Cyprus University of Technology | Faculty of Health Sciences

Doctoral Dissertation

Repositioning Bioethics in Digital Health Innovation Ecosystems:
A Human-Rights Grounded Educational Architecture for Ethical Learning

Georgia E. Livieri

Limassol, June 2026

CYPRUS UNIVERSITY OF TECHNOLOGY
FACULTY OF HEALTH SCIENCES
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Approval Form

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Cyprus University of Technology
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«Ἐς γῆν ἐναλίαν Κύπρον, οὗ μ' ἐθέσπισεν οἰκεῖν Ἀπόλλων...»
Ευριπίδης, «Ελένη», στίχοι 148-150.

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I dedicate this dissertation to my two sons, *Faidon (10 years old) and Evangelos (10 months old)*, with the hope that it may stand as a lighthouse, guiding and inspiring them along their own paths.

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STATEMENT ON THE USE OF ARTIFICIAL INTELLIGENCE TOOLS

The author takes full responsibility for the content of this dissertation. Generative artificial intelligence tools, specifically ChatGPT (OpenAI), were used to support language editing, grammar correction, and brainstorming processes during the preparation of the manuscript. In addition, AI-based tools, such as Napkin.ai, were used for the visualisation of concepts and the creation of illustrative figures.

AI tools were also used to assist in the organisation and formatting of tables, as well as to support aspects of data handling related to questionnaire responses from experts and end-users. All outputs were critically reviewed, validated, and interpreted by the author. No content was included without human evaluation, and all substantive ideas, analyses, interpretations, and conclusions are the sole responsibility of the author.

The use of artificial intelligence tools in this dissertation was conducted in accordance with the relevant academic integrity and artificial intelligence guidance provided by the Cyprus University of Technology Library AI Guidelines.

ΠΕΡΙΛΗΨΗ

Η παρούσα διδακτορική διατριβή εξετάζει μία κεντρική πρόκληση της ψηφιακής υγείας: τη μετάφραση αφηρημένων ηθικών αρχών σε πρακτικά και λειτουργικά εργαλεία που μπορούν να υποστηρίξουν την ηθική μάθηση και τον ηθικό αναστοχασμό σε διαφορετικά επαγγελματικά περιβάλλοντα. Σκοπός της μελέτης ήταν η ανάπτυξη ενός λειτουργικού και ανθρωποκεντρικού "Πλοηγού Ηθικής", ικανού να ενσωματώνει την ηθική σκέψη στις πραγματικές εφαρμογές της ψηφιακής υγείας.

Για την επίτευξη του σκοπού εφαρμόστηκε μία πολυφασική, αναπτυξιακή και μικτή μεθοδολογική προσέγγιση. Αρχικά, συλλέχθηκαν, συντέθηκαν και αναλύθηκαν συστηματικά δημοσιευμένα δεδομένα σχετικά με τα ηθικά κενά και τις προκλήσεις που βιώνουν ασθενείς και επαγγελματίες υγείας στο πλαίσιο της ψηφιακής υγείας. Τα ευρήματα αυτά μεταφράστηκαν σε δομημένες και σχεδιαστικά αξιοποιήσιμες διαστάσεις προβλημάτων. Στη συνέχεια, τα δεδομένα αυτά αξιοποιήθηκαν για την ανάπτυξη της αρχικής αρχιτεκτονικής του συστήματος (Alpha), η οποία βελτιώθηκε επαναληπτικά μέσω διαδικασίας αξιολόγησης από ειδικούς, οδηγώντας στην ανάπτυξη της αρχιτεκτονικής (BETA) και της εκπαιδευτικής της εκδοχής (BETA-EDU). Τέλος, η αξιολόγηση από τελικούς χρήστες προερχόμενους από έξι διαφορετικούς τομείς επέτρεψε την αναγνώριση αναγκών που σχετίζονται με το εκάστοτε πλαίσιο εφαρμογής και τη διαμόρφωση διατομεακών απαιτήσεων, καταλήγοντας στην τελική αρχιτεκτονική (Gamma).

Τα ευρήματα καταδεικνύουν ότι οι ηθικές προκλήσεις στην ψηφιακή υγεία είναι άμεσα εξαρτώμενες από το εκάστοτε πλαίσιο και απαιτούν προσαρμοστικές και ανθρωποκεντρικές λύσεις. Η τελική αρχιτεκτονική συνιστά ένα επεκτάσιμο, πολυεπίπεδο και αρθρωτό σύστημα, το οποίο ενσωματώνει την ηθική συλλογιστική, τη χρηστικότητα και τη διατομεακή εφαρμοσιμότητα. Η διατριβή συμβάλλει στο πεδίο της ηθικής της ψηφιακής υγείας, επαναπροσδιορίζοντας την ηθική ως διαδικασία καθοδηγούμενου αναστοχασμού και προτείνοντας έναν συγκεκριμένο, εφαρμοστικά προσανατολισμένο Πλοηγό Ηθικής για την υποστήριξη της ηθικής πρακτικής σε σύνθετα κοινωνικο-τεχνολογικά περιβάλλοντα.

Λέξεις-κλειδί: «ηθική της ψηφιακής υγείας», «ηθική εκ σχεδιασμού», «ανθρώπινα δικαιώματα στην υγεία», «ηθικός αναστοχασμός βασισμένος σε σενάρια», «μικτές μέθοδοι».

ABSTRACT

This dissertation addresses a central challenge in digital health: the translation of abstract ethical principles into practical, usable tools that can support ethical learning across diverse professional contexts. The study aimed to develop an operational, user-centred ethics navigator capable of embedding ethical reflection into real-world digital health practices.

A multi-phase, design-oriented mixed methodology was employed. First, published evidence on ethical gaps and challenges experienced by patients and healthcare professionals was systematically collected, synthesized and translated into structured, design-relevant problem dimensions. Second, these insights informed the development of an initial (Alpha) architecture, which was iteratively refined through expert validation, leading to the BETA architecture and its educational (BETA-EDU) version. Third, end-user engagement across six relevant sectors enabled the identification of context-specific needs and cross-sector requirements, culminating in the final (Gamma) architecture.

The findings demonstrate that ethical challenges in digital health are context-dependent and require adaptive, user-centred solutions. The resulting architecture provides a scalable, modular, and layered system that integrates ethical reasoning, usability, and cross-sector applicability. This work contributes to digital health ethics by reframing ethics as a process of guided reflection and by offering a concrete, implementation-oriented ethics navigator to support ethical practice in complex socio-technical environments.

Keywords: “digital health ethics”, “ethics-by-design”, “human rights in healthcare”, “scenario-based ethical reflection”, “mixed methods”.

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LIST OF ABBREVIATIONS

Abbreviation	**Meaning**
AI:	Artificial Intelligence
API:	Application Programming Interface
CMS:	Content Management System
COVID-19:	Coronavirus Disease 2019
CRAs:	Clinical Research Associates
CUT:	Cyprus University of Technology
DHI:	Digital Health Intervention
DHIs:	Digital Health Interventions
DHT:	Digital Health Technology
DHTs:	Digital Health Technologies
EFPIA:	European Federation of Pharmaceutical Industries and Associations
EHDS:	European Health Data Space
HER:	Electronic Health Record
EHRs:	Electronic Health Records
EMR:	Electronic Medical Record
EMRs:	Electronic Medical Records
EPRs:	Electronic Personal Records
EU:	European Union
FAQ:	Frequently Asked Questions
GDPR:	General Data Protection Regulation
GPs:	General Practitioners
GPAI:	General-Purpose Artificial Intelligence
HCPs:	Healthcare Professionals
HIEs:	Health Information Exchanges
HTA:	Health Technology Assessment
ICT:	Information and Communication Technology
ICTs:	Information and Communication Technologies
IT:	Information Technology
KPIs:	Key Performance Indicators
LMS:	Learning Management System
LMICs:	Low- and Middle-Income Countries
mHealth:	Mobile Health
mHealth apps:	Mobile Health Applications
NGO:	Non-Governmental Organization
NGOs:	Non-Governmental Organizations
NIS2:	Network and Information Security Directive 2 (EU)

Abbreviation	**Meaning**
PGHD:	Patient-Generated Health Data
PICO:	Population, Intervention, Comparison, and Outcome
PRISMA:	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PROs:	Patient-Reported Outcomes
R&D:	Research and Development
SSO:	Single Sign-On
UCD:	University College Dublin
UNESCO:	United Nations Educational, Scientific and Cultural Organization
UX/UI:	User Experience / User Interface
WHO:	World Health Organization

GLOSSARY

Alpha, BETA, BETA-EDU, and Gamma architectures: Successive developmental architectures of the BRAIN health-tech Ethics Navigator created through the iterative phases of this research. The terms are intentionally retained to distinguish different stages of conceptual, structural, and educational refinement throughout the dissertation. The capitalisation of BETA and BETA-EDU is purposefully maintained to denote the expanded and educationally oriented forms of the architecture.

BETA Architecture: The BETA Architecture is the refined version of the BRAIN Health-Tech Ethics Navigator, developed after expert validation and feedback analysis. It represents the consolidated structural design of the navigator, integrating its ethical foundations, procedural logic, functional components, and governance mechanisms into a coherent multi-layer architecture. The BETA version preserves the navigator's core ethical principles while incorporating improvements aimed at enhancing clarity, usability, and practical applicability. As such, it serves as the validated analytical configuration of the Ethics Navigator, providing the basis for further adaptations, including its educational extension (BETA-EDU).

BETA-EDU Architecture: The BETA-EDU Architecture refers to the educational re-architecture of the beta version of the BRAIN Health-Tech Ethics Navigator. It represents the pedagogical adaptation of the validated navigator, restructuring its analytical components into a staged learning design that supports ethical literacy, reflective reasoning, and facilitated discussion. While preserving the navigator's core ethical foundations, such as the five axons, associated challenges, and underlying principles, the BETA-EDU architecture reframes technical and analytical elements into learning-oriented formats, including scenario-based deliberation, stakeholder perspective analysis, and reflective synthesis. This configuration positions the navigator as a structured educational tool for teaching and training in digital health ethics rather than as a decision-support or compliance instrument.

BRAIN health-tech Ethics Navigator (alpha version): An Ethics Navigator refers to a structured tool developed in this thesis to guide users through systematic ethical deliberation, reflection, and learning in the context of digital health. It is designed to navigate individuals and stakeholders through ethically relevant questions, considerations, and prompts derived from empirically identified gaps and challenges in digital health use. Grounded in the experiences and perceptions of patients and healthcare professionals, the Ethics Navigator translates identified empirical challenges into guided reflection pathways that facilitate critical engagement, ethical awareness, and responsible practice. Rather than prescribing fixed solutions, the tool supports users in navigating complex ethical landscapes by encouraging structured inquiry, contextual sensitivity, and reflective learning.

Challenge: In this systematic review, a challenge refers to any reported barrier, concern, limitation, or contextual difficulty affecting the adoption, implementation, experience, or outcomes of digital health use, as perceived by patients and healthcare professionals. Operationally, challenges were identified through explicit references to barriers, fears, mismatches between user needs and technological solutions, perceived risks, downsides, concerns, potential pitfalls, or structural and organisational limitations.

Educational: In the context of this study, educational refers broadly to activities, structures, or resources designed to support learning, knowledge development, and ethical awareness. Educational elements aim to facilitate understanding of concepts, frameworks, and practical implications, enabling learners to engage with complex topics, such as digital health ethics, in an accessible, structured way. Within the Ethics Navigator, the educational orientation refers to adapting the navigator to support teaching, training, and capacity-building across diverse learner groups.

Gamma Architecture: Final implementation-oriented and stakeholder-informed architecture of the BRAIN health-tech Ethics Navigator developed following end-user engagement across multiple sectors. The Gamma architecture represents the most mature and scalable version of the system, integrating empirical evidence, expert refinement, usability considerations, cross-sector requirements, and educational functionality into a modular and adaptable ethical support architecture.

Gap: In the context of this systematic review, a gap refers to an identified absence, insufficiency, or unmet need in relation to the use of digital health technologies, as perceived by patients and healthcare professionals. Operationally, relevance was determined based on explicit references to a "lack of" evidence, resources, competencies, infrastructure, regulatory clarity, usability, accessibility, or structured implementation support, as well as articulated "needs for" improvement or further development.

Health Public Intelligence Recommender: A structured recommendation-generating mechanism developed in this thesis to translate empirically identified challenges in digital health use into actionable ethical guidance. The term denotes a system that synthesises collective experiential evidence ("public intelligence") derived from patients and healthcare professionals and produces context-sensitive recommendations to support ethics deliberation, reflection, and learning. In this study, the Health Public Intelligence Recommender was conceptually grounded in the empirical mapping of gaps and challenges identified through a systematic review. These challenges served as the foundational inputs for generating structured prompts and guidance aimed at supporting ethical awareness, decision-making, and responsible digital health implementation.

Pedagogical: Pedagogical refers more specifically to the methods, strategies, and design principles used to facilitate effective learning and teaching. Pedagogical elements focus on how learning is structured, delivered, and experienced, including the use of learning stages, reflective prompts, scenario-based exercises, and participatory discussion. In the context of the BETA-EDU architecture, pedagogical adaptation involves restructuring the Ethics Navigator's analytical components into guided learning pathways that promote ethical reasoning, critical reflection, and stakeholder perspective-taking.

ORIGINALITY OF THE THESIS

This dissertation contributes to the field of digital health ethics by moving beyond the development of abstract ethical principles toward the creation of an implementation-oriented educational ethics architecture. While existing approaches in digital health ethics predominantly focus on normative frameworks, guidelines, or principle-based recommendations, this study addresses the persistent gap between ethical theory and practical application in real-world healthcare technology environments.

The originality of the thesis lies primarily in the development of the BRAIN Health-Tech Ethics Navigator, a structured and user-oriented system designed to support ethical reflection, learning, and decision support across diverse digital health contexts. Rather than proposing an additional set of ethical principles, the study operationalises existing ethical and human rights commitments into a navigable architecture that translates ethical concerns into practical pathways, contextual challenges, graded scenarios, and structured recommendations.

The study's iterative and multi-phase methodological approach further contributes to the thesis originality in that the architecture was not developed solely through theoretical reasoning but emerged progressively through the integration of:

1. published evidence on ethical challenges in digital health,
2. expert validation and architectural refinement, and
3. end-user engagement across multiple sectors involved in healthcare technology.

This process enabled the architecture to evolve from an initial conceptual model into a more robust, scalable, and context-sensitive system grounded in empirical evidence and stakeholder perspectives.

The thesis further contributes by introducing a stakeholder-sensitive and challenge-oriented structure. Ethical issues are not treated as universal or static concerns but are organised according to distinct user perspectives, particularly those of patients and healthcare professionals, and across thematic domains such as human values, data and algorithmic transparency, governance and accountability, equity and sustainability, and clinical integrity. This layered structure allows ethical reflection to remain adaptable to varying technological, institutional, and sociocultural contexts.

Another important contribution is the educational orientation of the navigator. The architecture conceptualises ethics not as a compliance exercise but as a process of guided ethical reasoning and ethical capacity-building. Through scenario-based learning, structured navigation, and risk-oriented recommendations, the system supports the development of ethical literacy and practical judgment among users operating in digitally mediated healthcare environments.

Finally, the study contributes to the broader field of digital health implementation research by demonstrating how ethical reflection can be embedded into system design through an interdisciplinary, human rights-informed, and implementation-oriented process. The resulting Gamma architecture represents a modular and adaptable ethics support system that may inform future educational tools, governance initiatives, and responsible digital health innovation practices.

Collectively, this dissertation advances the discussion from "*what ethical principles should guide digital health*" toward "*how ethical reflection can be operationalised, taught, navigated, and applied in practice*."

1 INTRODUCTION

1.1 The Digital Healthcare Ecosystem as an Ethical Pressure Environment

1.1.1 The Emergence of a Digital Healthcare Ecosystem

In the rapidly evolving landscape of digital technologies, the concept of *digital ecosystems* has emerged as a foundational field of exploration(1). Originally developed to describe interconnected digital environments in which technologies, actors, and institutions co-evolve, the "*ecosystem*" way of thinking has been applied across several domains of innovation, including industry, public services, and complex socio-technical systems(2,3). During recent years, this conceptual lens has been extended to the healthcare sector at an increasing pace, recognising that modern healthcare can no longer be adequately understood through isolated technologies or single institutional actors(1,3).

Digital health represents a central manifestation of this ecosystemic shift within the field of healthcare. Instead of referring to discrete digital tools or applications, digital health functions as a platform through which digital technologies act as intermediaries among patients, healthcare professionals, institutions and data infrastructures(4). Through mechanisms such as remote monitoring, decision-support systems, and patient-facing digital services, digital health technologies reshape how care is coordinated across settings and organisational boundaries(3,4).

The rapid evolution and diffusion of health technologies has, in turn, transformed the way in which healthcare services are delivered, regulated and perceived by stakeholders across the healthcare system(5). Developments such as semantic interoperability in electronic health records, cloud-based infrastructure, artificial intelligence-enabled decision-support systems, and data-driven approaches to precision medicine illustrate a broader shift toward integrated, data-intensive healthcare infrastructure(5). All these developments operate not as standalone technological interventions, but as interconnected components of wider systems that depend on continuous data flows, shared standards and cross-organisational coordination(1,3).

Within this context, the notion of a digital healthcare ecosystem provides a useful conceptual lens for capturing the complexity and interdependence of the contemporary digital health innovation ecosystem. Iyawa et al. define a digital health innovation ecosystem as *"a network of digital health communities consisting of interconnected, interrelated and interdependent digital health species, including healthcare stakeholders, healthcare institutions and digital healthcare devices situated in a digital health environment"(3).* This definition highlights that digital health ecosystems are not defined solely by technological connectivity, but by the coordinated interaction of actors, practices and infrastructures aimed at improving health outcomes and empowering patients.

An ecosystem perspective also highlights the increasing convergence of domains that were previously more clearly delineated. In digital healthcare ecosystems, the boundaries between research and care, industry and clinical practice, and governance and innovation are becoming progressively blurred(1,6,7). Digital tools developed within research settings may rapidly enter clinical practice; commercial infrastructures may mediate public care functions; and governance logics may be embedded directly within technical architectures. As a consequence, responsibility, accountability, and decision-making authority may be distributed across several actors operating at different levels of the healthcare system(1,3).

Therefore, understanding digital health as an ecosystem shifts analytical attention away from individual technologies toward the interactions, dependencies, and relationships that shape innovation at a system level(3,8). From this perspective, many challenges associated with digital health do not arise solely from the technical properties of individual tools, but from how technologies are designed, integrated, governed, and used within complex socio-technical environments(1,6,7). Consequently, ethical analysis confined to individual technologies or isolated decision points risks overlooking the systemic dynamics through which ethical tensions are generated, distributed, and amplified across the ecosystem.

The digital healthcare ecosystem thus operates as an ethical pressure environment: a structurally dynamic context in which rapid innovation, distributed responsibility, commercial incentives, regulatory uncertainty and evolving professional roles interact to generate continuous normative demands. Within such an environment, ethics cannot remain external or episodic but must be understood as a structural component of how innovation is interpreted, negotiated and integrated into practice.

1.1.2 From Risk Mitigation to Ethical Sense-Making

Within the field of digital health, ethics has been framed as a matter of risk identification, harm prevention and regulatory compliance, mainly concerning bias, privacy, safety and accountability(9). Moreover, this framing is reflected in the proliferation of ethical principles, governance mechanisms and guidelines designed to mitigate potential harms relevant to digital health technologies(10). Doubtlessly, these approaches have played a significant role in raising ethical risk awareness; on the other hand, they treat ethics as a checklist activity aimed at achieving procedural compliance instead of being an ongoing interpretive practice(11).

However, in complex digital health ecosystems, ethical challenges are rarely static or fully predictable, emerging instead through evolving interactions among technologies, users, institutions and contexts of use(12). Risk-based approaches tend to fragment ethical issues into discrete categories, obscuring how ethical tensions accumulate, transform or reappear across the lifecycle of innovation and deployment(13). As digital systems evolve through iterative updates, machine learning adaptation and infrastructural integration, ethical implications become temporally extended and relational rather than discrete and event-based.

From this perspective, the core ethical challenge in digital health is not solely what risks exist, but how professionals understand, interpret and respond to ethical complexity within situated decision-making contexts(14). The central question shifts from "*Which* *risks must be mitigated?*” to “*How are ethical meanings constructed, negotiated and justified within evolving socio-technical environments?*” Under these conditions, addressing ethics as ethical sense-making foregrounds the development of reflective capacities, contextual judgement and shared interpretive frameworks that enable stakeholders to reason ethically across diverse scenarios and stages of innovation(15). Ethical sense-making emphasises the cultivation of ethical learning, that is, the development of interpretive competence, deliberative capacity and human-rights-grounded judgement that can be exercised across roles and institutional settings.

This shift reframes ethics from a peripheral mechanism of control toward a constitutive element of professional learning and practice within the digital healthcare ecosystem(10). Accordingly, the challenge is not merely to strengthen governance instruments, but to reconsider how bioethics itself is positioned within digital innovation processes, whether as an external evaluative authority or as an embedded educational architecture that supports ongoing ethical learning across the ecosystem.

1.2 The functional positioning of Bioethics in healthcare and innovation

1.2.1 Traditional roles of Bioethics in healthcare

Bioethics has played a significant role in shaping the moral foundations of healthcare by systematically addressing ethical dilemmas arising in medical practice and biomedical research(16). Although often perceived as a contemporary discipline, its intellectual roots extend deep into the history of moral philosophy and medical ethics(17). The term “*bioethics*” itself derives from the Greek words *bios* (life) and *ethos* (character), reflecting its concern with the moral dimensions of life sciences and healthcare(18). From its inception, philosophical reflection has enriched medicine by foregrounding ethical reasoning as central to clinical judgment and professional integrity(17).

While the formal field of bioethics emerged in the twentieth century, its historical foundations are intertwined with the evolution of medical ethics(16). Ethical guidance for medical practice predates the Hippocratic tradition, as many early societies articulated professional obligations through oaths and moral codes(19). The Hippocratic Oath, commonly dated to the fifth century BC, became the most influential ethical reference point in Western medicine and established enduring principles concerning professional conduct and patient welfare(20). Traditional medical ethics primarily focused on the doctor-patient relationship and emphasised the virtues and character of the physician as the cornerstone of good medical practice(21).

Bioethics, however, developed as a broader and more critical enterprise that extended beyond professional virtue and bedside decision-making(16). In the 1960s and 1970s, the term was popularised by Van Rensselaer Potter, who envisioned bioethics as a "*science of survival*" linking biological knowledge with human values in response to technological and ecological challenges(22). During this period, rapid advances in biomedical science and clinical innovation, including organ transplantation, life-sustaining technologies, reproductive medicine, and genetic engineering, generated ethical questions that exceeded the traditional boundaries of medical ethics(23). At the same time, public revelations of egregious research abuses, including the experiments conducted during the Second World War and the Tuskegee syphilis study, exposed profound failures in the protection of human subjects and catalysed the institutionalisation of research ethics(24,25).

These historical developments led to the formalization of bioethics as a normative discipline concerned with the protection of human dignity and rights in medicine and research(16). The Belmont Report articulated foundational ethical principles, respect for persons, beneficence, and justice, that became cornerstones of research oversight and regulatory frameworks(26). Building on this foundation, principalism, most prominently formulated by Beauchamp and Childress, provided a systematic framework for analyzing clinical and research dilemmas through the principles of autonomy, beneficence, non-maleficence, and justice(27). Through these developments, bioethics established itself as an interdisciplinary field spanning medicine, philosophy, law, public policy, and the social sciences(18).

Traditionally, bioethics has operated across three central domains within healthcare. First, in clinical ethics, it has guided decision-making in cases involving end-of-life care, informed consent, capacity, and treatment refusal, offering structured approaches to resolving moral conflict at the bedside(21,27). Second, in research ethics, it has institutionalized oversight mechanisms such as Institutional Review Boards and articulated normative standards for ethical experimentation and the protection of vulnerable populations(26,28). Third, at the level of policy and governance, bioethics has informed legislative deliberations and public debates concerning emerging technologies, healthcare allocation, and questions of distributive justice(16,29).

Across these domains, bioethics has primarily functioned as a reflective and evaluative discipline: clarifying principles, adjudicating dilemmas, and guiding decision-making within relatively bounded institutional settings. This functional positioning presupposes identifiable decision points, stable professional roles and clearly demarcated institutional boundaries. It assumes that ethical analysis can be applied at discrete moments of deliberation or review. These conditions, however, are increasingly destabilised within digital health innovation ecosystems.

1.2.2 Bioethics in the Context of Digital Innovation Practices

Digital health innovation is characterised by rapid development cycles, large-scale data integration, and interdisciplinary collaboration across clinical, technical, commercial, and regulatory domains(6,7). Such innovation ecosystems operate through iterative design, agile development, and continuous deployment, conditions that differ substantially from the slower, episodic structures within which traditional bioethical oversight evolved(12). As a result, the speed and scale of digital innovation often outpace conventional ethical review mechanisms designed for discrete clinical interventions or research protocols(30).

Traditional bioethical governance has relied heavily on episodic ethics review, particularly through institutional review boards and regulatory approval processes structured around clearly bounded projects(26,28). However, digital health technologies frequently evolve after deployment through software updates, machine learning adaptation, and integration with new datasets, rendering one-time ethical assessments insufficient(13).

In such environments, ethical implications are not confined to the moment of approval but unfold dynamically across design iterations, data flows, user interactions, and infrastructural integrations. Ethical questions become continuous rather than episodic, distributed rather than centralized, and embedded within technical decision-making processes. Moreover, expert-driven oversight models position ethics as an external evaluative function rather than as an integral component of design and implementation practices(14). Consequently, value-laden decisions may be negotiated implicitly within engineering, procurement, and deployment processes, even when formal ethical authority remains institutionally separate(30).

This structural separation creates a functional gap: ethics retains formal authority at the level of review and governance. At the same time, practical normative decisions are made within innovation teams that may lack structured support for ethical reasoning.

1.2.3 The Structural Repositioning Problem

In light of this misalignment, the issue is not merely procedural but structural. Bioethics remains institutionally positioned as an evaluative checkpoint, whereas digital innovation processes distribute ethical decision-making across technical and organisational actors. Embedding ethics within design and development processes aligns with approaches such as Value Sensitive Design, which emphasize the integration of normative reflection into technical development(31). However, embedding ethics cannot be reduced to inserting additional checkpoints into development cycles. It requires rethinking the functional role of bioethics within the ecosystem itself, from an external arbiter of compliance to an internal infrastructure that supports ethical learning and deliberation across roles and stages of innovation.

Repositioning bioethics, therefore, entails a shift from external oversight to internal capacity-building. Complex digital ecosystems demand participatory and distributed forms of ethical engagement, as responsibility is dispersed among developers, clinicians, data scientists, managers, and policymakers(32).

In this context, the central challenge becomes educational rather than exclusively regulatory: *how can stakeholders cultivate the interpretive capacities required to recognize, articulate and negotiate ethical tensions as they arise within innovation practice?* Supporting ethical sense-making across these roles transforms bioethics into an enabling infrastructure for reflective practice rather than a compliance-oriented checkpoint, thereby situating it as an active and strategic component of digital health innovation(10).

Accordingly, the repositioning required is architectural. Bioethics should function as a human-rights grounded educational architecture capable of scaffolding ethical learning, sustaining deliberative capacity and embedding normative reflection into the evolving fabric of digital healthcare systems. This structural misalignment thus raises a broader question*: how has digital health ethics been operationalized in practice, and what conceptual limitations follow from its prevailing governance orientation?*

1.3 Ethics as Governance: Structural limits in digital health ecosystems

1.3.1 The governance turns in digital health ethics

Over the past decade, digital health and artificial intelligence have been accompanied by a rapid proliferation of ethical principles, guidelines, and governance toolkits developed by academic institutions, professional bodies, governments, and international organizations(10,33). Comparative analyses have identified dozens of AI ethics frameworks globally, many converging on shared principles such as transparency, accountability, fairness, privacy, and human oversight(33). In parallel, health-specific guidance documents have emerged that address clinical AI, digital platforms, and data-driven medicine, reflecting efforts to adapt traditional bioethical principles to digitally mediated healthcare contexts(6,34). These frameworks have contributed significantly to raising awareness of ethical risks and to embedding normative language within digital health governance discussions(10).

This proliferation reflects what may be described as a governance turn in digital health ethics: a collective attempt to stabilise rapidly evolving technological environments through the articulation of principles, standards, and oversight mechanisms(35). The development of such frameworks represents an important maturation of ethical reflection in response to technological transformation and regulatory uncertainty(30). By articulating shared values and high-level principles, they provide common reference points for policymakers, developers, and healthcare organizations navigating emerging digital infrastructures(34). Furthermore, governance-oriented ethics guidance has supported the integration of accountability mechanisms, impact assessments, and risk-management strategies into innovation processes(13).

In this sense, governance-oriented ethics has performed a crucial system-stabilizing function: it renders technological development normatively visible and institutionally accountable. Seen in this light, contemporary digital health ethics has largely evolved as a governance response to uncertainty, seeking to render emerging technologies ethically legible through codification, standard-setting, and compliance instruments. Nonetheless, the existence of numerous frameworks has also produced fragmentation and overlap, raising questions about their practical coherence and operational effectiveness(33). The issue is therefore not the absence of ethical articulation, but the structural form through which ethics has been operationalized.

1.3.2 Compliance, Risk and Principle's Articulation

Despite their normative contributions, many existing ethics frameworks remain principle-heavy and abstract, offering high-level values without clear pathways for contextual interpretation and implementation(30). Scholars have noted that principles alone are insufficient to resolve concrete ethical tensions, particularly in complex socio-technical systems where values conflict, and trade-offs are unavoidable(10). Moreover, numerous frameworks are prescriptive or compliance-oriented, positioning ethics primarily as a matter of risk mitigation and regulatory conformity rather than as a practice of ongoing moral reasoning(11). This orientation may limit their capacity to guide reflective engagement during iterative design and deployment processes(12).

Within such approaches, ethics is frequently operationalized as procedural compliance: adherence to checklists, completion of impact assessments, and satisfaction of predefined safeguards. Ethical robustness becomes equated with documentation, reporting, and risk containment, rather than with the cultivation of interpretive judgement and deliberative competence.

In addition, many ethics frameworks are designed primarily for policy-level governance or institutional oversight, rendering them difficult to translate into everyday professional practice across interdisciplinary teams(34). Their structure often assumes centralized authority or expert-led evaluation, which may not align with distributed innovation environments in digital health ecosystems(14). As a result, such frameworks can be unevenly applicable across sectors, particularly where technological development occurs in commercial or hybrid public–private contexts(6). The structural limitation, therefore, lies not in the normative content of these frameworks, but in their predominant logic of application: they regulate outcomes but rarely scaffold ethical reasoning processes within innovation workflows.

These dynamics reveal a deeper orientation: ethics is positioned primarily as supervisory governance rather than as embedded professional practice. While governance