Economic Co-operation and Development (OECD), *AI in Health: Huge potential, huge risks*, Paris, 2024; J. Zhang, Z. Zhang, *op.cit*; X. Liu, B. Glocker, M.M. Mccradden, M. Ghassemi, A.K. Denniston, L. Oakden-Rayner, *op.cit.*, e384–e397; Z. Obermeyer, E. J. Topol, *op.cit.*, 2038.

Limitations. This is a doctrinal/policy mapping rather than an empirical trial. Proposed KPIs for audits and HTA/insurance reflect current guidance/literature and will require empirical calibration across domains (radiology, cardiology, oncology, mental health). Dates/duties were anchored in official sources.[37]
Practice points. (i) Build a single integrated technical file satisfying MDR/IVDR and AI Act obligations; (ii) appoint a multidisciplinary audit committee; (iii) publish audit abstracts and fairness dashboards; (iv) link insurance cover to lifecycle compliance; (v) implement living guidelines with update triggers; (vi) train clinicians to document AI use and reasons for divergence.[38]

5. Conclusion

European socialised medicine can integrate AI safely and fairly by treating MDR/IVDR and the AI Act as a single, continuous lifecycle. The law already provides the building blocks: device safety/performance requirements; horizontal AI governance; revised strict product liability; and national regimes such as Italy's Law 24/2017. The operational challenge is to weave these into a co-regulatory cycle living guidelines, algorithmic audits, transparent logging, adaptive HTA and risk-based insurance that preserves professional autonomy and ensures distributive justice. The blueprint offered here integrated documentation; pre/post-market audits with KPIs/fairness metrics; documented oversight and justified deviation; coverage/reimbursement aligned to lifecycle compliance and real-world performance translates ethical imperatives of dignity, transparency and equity into day-to-day governance, turning AI's technical reliability into social reliability.[39]

---

[37] European Parliament and Council, *Regulation (EU) 2024/1689 (Artificial Intelligence Act)*, in *Official Journal of the European Union*, 2024, 1-120; Id, *Regulation (EU) 2017/745 on medical devices (MDR)*, cit., 2017, 1-175; Id, *Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR)*, cit., 2017, 176-332; Id, *Directive (EU) 2024/2853 on liability for defective products (revised Product Liability Directive)*, 2024, 1-41.

[38] W. Nicholson Price Ii, S. Gerke, I. G. Cohen, *op.cit.,* in B. Solaiman, I.G. Cohen (eds.), *op.cit.*, 123-140; European Parliament and Council, *Regulation (EU) 2024/1689 (Artificial Intelligence Act)*, cit., 2024, 1-120; Id, *Regulation (EU) 2017/745 on medical devices (MDR)*, cit., 2017, 1-175; Id, *Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR)*, cit., 2017, 176-332; Medical Device Coordination Group (MDCG), *MDCG 2019-11 rev.1: Guidance on Qualification and Classification of Software under MDR/IVDR*, Brussels, European Commission, June 2025; Medical Device Coordination Group (MDCG), AI Board, *MDCG 2025-6 / AIB 2025-1: Interplay between MDR/IVDR and the AI Act*, 19 June 2025; European Medicines Agency (EMA), *Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle*, Amsterdam, 30 September 2024; World Health Organization, *Ethics and governance of artificial intelligence for health*, Geneva, 2021; High Level Expert Group on Artificial Intelligence, *Ethics guidelines for trustworthy AI*, Brussels, European Commission, 2019; Organisation for Economic Co-operation and Development (OECD), *AI in Health: Huge potential, huge risks*, Paris, 2024; European Parliament and Council, *Directive (EU) 2024/2853 on liability for defective products (revised Product Liability Directive)*, cit., 2024, 1-41; X. Liu, B. Glocker, M.M. Mccradden, M. Ghassemi, A.K. Denniston, L. Oakden-Rayner, *op.cit.*, e384–e397; A.J.L. Cross, M.A. Choma, J.A. Onofrey, *op.cit*., 1-19; S.C. Nouis, V. Uren, S. Jariwala, *op.cit*.

[39] L. Floridi, J. Cowls, M. Beltrametti, *et al*., *op.cit.,* 689–707; B. Mittelstadt, *op.cit.,* 501-507; W. Nicholson Price Ii, S. Gerke, I.G. Cohen, *op.cit*., in B. Solaiman, I.G. Cohen (eds.), *op.cit.*, 123-140; European Medicines Agency (EMA), *Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle*, Amsterdam, 30 September 2024; World Health Organization, *Ethics and governance of artificial intelligence for health*, Geneva, 2021; High Level Expert Group on Artificial Intelligence, *Ethics guidelines for trustworthy AI*, Brussels, European Commission, 2019; Organisation for Economic Co-operation and Development (OECD), *AI in Health: Huge potential, huge risks*, Paris, 2024; European Parliament and Council, *Directive (EU) 2024/2853 on liability for defective products (revised Product Liability Directive)*, cit., 2024, 1-41.

As an original contribution, the proposed co-regulatory cycle can be read as a synthetic conceptual framework that operationalizes the continuum between ethical principles, legal duties and clinical governance, offering a replicable model for the safe and equitable deployment of AI in socialized healthcare systems.