

Scaling Gender-Responsive Digital Health in the European Union: A Policy Commentary

Laura Wagon ^a

School of Medicine, University of St. Gallen, St. Gallen, Switzerland

Laura.bitomsky@student.unisg.ch

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Abstract: Persistent gender inequities in research, innovation, and care continue to shape women's and gender-diverse populations' health across Europe. Gender-responsive digital health (GRDH) seeks to address these gaps by integrating the needs and preferences of all genders into the design, implementation, and evaluation of digital health interventions, yet progress remains constrained by structural, regulatory, and institutional barriers. This commentary examines how current European Union (EU) policies, regulations, and strategies enable or constrain the scalability of GRDH. Ten cornerstone frameworks were reviewed for structural enablers and barriers across the three domains vision and strategy, infrastructure and regulation, and implementation levers. Findings reveal substantial strategic and regulatory coherence, yet persistent asymmetries between normative ambition and operational reality. While the EU has built a strong foundation for digital transformation, institutionalization of gender equity remains limited. Three cross-cutting dynamics are identified that shape Europe's capacity to embed gender equity into digital health governance: policy interdependence, institutional asymmetry, and implementation opportunity. As major frameworks such as the European Health Data Space and AI Act enter implementation, the EU faces a critical window of opportunity to translate its normative commitments into measurable equity outcomes and ensure that digital health is not only innovative, but truly inclusive.

1 INTRODUCTION

Women's health remains underrepresented in research and innovation (Figuroa, Luo, Aguilera, & Lyles, 2021). Conditions such as endometriosis, polycystic ovary syndrome (PCOS), menopause-related disorders, and cardiovascular disease in women remain underdiagnosed, underfunded, and underrepresented in research (Mirin, 2021). This inequity reflects a persistent gender health gap, a systemic imbalance in how knowledge, evidence, and innovation are distributed across sexes and genders (World Economic Forum & McKinsey Health Institute, 2024). Central to this gap is the gender data gap, based on decades of clinical research and health data collection built primarily around male bodies and experiences (Hawkes, Haseen, & Aounallah-Skhiri, 2019; Merone, Tsey, Russell, & Nagle, 2022). Women and gender-diverse populations have been historically excluded from biomedical trials, and health datasets of-

ten fail to capture sex-disaggregated or gender-specific variables (Merone et al., 2022). The result is an enduring bias that shapes diagnostic accuracy, therapeutic effectiveness, and ultimately, health outcomes.

Digital health technologies offer a promising opportunity to close these gaps. From wearables and mobile health applications to telemedicine platforms and AI-assisted diagnostics, digital innovation offers the potential to generate more representative data, expand access to underserved populations, and support personalised prevention and care (Borges do Nascimento et al., 2025; Cummings, Allen, Clennon, Ji, & Druss, 2017; Jacobson, Quist, Lee, & Marsch, 2023; Vishkaie, 2018). This potential is particularly visible in the growing field of digital women's health, which has catalysed new tools for reproductive health, menopause tracking, fertility management, and maternal care (Borges do Nascimento et al., 2025; Vishkaie, 2018).

 <https://orcid.org/0009-0002-9545-0268>

However, digital health technologies are not neutral by design and may risk perpetuating existing gender inequalities or lead to the emergence of new inequalities without intentional safeguards (Borges do Nascimento et al., 2025; Makri, 2019).

Gender-responsive digital health (GRDH) presents a promising opportunity to mitigate these risks. GRDH is used in this commentary as an umbrella term for sex- and gender responsive or sensitive, intersectional approaches. As such, GRDH recognizes and seeks to redress harmful gender norms, roles, and power relations by integrating the needs, rights, and preferences of all genders into the design, implementation, and evaluation of digital health programs (Figuroa et al., 2021; Morgan et al., 2024; Udenigwe, Omonaiye, & Yaya, 2023). Thereby it goes beyond collecting sex- or gender-disaggregated data, aiming to actively challenge and transform the underlying causes of gender-based health inequities, such as unequal access to technology, exclusion from leadership, harmful stereotypes, and structural barriers in technology ecosystems (Figuroa et al., 2021). GRDH does not resolve all structural determinants of gender health inequities, nor can digital tools substitute for broader health system reform. Rather, it intervenes at the level of data generation, governance, design, and implementation, shaping whether digital health innovation amplifies or mitigates existing inequities. As such, GRDH represents a paradigm shift from addressing women's and gender-diverse populations' health as a niche to embedding gender equity across the full spectrum of digital health design, governance, and evaluation.

Despite this transformative potential, scalability remains the Achilles' heel of digital health, and even more so for GRDH given its unique and persistent challenges. Structural barriers such as fragmented data infrastructures, insufficient interoperability, and limited regulatory clarity continue to impede integration into mainstream healthcare systems (Berardi et al., 2024; Borges do Nascimento et al., 2023; Schlieter et al., 2022; Spreafico, Tarricone, & Stern, 2025). Although FemTech companies reached US\$ 2.5bn in funding in 2021, this only represents about 3% of all digital health investments, underscoring its persistent underfunding ("Funding research on women's health," 2024). These obstacles reveal that the challenge is not only technological but systemic. Innovation does not scale in a vacuum but within policy ecosystems that define the terms of data access, safety, trust, and market entry.

Thus, policy frameworks play a critical role in determining whether GRDH can move from aspiration

to implementation (Al Meslamani, 2024). They establish who can share and reuse health data, how algorithms are validated, what evidence is required for regulatory approval, and how public resources are allocated. In the European Union (EU), these determinants are undergoing profound transformation. A series of landmark initiatives (e.g., the European Health Data Space, Artificial Intelligence Act, Data Governance Act, and Data Act) are collectively reshaping how health data, AI, and innovation are governed. Complementary strategies such as the Digital Decade Policy Programme and EU4Health link this regulatory infrastructure to investment and capacity-building priorities. Together, these instruments form a comprehensive digital health reform in the EU, carrying far-reaching implications for inclusion and equity. As these frameworks move from adoption to implementation, the next years constitute a critical window of opportunity. Decisions currently being made on interoperability standards, secondary-use governance, bias monitoring, and funding criteria will determine whether Europe's digital health ecosystem becomes more equitable or inadvertently entrenches existing disparities.

This commentary therefore examines how current EU policies, regulations, and strategies enable or constrain the scalability of GRDH. By analysing ten cornerstone frameworks across strategy, regulation, and implementation, it identifies key enablers and barriers shaping Europe's capacity to scale equitable digital health innovation. In doing so, it argues that closing the gender health gap requires more than technological advancement; it demands embedding equity within the very rules, infrastructures, and incentives that govern digital transformation.

2 METHOD

This commentary adopts a comparative policy analysis (Wee, 2022) to examine how current EU frameworks enable or constrain the scalability of GRDH. The analysis utilises official EU legal and strategy documents combined with secondary sources such as OECD, WHO Europe, EIT Health analyses, and peer-reviewed literature. Throughout, GRDH is deployed as the analytical lens.

2.1 Sampling and Policy Selection

To capture the multi-dimensional governance of digital health, this commentary categorizes EU frameworks into three analytic domains: *Vision & Strategy*, *Infrastructure & Regulation*, and *Implementation*

Levers. This structure is inspired by the policy design and delivery chain (Tomai, Ramani, & Papachristos, 2024) and reflects how political vision translates into regulatory frameworks and into on-the-ground deployment. Policies were chosen according to following criteria: direct relevance to the digital health ecosystem (data, AI, devices, service delivery), current or near-term implementation, and potential equity implications, whether explicit or implicit.

The Vision & Strategy domain includes the *Digital Decade Policy Programme* and the *EU Gender Equality Strategy 2020–2025* (and its post-2025 roadmap). Together they link Europe’s digital transformation goals with its social-equity mandate. The Digital Decade defines how infrastructure, skills, and public services will digitalise, while the Gender Equality Strategy articulates why inclusion and gender-sensitive innovation are essential. Their combination ensures that technological scaling is anchored in societal objectives, supported by Commission-level monitoring mechanisms.

The Infrastructure & Regulation domain encompasses the *European Health Data Space (EHDS)*, *Artificial Intelligence Act (AI Act)*, *Medical Device Regulation (MDR)*, and the *GDPR-Data Governance Act (DGA)-Data Act cluster*. The GDPR, DGA, and Data Act were treated as a single analytical cluster due to their interdependence in shaping data governance within the EU. Together, these instruments operationalise the European Data Strategy (European Commission, 2020a) by establishing coherent rules for data protection, data sharing, and data reuse across sectors. Analysing these together allows for a holistic understanding of how Europe’s data governance regime affects equitable data availability.

Overall, these instruments represent the full digital health infrastructure stack: the data layer (GDPR-DGA-Data Act cluster) governing access, sharing, and protection; the analytics layer (AI Act) establishing algorithmic governance and bias control; the clinical layer (MDR) defining safety and evidence standards; and the integration layer (EHDS) promoting interoperability and secondary data use.

Finally, the Implementation Levers domain includes the *Cross-Border Healthcare Directive* and the *EU4Health Programme*, which translate strategic and regulatory intent into practice through institutional coordination and targeted funding. The directive provides the legal framework for interoperability and patient mobility, while EU4Health serves as the EU’s financial instrument for supporting digital and equity-focused initiatives.

This three-pillar design ensures coverage of the entire governance continuum from vision to regulation and implementation, capturing how political intent, legal frameworks, and implementation mechanisms collectively shape the conditions for scaling equitable and GRDH across Europe.

2.2 Data Extraction and Analysis

Primary sources included EU legislative texts, communications, and impact assessments. Secondary sources included European Parliament briefings, OECD reports, WHO Europe analyses, and peer-reviewed research on digital health and equity.

The analytical process proceeded in three steps. First, policy texts were scanned for explicit references to health equity, gender, or inclusion, and implicit indicators of supportive or constraining mechanisms. Second, key mechanisms likely to facilitate or impede GRDH were extracted, such as interoperability rules, bias auditing, or funding conditions. Finally, extracted mechanisms were organized into a comparative analytic matrix across policy domains, enabling systematic identification and comparison of cross-cutting enablers, barriers, and governance gaps.

This analysis focuses on policy design and governance intent, rather than empirical outcomes at the national or regional level. Since many instruments are still in early implementation stages, the emphasis is on structural readiness and the potential alignment (or misalignment) with equity goals. By synthesising across regulatory, strategic, and implementation domains, the analysis provides a robust overview of how Europe’s governance architecture may shape the potential for scalable and equitable digital health.

3 FINDINGS

In the following, the analysis insights are presented structured along the analytical domains. A synthesis of the findings is visualized in Figure 1.

3.1 Vision & Strategy

3.1.1 Digital Decade Policy Programme – Decision (EU) 2022/2481

As the EU’s overarching digitalization roadmap, the Digital Decade Policy Programme sets measurable targets for skills, infrastructure, digital public services, and digital business transformation by 2030 (European Parliament & Council, 2022a). It requires member states to submit national *Digital Decade*

roadmaps, aligning investments and accountability mechanisms with the EU's broader digital transition.

Contribution to GRDH: The program provides a foundational enabling environment. Its targets for digital infrastructure, connectivity, and digital literacy can create preconditions for equitable participation in digital health ecosystems (Richardson, Lawrence, Schoenthaler, & Mann, 2022). By promoting digital skills and universal connectivity, it may indirectly support the inclusion of women and gender-diverse populations who often face digital access barriers (Figueroa et al., 2021; Mariscal, Mayne, Aneja, & Sorgner, 2019). Moreover, its monitoring mechanism, the *State of the Digital Decade* report, could become a useful accountability tool for tracking gender-responsive digital progress.

Shortcomings: Its non-binding nature limits its capacity to enforce equity outcomes. The program does not mandate gender-disaggregated monitoring, and member states retain discretion over national targets and reporting methods. Consequently, while the framework aligns national efforts and provides an enabling environment for GRDH, it lacks mechanisms to ensure that gender-responsive considerations are systematically integrated.

3.1.2 EU Gender Equality Strategy 2020–2025 (and Successor Roadmap)

The Gender Equality Strategy establishes gender equality as a cross-cutting policy objective across all EU domains, aiming to achieve a “Union of Equality” (European Commission, 2020b). It explicitly highlights technology, digitalization, and AI as areas requiring attention to bias and discrimination, setting a normative foundation for embedding gender equity in emerging policy fields.

Contribution to GRDH: While the original 2020–2025 roadmap did not address health in detail, it provided political and institutional support for embedding gender within digital health calls, funding criteria, and evaluation frameworks. The Roadmap for Women's Rights (European Commission, 2025b) adopted in March 2025 as a successor sets core principles and policy objectives, of which one directly refers to health. Principle 2 states that “Every woman has a right to the highest attainable standards of physical and mental health” (European Commission, 2025a), explicitly referring to gender-sensitive principles in its sub-dimensions. As such, the roadmap can play an important normative and institutional role in enabling GRDH.

Shortcomings: Its main weakness is its enforceability. The roadmap is not legally binding, and responsibility for implementation lies within each EU state's discretion. There are no sanctions or binding

targets for gender equity in digital health, and monitoring relies on voluntary reporting. As such, the strategy functions more as a political compass than as a technical lever, as it legitimizes the pursuit of GRDH but does not guarantee it.

3.1.3 Synopsis

Together, the Digital Decade and Gender Equality Strategy articulate the EU's strategic vision for an inclusive digital transformation. However, both rely on political persuasion rather than enforceable obligations and lack concrete pathways, instruments, or operational mechanisms for achieving these goals. As such, they depend on regulatory and financial instruments to translate vision into measurable GRDH outcomes.

3.2 Infrastructure & Regulation

3.2.1 European Health Data Space (EHDS) – Regulation (Eu) 2025/327

The EHDS establishes a common legal, technical and governance framework for both primary use (healthcare delivery) and secondary use (research, innovation, policymaking) of electronic health data across member states. The regulation introduces the MyHealth@EU infrastructure for cross-border data exchange and creates Health Data Access Bodies (HDABs) responsible for authorising data reuse (European Parliament & Council, 2025).

Contribution to GRDH: The EHDS could be a key structural enabler. It promotes interoperability, standardised data formats, and legal clarity for cross-border access, all of which is essential for collecting and analysing representative datasets (Gyrard et al., 2025; Martins, Lewerenz, Carmo, & Martins, 2025). The regulation's provisions on data subject rights (e.g., access, rectification, opt-out) may enhance trust and participation among underrepresented populations. As such, if implemented with equity safeguards, the EHDS could address elements of the gender data gap by expanding access to high-quality, disaggregated health data for research and innovation.

Shortcomings: Key barriers remain. Roll-out will be phased through 2025–2031, and disparities in national digital maturity persist (Pinto, Nogueira, & Vieira, 2023). Without explicit requirements for sex-disaggregated or equity-related variables, there is a risk that existing data biases could be replicated at scale. The regulation's success for GRDH will therefore depend on how implementing acts operationalise inclusion, particularly through metadata standards and governance criteria.

Included policies		Key contributions to GRDH	Key shortcomings
Vision & Strategy	<i>Digital Decade Policy Programme</i>	Creates enabling conditions through digital infrastructure, connectivity, skills, and accountability mechanisms	Non-binding with limited gender-specific monitoring
	<i>EU Gender Equality Strategy 2020–2025</i>	Positions gender equality as an EU-wide priority with digital-health relevance	Non-binding framework with voluntary, member-state-driven implementation
Infrastructure & Regulation	<i>European Health Data Space (EHDS)</i>	Creates interoperable cross-border data infrastructure enabling trusted, representative datasets	No explicit requirement for sex- or gender-disaggregated variables, with uneven national readiness
	<i>GDPR-Data Governance Act (DGA)-Data Act Cluster</i>	Creates trustworthy, privacy-enhancing data environments supporting responsible reuse	Data minimization, purpose limitation, and anonymization may constrain linking sex- or gender-disaggregated information
	<i>Artificial Intelligence Act (AI Act)</i>	Imposes strict data, fairness, and accountability standards	High compliance burdens may disadvantage smaller GRDH innovators
	<i>Medical Device Regulation (MDR)</i>	Sets EU-wide safety, efficacy, and transparency standards for digital health devices	No sex-disaggregated clinical evidence or subgroup monitoring requirements and high cost burdens
Implementation Levers	<i>Cross-Border Healthcare Directive</i>	Facilitates cross-border care access, interoperability, and continuity of services	Outdated scope with uneven national implementation and no gender-equity focus
	<i>EU4Health Programme</i>	Finances digital tools and can embed gender-responsive funding criteria	Complex, competitive funding with no explicit global gender requirements

Figure 1: Synthesis of policy analysis.

3.2.2 GDPR-DGA-Data Act Cluster

Together, the General Data Protection Regulation (GDPR) (European Parliament & Council, 2016), the Data Governance Act (European Parliament & Council, 2022b), and the Data Act (European Parliament & Council, 2023) form the EU's data-governance backbone, providing the legal foundation for data protection, sharing, and reuse.

Contribution to GRDH: The cluster's main contribution to GRDH lies in establishing trustworthy and transparent data environments. GDPR protects individuals' rights to privacy and consent. The DGA enables controlled data sharing through trusted intermediaries and data altruism mechanisms, which could enable voluntary contributions of gender-relevant data for research. The Data Act extends data-access rights to non-personal and co-generated data, including those from connected medical devices and wearables, potentially diversifying the data ecosystem underpinning GRDH innovation. Collectively,

these frameworks foster legal certainty and interoperability, supporting responsible data reuse, all of which essential for equitable digital innovation (Gyrard et al., 2025; Martins et al., 2025; O'Neil, Taylor, & Sivasankaran, 2021).

Shortcomings: The frameworks' protective orientation could also pose barriers to inclusivity. Divergent national enforcement, complex consent requirements, and uncertainty around lawful reuse may discourage organisations, particularly smaller GRDH innovators, from leveraging existing datasets. The GDPR principles of data minimization, purpose limitation, and consent requirements as well as anonymization requirements may inadvertently be perceived to limit the ability to link sex- and gender-disaggregated information, constraining bias detection and subgroup analysis. To reconcile data protection with equity, sector-specific guidance and regulatory sandboxes could facilitate lawful, inclusive data reuse models.

3.2.3 Artificial Intelligence Act (AI Act) – Regulation (EU) 2024/1689

The AI Act is the first comprehensive regulatory framework for AI globally, classifying health-related AI systems as “high-risk” and subjecting them to strict requirements for data governance, transparency, human oversight, and post-market monitoring (European Parliament & Council, 2024). The regulation also references the Ethics Guidelines for Trustworthy AI (European Commission, 2019), which explicitly includes a principle on diversity, non-discrimination and fairness.

Contribution to GRDH: The AI Act creates binding obligations for algorithmic accountability. By requiring quality management systems, bias testing, and documentation of training data, it strengthens safeguards against gender bias in AI-driven health applications. These provisions offer a promising foundation for trustworthy AI in healthcare and could enhance user confidence in GRDH technologies.

Shortcomings: The benefits also come with compliance burdens. Conformity assessment, documentation, and certification costs may disproportionately affect small and medium-sized enterprises (Aboy, Minssen, & Vayena, 2024), including start-ups specialising in GRDH. As such, the AI Act could unintentionally constrain smaller GRDH actors unless accompanied by guidance and capacity-building measures tailored to the health sector.

3.2.4 Medical Device Regulation (MDR) – Regulation (EU) 2017/745

The MDR standardises safety, clinical evidence, and post-market surveillance for medical devices, including software-as-a-medical-device (European Parliament & Council, 2017).

Contribution to GRDH: The MDR provides a stable regulatory pathway to market for digital health products, ensuring that safety and efficacy standards apply consistently across member states. Transparency mechanisms, such as the database on medical devices EUDAMED², can improve accountability and could build user trust in digital tools addressing women's and gender-minority health.

Shortcomings: The regulation remains largely gender-neutral, since it does not explicitly require

sex-disaggregated clinical evidence or subgroup performance monitoring. High evidence requirements and related costs may deter smaller GRDH innovators, especially for niche or intersectional subgroups (Aboy et al., 2024). Moreover, overlap and ambiguity between MDR and AI Act may add additional burden to developers and providers of AI-backed medical devices as they will have to conform to both regulatory requirements (Aboy et al., 2024). To leverage the MDR for GRDH, regulators should require disaggregated evidence and post-market data as part of conformity and surveillance obligations as well as dedicated support options for smaller organisations or medical devices targeting gender-minorities.

3.2.5 Synopsis

Across all regulatory instruments, the EU has built a robust legal infrastructure to promote trustworthy, interoperable, and data-driven digital health. However, while regulations are technically comprehensive, few embed explicit gender or equity requirements. Thus, these frameworks strengthen downstream safeguards such as bias monitoring and accountability but remain less equipped to address upstream biases in data generation, including underrepresentation in clinical studies and digital data capture. As such, the challenge ahead lies not in legislation design, but in ensuring that implementation processes translate neutrality into inclusivity, especially for those regulations that are still in early implementation.

3.3 Implementation Levers

3.3.1 Cross-Border Healthcare Directive – Directive 2011/24/EU

The Cross-Border Healthcare Directive establishes patient rights to access care in other member states and to be reimbursed under specific conditions (European Parliament & Council, 2011). It also created the eHealth Network, which coordinates the development of interoperability standards for services such as e-prescriptions and patient summaries through MyHealth@EU³.

Contribution to GRDH: The directive's main contribution lies in its support for cross-border interoperability and patient mobility, which could re-

² EUDAMED is the European database on medical devices, a centralized IT system established by the EU to strengthen transparency, traceability, and market surveillance for medical devices across Europe (<https://ec.europa.eu/tools/eudamed>)

³ MyHealth@EU is the European Union's digital infrastructure that enables secure, cross-border access to health data, such as electronic prescriptions and patient summaries, allowing EU citizens to access and manage their health information across member states.

duce access disparities for specialised or gender-specific care. By providing a legal framework for electronic data exchange, it enables continuity of care for individuals using digital health services across borders.

Shortcomings: Its scope remains narrow. Its provisions pre-date widespread telemedicine, digital therapeutics, and AI-based services. National implementation remains uneven, and there is no explicit reference to equity or gender considerations in reporting requirements (European Commission, 2022). Updating the directive or issuing interpretative guidance aligned with the EHDS could enhance its role as a governance mechanism for equitable digital service delivery.

3.3.2 Eu4health Programme – Regulation (EU) 2021/522

EU4Health is the EU’s flagship health funding instrument for 2021–2027, with a budget of €4.4 billion (European Parliament & Council, 2021). Its objectives include reinforcing health data, digital tools and services, supporting digital transformation of healthcare as well as enhancing access to healthcare.

Contribution to GRDH: EU4Health represents a direct financial lever to support scaling. It can further incentivise equity by embedding gender-responsive criteria into funding calls and evaluation frameworks, requiring gender-disaggregated data, inclusion objectives, or underserved population reach.

Shortcomings: Persistent administrative and structural barriers remain. Co-funding requirements and complex application procedures may disproportionately affect smaller or less resourced organisations focusing on GRDH. Without explicit gender indicators and sustainability criteria, funded projects may default to general digital health, not inclusion. Finally, the volume of funds is limited, resulting in high competition. Overall, integrating gender-responsive budgeting and evaluation criteria could substantially enhance the program’s contribution to translating regulatory and strategic aspirations into real-world GRDH impact.

3.3.3 Synopsis

Overall, implementation mechanisms such as the Cross-Border Healthcare Directive and EU4Health operationalise Europe’s digital and equity ambitions. Yet, they remain constrained by legacy frameworks and limited gender-specific focus. As the “translation layer” between vision and regulation, their evolution will determine whether GRDH transitions from pilot projects to sustainable practice.

4 DISCUSSION

This commentary set out to examine how current EU policies, regulations, and strategies enable or constrain the scalability of GRDH by analysing cornerstone frameworks across strategy, regulation, and implementation. Analysis revealed a high degree of strategic and regulatory coherence within Europe’s digital health ecosystem, yet also persistent gaps in translating inclusion principles into operational practice. Overall, the frameworks form a strong institutional backbone for digital transformation but remain unevenly equipped to advance GRDH. Across the policy landscape, three cross-cutting dynamics emerged that may influence the scalability of GRDH: *policy interdependence*, *institutional asymmetry*, and *implementation opportunity*.

4.1 Policy Interdependence

The EU’s digital health governance functions as a multilayered, interdependent policy system. For example, the EHDS depends on the broader data-governance environment created by the GDPR, Data Governance Act (DGA), and Data Act to make lawful data reuse for research and innovation possible. The AI Act and MDR overlap in regulating AI-based medical tools, while the Digital Decade Policy Programme and EU4Health provide the strategic and financial scaffolding that enable deployment. This coherence enhances legal certainty, creates consistent expectations for data stewardship, and builds a shared foundation for trust and interoperability across member states.

However, this interdependence also creates structural dependencies; delays or inconsistencies in one framework may reverberate across others. For GRDH, this interconnectedness means that embedding gender responsiveness requires alignment across the entire policy stack, from data standards, AI validation procedures, funding criteria, and monitoring indicators, to ensure that gender responsiveness is not lost in translation between policy layers. Achieving this form of cross-policy integration is critical to prevent well-intentioned regulatory instruments from reinforcing existing inequities through fragmented implementation.

4.2 Institutional Asymmetry

While regulatory and strategic frameworks are formally aligned, their treatment of equity and gender remains uneven. Hard-law instruments such as the EHDS, AI Act, and MDR prioritise data protection,

safety, and interoperability but contain few binding provisions on sex-disaggregated data, gender-responsive design, or performance monitoring across demographic subgroups. Conversely, soft-law strategies such as the Gender Equality Strategy and the Digital Decade Policy Programme articulate strong normative commitments but lack enforcement mechanisms. This creates an asymmetry between what is politically envisioned and what is legally operationalised.

Additionally, national disparities in digital health readiness may lead to capacity asymmetries. Member states differ substantially in digital maturity (Tutak & Brodny, 2022), which may risk producing uneven benefits, particularly for groups already facing structural disadvantage, undermining the benefits of EU-level innovation. To ensure equitable scaling, regulation must be accompanied by capacity-building initiatives that strengthen institutional capabilities in lagging regions.

Finally, regulatory burden and innovation access may contribute to market asymmetries. Regulatory compliance, especially with the AI Act and MDR, requires significant technical and financial resources, which may disadvantage or discourage smaller or less resourced organisations developing niche GRDH solutions. To avoid a regulatory chilling effect, proportional implementation pathways, regulatory sandboxes, and targeted financial instruments will be essential. Without such provisions, innovation in gender-responsive domains may inadvertently be pushed to the sidelines.

4.3 Implementation Opportunity

The EU now enters a decisive phase in which most major instruments (the EHDS, AI Act, Data Act, and EU4Health) are moving from adoption to implementation. This creates a rare window of opportunity to embed gender-responsive standards before operational practices and market norms become fixed.

Because many of the details will be defined through implementing acts, technical standards, and funding work programs, there is still scope to integrate equity-related provisions. Examples could include mandating gender indicators in the State of the Digital Decade reporting framework, requiring sex- and gender-disaggregated data fields within EHDS secondary-use permits and metadata standards, or integrating equity-based eligibility criteria within EU4Health funding calls and evaluations. Moreover, phased rollouts and pilot projects (e.g., under EU4Health or national digital health strategies) could serve as gender-responsive test beds, generating empirical evidence on what works for equitable scaling

while allowing proportional compliance pathways for smaller or less resourced organizations.

Therefore, the current momentum offers an opportunity to align technological governance with social accountability before institutional routines become fixed.

Across these dynamics, a clear pattern emerges. The EU's digital health governance is technically mature but socially incomplete. Its success in scaling GRDH will depend on whether policy interdependence becomes a source of coherence or constraint, whether institutional asymmetries are corrected through binding accountability, and whether the implementation window is used to hard-wire equity into Europe's digital health architecture. By embedding equity into the operational DNA of its digital transformation, the EU can demonstrate that technological progress and social justice are not parallel goals but interdependent conditions of sustainable innovation.

While this commentary adopts an intersectional understanding of GRDH, the analysis primarily focuses on gender due to the scope and structure of current EU policy instruments. Gender intersects with multiple social determinants of health such as migration status, socioeconomic position, disability, and age in shaping digital health access and outcomes. However, these dimensions are unevenly operationalized across EU frameworks. Future work could examine how intersectional equity indicators can be more systematically embedded into digital health governance. Furthermore, this commentary synthesizes insights from across major EU digital health frameworks, it remains primarily a policy-level analysis based on publicly available legislative and strategic sources. As such, it cannot capture the full diversity of national implementation contexts or the empirical outcomes that will emerge as these instruments mature. In practice, the EU's 27 member states vary widely in their levels of digitalization, governance structures, infrastructure readiness, and interoperability capacity (Pinto et al., 2023), with particularly pronounced divides between Northern, Southern, and Eastern European health systems. For example, Nordic countries such as Finland and Estonia have achieved advanced eHealth integration (Ardielli, 2020), while several southern and eastern member states continue to face infrastructural and literacy barriers to digital implementation (Ćwiklicki, Schiavone, Klich, & Pilch, 2020; Tornero Costa et al., 2025). Recent WHO and EU analyses further highlight governance disparities, noting that while over 80% of European states report having national digital health strategies, implementation and monitoring

mechanisms remain uneven across regions (Fernandes, Chaltikyan, Adib, Caton-Peters, & Novillo-Ortiz, 2024). Thus, future research and monitoring efforts should therefore evaluate how gender-responsive provisions are enacted in practice across member states. Nonetheless, by identifying structural patterns and governance levers, this analysis provides a foundation for such follow-up work and highlights where early adjustments could result in long-term equity benefits.

Overall, the coming years represent a defining moment for Europe's digital health governance. As the EHDS, AI Act, and related frameworks move from theory to practice, the EU has the rare chance to hard-wire fairness, representation, and accountability into the infrastructures that will underpin 21st-century healthcare. Doing so could not only close the gender data gap but also strengthen public trust, innovation legitimacy, and the overall resilience of Europe's health systems, ensuring that digital health is not only for all, but truly equitable for all.

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