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A roadmap for federated learning projects using health data to guide sustainable artificial intelligence development in the European Union

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ABSTRACT

Background: The rise of digital health data has expanded opportunities for data-driven innovation, yet privacy, legal and ethical barriers frame data sharing and collaborative artificial intelligence development. Federated Learning (FL) offers a privacy-preserving alternative, but current research considers mainly technical aspects. There is no end-to-end roadmap that integrates ethical, legal, technical and administrative principles tailored to FL projects in healthcare. This study addresses that gap by developing a roadmap to guide responsible and scalable FL research in the European context.

Methods: A multi-method participatory approach was used to develop a roadmap for scientific projects using FL on health data. The iterative process involved three phases. First, key questions were defined and existing evidence was explored through (i) a survey of domain experts (researchers, data governance specialists and infrastructure providers), (ii) a targeted literature review of FL applications in health research and (iii) systematic mapping of relevant EU-level legislation and policy frameworks. Evidence from these sources was synthesized to identify technical, organizational, legal and sustainability-related requirements for FL-based research. Second, preliminary roadmap components were refined through stakeholder engagement in an online workshop, where feasibility, scalability and sustainability considerations were explicitly discussed. Third, the roadmap was validated and iteratively refined by an expert panel through a structured group discussion, focusing on long-term sustainability, governance and transferability across research contexts. The process was carried out within a Baltic-Nordic collaboration in 2023–2025.

Results: The developed roadmap integrates ethical, legal, technical, administrative and sustainability-related considerations essential for applying FL to health data. It emphasizes the importance of multidisciplinary collaboration throughout the FL project lifecycle, with particular attention to long-term governance, scalability and reuse of infrastructures and practices. The process is structured into six phases: (1) Planning, (2) Execution refinement, (3) Data, (4) FL platform, (5) FL experiment and (6) Dissemination. Across these phases, sustainability is addressed through mechanisms such as regulatory alignment, shared governance models, capacity building and integration with existing research and health data infrastructures. By merging ethical, legal, technical and administrative aspects into a unified, end-to-end framework, the roadmap provides actionable, novel guidance beyond existing recommendations.

Conclusions: This work consolidates early lessons from FL in healthcare into a practical, step-by-step roadmap that integrates ethical, legal, technical and administrative aspects in the European context. By offering a shared framework for diverse stakeholders, it supports more trustworthy, scalable and compliant AI collaborations across healthcare systems.

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1. Introduction

Accelerated adoption of digital health solutions has significantly increased the volume of health data generated and the potential for its use in improving healthcare delivery, diagnostics and research [1]. However, this has raised several key issues relating to data sharing, including technical barriers, privacy and security concerns, legal and ethical considerations, trust issues, professional and public attitudes, as well as questions about perceived benefits [2,3]. At the same time, advances in artificial intelligence (AI) have created new opportunities for data-driven innovation [4]. Still, the sensitive nature of health data and strict data protection regulations pose significant barriers to centralized data sharing and collaborative AI model development [5].

Federated Learning (FL) has emerged as a promising approach to address these challenges because it allows multiple institutions to work together without sharing raw health data while preserving privacy and complying with legal frameworks [6–8]. Unlike conventional centralized machine learning, which requires pooling all data into a single repository, FL involves training statistical models on remote devices or siloed data centres while maintaining data locality. This reduces privacy risks and enhances scalability in sensitive domains such as healthcare [9,10]. FL is typically categorized into two main variants: horizontal FL, where participants share the same feature space but differ in data samples and vertical FL, where participants share the same sample space but possess different feature sets [11].

The current state of FL in healthcare is rapidly evolving, with numerous applications developed across various healthcare domains [12,13], including medical imaging [14], electronic health records analysis [10] and predictive modeling [15]. However, significant shortcomings remain, particularly in relation to reproducibility [12], standardization [10] and governance [16]. Ethical and legal concerns further complicate deployment [5,17]. In addition to these challenges, the environmental sustainability of AI systems, including FL, is increasingly under scrutiny. These systems demand substantial computational resources, leading to high energy consumption and increased carbon emissions, which contribute to the environmental impact of digital health technologies [18,19]. Addressing these concerns requires coordinated efforts among researchers, healthcare providers and policymakers [19]. Ethical considerations are also critical, as AI can worsen healthcare disparities through algorithmic bias and unequal access to technology, undermining sustainability goals [19]. Equitable access to AI capacity can be promoted through collaborative initiatives, education in digital health and AI [20] and the integration of environmental sustainability principles into system design [21].

Researchers need to develop a range of competencies, such as technical competence with and understanding of FL frameworks [22] and expertise in data privacy and security [23], to effectively contribute to FL projects. They also require competence in transdisciplinary collaboration, which involves integrating diverse disciplinary perspectives, knowledge and skills to address complex problems [24].

While existing literature has extensively explored the technical foundations and algorithmic performance of FL [7,8,17], this body of work is largely fragmented and predominantly technology-driven. Most studies focus on model optimization, data partitioning or privacy-preserving mechanisms in isolation, with limited consideration of how these components interact with regulatory requirements, organizational processes and long-term operational sustainability in real healthcare environments [10,13,25,26].

Existing reviews and frameworks on FL in healthcare tend to address ethical, legal or governance aspects separately from technical implementation, or discuss them at a conceptual level without translating them into actionable guidance for research projects spanning planning, execution and dissemination phases [5,16,26]. As a result, researchers lack practical, end-to-end support for designing and conducting FL studies that are not only technically robust but also legally compliant, ethically grounded and sustainable over time. This gap is particularly pronounced in the European Union context, where complex regulatory and infrastructural conditions further shape FL feasibility.

This work therefore aims to address this gap by developing a lifecycle-oriented roadmap for FL research using health data. The roadmap is intended for use in the EU context, which features regulatory, infrastructural and ethical considerations that uniquely shape the development and deployment of FL in healthcare. The work presented here will promote responsible AI use in healthcare and facilitate scalable, multi-institutional collaborations that are effective and ethically sound by mapping the FL research process.

2. Methods

We used a multi-method participatory approach [27,28] to develop a roadmap for scientific projects using FL on health data. Our communication involved both international scientific and field experts and was characterized by a back-and-forth circulation of ideas. The iterative process involved three phases: (1) defining the questions and exploring available evidence, (2) stakeholder engagement and (3) expert panel validation and refinement (Fig. 1). These phases ensured iterative validation and stakeholder engagement throughout the development process to create a comprehensive and applicable roadmap that addresses ethical, legal, technical and administrative considerations. The process was carried out within a Baltic-Nordic collaboration from 2023 to 2025, as part of a research project (FederatedHealth: A Nordic Federated Health Data Network) aiming to develop a Nordic federated health data network to enable privacy-preserving analysis of multilingual electronic health records. Experts and stakeholders involved in the validation process were also recruited from this project. However, they were not part of the core research team for roadmap development. Detailed descriptions of participant expertise and recruitment, literature review strategy, workshop protocol, and data analysis methods are provided in Sections 2.1–2.3 and Appendices 1-3.

2.1. Exploring available evidence and defining the questions

The initial phase involved collecting data by surveying a panel of international experts on research ethics relating to FL projects, conducting a literature review on ethical and regulatory frameworks for using FL on health data and mapping the key legislation pertaining to FL at the EU level. In the expert panel survey, the REDCap electronic survey tool was used to collect empirical data based on open-ended questions that were designed to produce insights into the challenges, opportunities and considerations arising from research applying FL to health data. The panel included senior researchers (n = 7) from Denmark, Estonia, Finland, Norway and Sweden (Appendix 1). The criterion for expert recruitment was active involvement in a research project utilizing FL for health data, ensuring relevant expertise and practical experience. Thematic analysis [29] was used to analyze survey responses. The analysis followed an inductive approach, with themes iteratively discussed and refined within the research team.

For the literature review, we used databases including PubMed, CINAHL and Scopus, as well as Google Search, to collect scientific and grey literature. The search terms used were: “federated learning”, “distributed learning”, “health*”, “ethic*”, “legisl*” and “legal”. Search terms were combined with Boolean operators OR and AND (Appendix 2)). The literature searches and legislation mapping helped to identify the core ethical and legal issues and guidelines that must be considered at the EU and national levels when conducting FL projects using health data. We then synthesized the initial findings based on the gathered data to produce a preliminary roadmap for scientific projects utilizing the FL approach. This iterative process involved numerous discussions and refinements within the research team, ensuring that each aspect of the roadmap was thoroughly examined and adjusted based on the available feedback and insights. Our international Baltic-Nordic team included experts in nursing science, law, healthcare ethics and AI use in healthcare.

2.2. Stakeholder involvement

An interactive online workshop was organized to engage with international stakeholders (n = 11) from Denmark, Estonia, Finland, Norway and Sweden (Appendix 1)). Stakeholders were recruited by inviting researchers involved in a research project utilizing FL for health data. They were also encouraged to share the invitation within their organizations to include individuals interested in the topic. The aims of the workshop were to (1) validate the preliminary roadmap, (2) gather additional insights and (3) ensure alignment with real-world needs. The workshop featured group discussions, allowing participants to share their insights and experiences. Participants were divided into four mixed groups whose discussions were facilitated by members of the research team (Appendix 3)). The developed roadmap was used as a framework for discussions. This collaborative format facilitated a deeper understanding of the ethical, legal, technical and administrative perspectives associated with FL projects. During the workshop, each facilitator took notes that were subsequently discussed collectively within the research

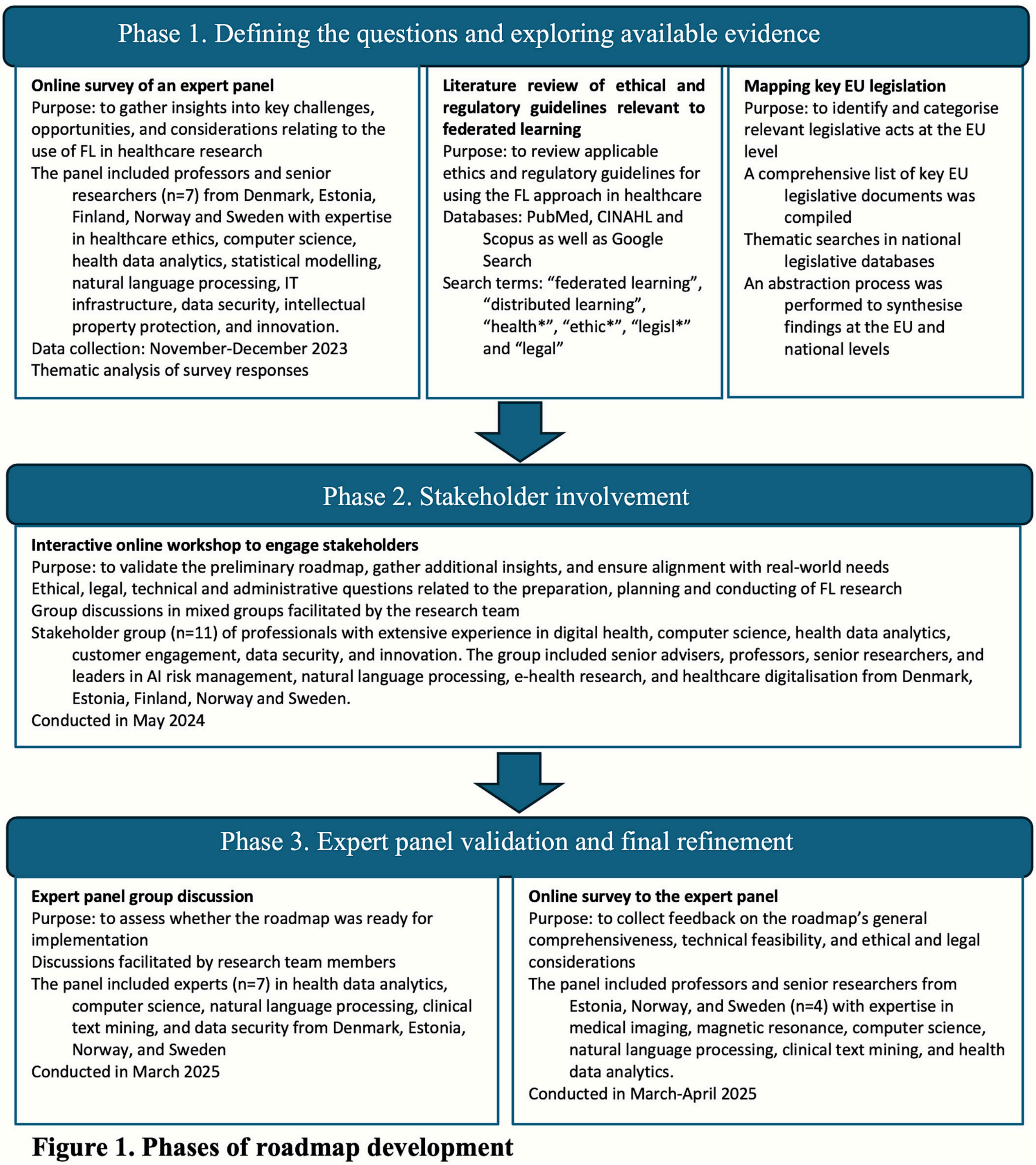

Fig. 1. Phases of roadmap development.

team. We further developed and enhanced the roadmap based on stakeholders' insights to better meet the needs of FL projects.

2.3. Expert panel validation and final refinement

The refined roadmap was presented to an international expert panel (Appendix 1)) to solicit feedback, guaranteeing its relevance to practice and confirming that no essential aspects were unaddressed. The participating experts (n = 7) were the same as those surveyed in the initial phase. Feedback was gathered through an online survey and group discussions facilitated by research team members. The online survey was designed to collect experts' opinions on the roadmap's general comprehensiveness, technical feasibility and ethical, legal and administrative considerations. These opinions were then used by the research team to systematically refine the roadmap.

3. Results

3.1. Roadmap design

The roadmap does not report empirical outcomes from a single implementation site. Instead, the results synthesize expert knowledge, regulatory requirements and practical experience into an operational framework. This roadmap explicitly identifies decision points, risks, transition criteria and process-level indicators that can be used to guide, monitor and sustain FL projects in real-world settings to enhance applicability. The developed roadmap addresses ethical, legal, technical and administrative considerations relevant to the application of FL with health data, highlighting the need for interdisciplinary collaboration between ethical, legal, technical and domain (healthcare) experts throughout an FL project. We divide the FL research process into six phases: (1) Planning, (2) Execution refinement, (3) Data, (4) FL platform, (5) FL experiment and (6) Dissemination. Each phase is further divided into main processes with clarifying sub-processes, highlighting key decision-making points and the influence of external actors (Fig. 2).

We present a hypothetical example of a cross-border FL study using multilingual EHR data to develop a disease risk prediction model across multiple healthcare organizations in the Baltic–Nordic region to illustrate the practical application of the roadmap:

- *Phases 1–2 Planning and execution refinement*: The project begins with the formation of an interdisciplinary consortium including clinicians, data scientists, legal experts, ethicists and technical coordinators from partners. Early activities focus on aligning the intended purpose of the algorithm, defining clinical use cases and clarifying whether the developed model falls within the scope of the EU AI Act and/or medical device regulation. Ethical approvals, secondary data access permissions and data-sharing agreements are coordinated across sites, supported by an initial Data Protection Impact Assessment (DPIA) and a shared governance framework to ensure consistent interpretation of regulatory and ethical requirements.
- *Phases 3–4 Data coordination and FL platform development*: Each participating institution maps local EHR data to a common data model (CDM) to enable interoperability while maintaining local data control. Privacy-enhancing technologies, such as secure aggregation and encryption, are implemented at each node. An FL platform is selected or configured to support cross-site training, role-based access control and secure communication between nodes. Initial testing using non-sensitive or synthetic data is conducted to verify technical

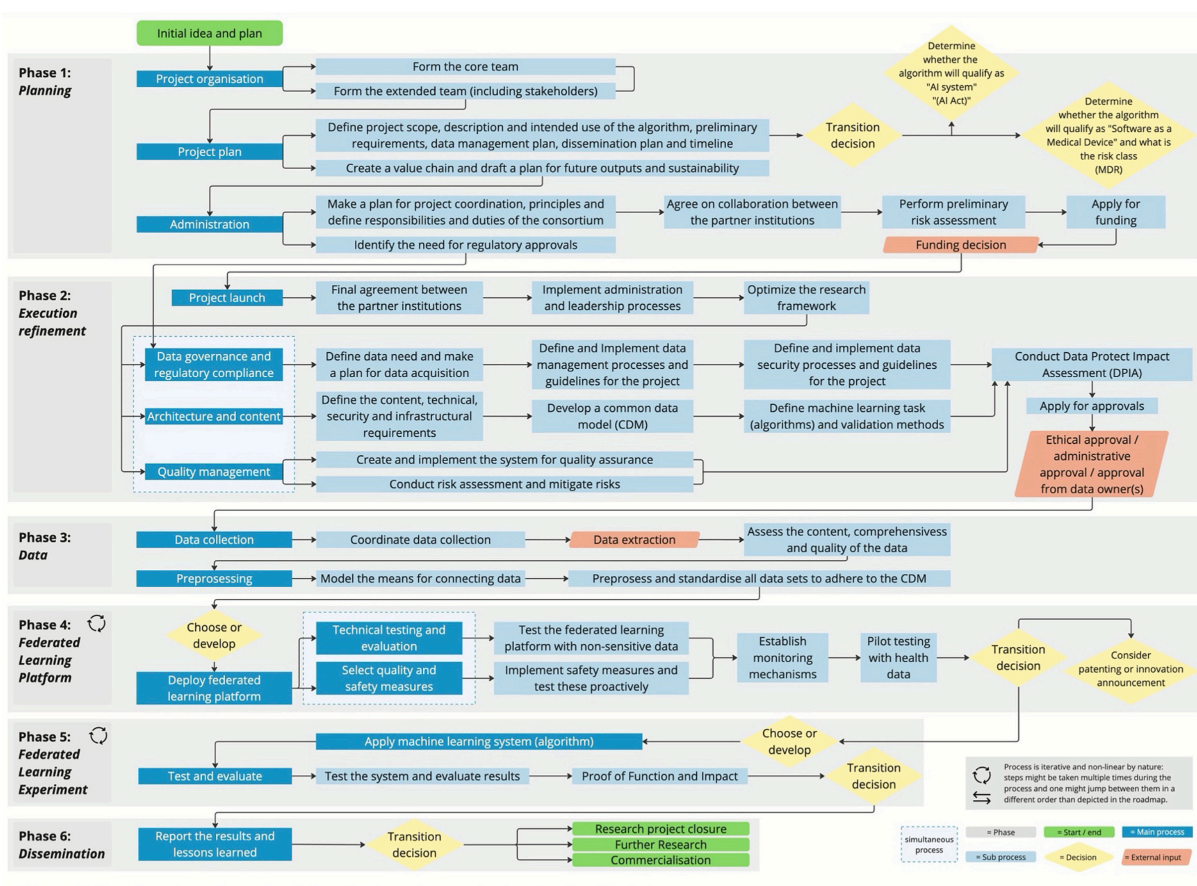

Fig. 2. Developed roadmap for federated learning projects using health data.

compatibility, security measures and workflow feasibility before full deployment.

- *Phase 5 FL experiment:* The FL experiment is conducted by iteratively training a shared global model across sites without transferring patient-level data. Model performance and system-level indicators, such as predictive accuracy, AUC/F1 scores, communication latency and node availability, are monitored throughout training rounds. These metrics support iterative refinement and inform go/no-go decisions regarding progression or termination of the experiment.
- *Phase 6 Dissemination and transfer*: Following completion of the experiment, results, methodological decisions and lessons learned are systematically documented and disseminated through scientific publications and stakeholder communication. Legal and administrative arrangements for intellectual property, potential clinical translation or further development are clarified. The project concludes with a transition decision regarding closure, continued research or progression towards deployment or commercialization, supported by predefined sustainability and governance considerations.

Table 1 offers a structured overview of key ethical, legal, technical and administrative considerations across all six roadmap phases of FL research projects, from initial planning to final dissemination. It highlights critical risks and potential red flags that could delay or derail the project. Phases 1–2 focus on project planning and strategy development. Early coordination across disciplines is essential to ensure all requirements are addressed and to prevent misalignment. A clear structure supports shared decision-making and lays the foundation for a trustworthy and scalable system. Phases 3–4 address data coordination and algorithm development. These stages are crucial for managing distributed, privacy-sensitive data and ensuring that models are both high-performing and compliant with ethical and legal standards. Collaboration among data scientists, clinicians, ethicists and legal experts is key to maintaining data integrity and clinical relevance. Phases 5–6 involve executing the FL experiment and communicating results. Key processes in these phases include model design, evaluation and iterative training, followed by dissemination through scientific reporting, stakeholder engagement and public outreach. Tailored communication strategies help build trust and translate technical outcomes into societal impact (Table 1).

3.2. Ethical and legal considerations related to FL projects

Legal and ethical considerations are integral to the entire lifecycle of an FL project; they must be systematically addressed to ensure compliance with applicable EU legal frameworks and ethical standards. A structured overview of these considerations, accompanied by relevant references, is provided to serve as a general framework for guiding the development of ethically and legally robust project implementations (Table 2). Notably, the table does not include specific national legislation, as such laws may vary across jurisdictions and are subject to change over time. Instead, it identifies broadly applicable legal domains that are typically governed or influenced by national legal frameworks, thereby allowing for contextual adaptation. The included ethical guidelines and EU-level regulatory references offer a foundational basis for constructing a project-specific legal and ethical compliance strategy.

3.3. Sustainability and long-term maintenance considerations

Sustainability is a cross-cutting requirement across all phases of the FL roadmap. It is essential for ensuring that technical, legal and organizational arrangements remain viable beyond the project. The roadmap explicitly incorporates sustainability through governance, operational, legal and technical mechanisms that support long-term use, maintenance and adaptation. Governance continuity is supported through the establishment of clearly defined roles, decision-making structures and escalation mechanisms that can persist after project funding ends. A designated coordinating body or host organization is necessary to oversee ongoing compliance, risk management and stakeholder engagement. Platform maintenance and monitoring are addressed through requirements for continuous system monitoring, version control, incident response procedures and security updates. Long-term operation of the FL platform requires assigned responsibilities for infrastructure maintenance, node management and performance monitoring. Legal and ethical validity over time is ensured by maintaining living documentation, including DPIAs, risk registers and data-sharing agreements, which must be periodically reviewed and updated in response to regulatory changes, evolving use cases or system modifications. Funding transition and institutional ownership are addressed by clarifying post-project responsibilities, ownership of technical assets and potential pathways for continued operation, further research or commercialization. Clear intellectual property and licensing arrangements are necessary to enable lawful reuse, transfer or scaling of the developed solutions. Model updating and lifecycle management are incorporated through defined procedures for retraining, validation and performance monitoring of deployed models. Ownership of model updates and responsibility for managing model drift, bias and clinical relevance are explicitly assigned to prevent degradation over time. The roadmap specifies the following indicative sustainability markers to operationalize these sustainability principles:

- The existence of a post-project governance or coordinating body.
- Maintained and regularly reviewed DPIAs and risk registers.
- Ongoing platform monitoring and incident management processes.
- Clearly defined intellectual property and licensing pathways.
- Explicitly assigned responsibility for model updating and lifecycle management.

4. Discussion

This study aimed to help guide sustainable AI development by developing a research process roadmap for FL projects using health data. The new roadmap merges ethical, legal, technical and administrative considerations into a single end-to-end workflow. Importantly, it offers genuinely new, actionable recommendations rather than re-stating existing guidance. This work builds on previous research by extending the existing digital-health and machine learning lifecycle and closing key gaps in standardization and sustainability metrics. The developed roadmap offers practical guidance for implementing FL in healthcare, with implications for diverse stakeholders – from healthcare providers and IT teams to policymakers and researchers. Moreover, it fosters collaboration, regulatory compliance and sustainable innovation across institutions and disciplines. To the authors' knowledge, this is the first study to map the FL research process with integrated consideration of ethical, legal, technical and administrative issues.

The goal of this roadmap is to provide a broadly applicable foundation that can be adapted to various project contexts rather than to serve as a prescriptive or exhaustive guide. Therefore, it does not delve into jurisdiction-specific regulatory or low-level technical implementation details. Previous studies proved that roadmaps are valuable tools for guiding complex research projects involving a transdisciplinary team [30,31]. The dynamic and iterative nature of the roadmap's development underscores the deep and complex interplay between ethical, legal, technical and administrative issues in FL projects using health data. Importantly, the development process revealed that many of these complexities only become fully apparent as such projects are evolving, making it exceptionally challenging to anticipate and appropriately plan for risks and challenges.

Although the roadmap is presented in a linear sequence for clarity, the development and implementation of FL projects are rarely straightforward [32]. Many steps in the process are often revisited and refined multiple times. Also, not all tasks across the developed roadmap

Table 1
Details of sub-processes for roadmap phases 1–6.

Phase and Aim	Key Administrative and Technical Aspects by Phase	Key Ethical and Legal Aspects by Phase	Critical Red Flags
1. Planning The aim of the phase is to create a competent team with an agreed goal for the algorithm and a successful research plan and funding application.	**Project Organization** · Ensure the project team is diverse and includes individuals with varied expertise in fields such as data science, healthcare, ethics, law and project management. · Form distinct sub-teams for relevant domains. · Identify key stakeholders such as patients, healthcare providers, researchers, policymakers and industry partners. · Implement a structured stakeholder engagement strategy to inform planning, address concerns and foster project support. **Project Plan and Timeline** · Create a comprehensive project plan with clearly defined goals, key milestones, deliverables and deadlines. · Draft the preliminary intended purpose of the developed algorithm. · Continuously review and adapt the project plan to changing circumstances. · Set clear and task-driven allocation of resources, identify dependencies and establish systems for monitoring progress and managing risks. · Develop a sustainability plan to outline long-term goals for post-funding continuity. **Administration** · Agree on key project terms and the roles, responsibilities and key deliverables of the project partners, assigning tasks based on team members' expertise and capabilities. · Ensure that the project's legal framework aligns with its objectives and there are clear guidelines for decision-making and conflict resolution. · Create a communication and coordination plan that outlines methods, meeting schedules and reporting mechanisms. · Research potential funding sources such as government grants, private foundations and industry partnerships. · Prepare funding proposal.	· Prepare contracts that clearly define the terms and conditions of collaboration, including confidentiality, data sharing, intellectual property, patents, publication rights and key deliverables of the project partners. · Ensure compliance with GDPR and other relevant data protection laws. · Outline data access rights, security measures and mechanisms to maintain data integrity. · Qualify the algorithm developed and determine whether it constitutes an "AI system" under the AI Act and/or a "medical device" under the EU Medical Device Regulation. · Develop a preliminary regulatory strategy for placing the product on the market if commercialization is in the project's scope or tech transfer is feasible. · If the project aims for commercialization, regulatory manufacturing process should be followed (AI Act + MDR, depending on the algorithm's intended purpose) · Secure funding to transition from planning to execution.	· Failure to recruit committed experts in key fields (e.g., clinical, data science, regulatory, project management). · Team members or stakeholders have conflicting views on the projects and/or algorithm's intended purpose or objectives. · Lack of clarity on roles, decision-making authority, or conflict resolution. · Legal framework, data access, or ethical considerations are not addressed early. · No clear funding path, low-quality proposal, or missed application deadlines.
	The planning phase concludes with the funding decision to transit the project from planning to execution.		
2. Execution refinement The aim of the phase is to create a clear and actionable execution plan for developing a FL platform and algorithm.	**Implementation of Governance Processes** · Implement governance structures by defining roles, responsibilities and decision-making frameworks. · Align the project's goals with clear timelines and communication plans. · Establish a strong central coordinating team that ensures all governance aspects are managed effectively throughout the project lifecycle. **Data Governance and Management** · Specify the types and sources of data required for the FL platform, including both structured and unstructured health data from various sources. · Formulate a data acquisition plan, detailing methods for data collection, storage and processing. · Establish measures to maintain data consistency and interoperability across datasets.	· Review data policies of partner institutions and formalize data-sharing agreements. · Gain familiarity with data access (secondary use of health data) rules and processes in each nodés jurisdiction · Establish ethical guidelines ensuring protection of human rights, fairness and explicability. · Address risks of fundamental rights violations and implement mitigation strategies. · Set up mechanisms for external feedback on fundamental rights concerns. · Set the data governance policy for the FL organization. · Sub-processes 2 to 4 culminate in a comprehensive preliminary risk assessment to identify potential risks, including ethical, legal and technical and operational challenges. · Conduct initial data protection impact assessment for the project.	· Lack of alignment on decision-making frameworks, unclear roles across partner institutions, or weak central coordination. · Failure to secure data-sharing agreements, navigate jurisdictional data access laws, or obtain ethical/administrative approvals. · Ethical applications submitted independently without alignment, resulting in conflicting decisions or requirements. · Ignoring or poorly mitigating risks to human rights, fairness and transparency in AI use (especially with health data). · FL architecture or infrastructure is under-defined or incompatible across nodes.

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Table 1 (*continued*)

Phase and Aim	Key Administrative and Technical Aspects by Phase	Key Ethical and Legal Aspects by Phase	Critical Red Flags
	· Design robust data security (including access) protocols to protect sensitive health data. **Technical Infrastructure Ideation** · Identify the necessary technical infrastructure for the FL platform, including software, communication protocols and FL frameworks. · Assess hardware requirements, such as GPUs and network bandwidth, to support the platform's computational needs. · Ensure compatibility with existing systems and technologies. · Design a Common Data Model (CDM) to harmonize diverse data sources and facilitate seamless data integration. **Quality Management System Implementation** · Establish a comprehensive quality management system to ensure project success, which includes defining quality control measures and performance metrics to evaluate progress and identify improvement areas. · Develop risk mitigation strategies to address technical, legal, ethical and operational challenges that may arise. · Implement a system for tracking key performance indicators (KPIs) to monitor the project's ongoing performance and ensure alignment with objectives. · Coordinate a comprehensive preliminary risk assessment. Potential risks, including technical, legal, ethical and operational challenges, are identified. · Coordinate an initial Data Protection Impact Assessment (DPIA) on the FL platform and algorithm to address privacy and regulatory concerns. · Apply for ethical and administrative approvals for secondary data usage in each relevant jurisdiction. Although each node will submit applications separately, a coordinated approach is recommended to prevent inconsistencies in approval decisions and ensure streamlined compliance across all participating entities.	· Coordinate the drafting of ethical committee and data access applications and secure ethical committee and administrative data access approvals for health data usage.	
	The project execution phase concludes with securing ethical committee and administrative data access approvals for health data usage.		
3. Data The aim of the phase is to ensure that raw data from multiple sources is collected, processed and standardized in a way that maintains accuracy, privacy and interoperability.	**Coordinating Data Collection** · Establish clear data collection protocols (necessary data types, sources and formats) such as protocols for data extraction and data accreditation to verify the integrity of the collected datasets. These protocols should include measures to identify and address potential anomalies, inconsistencies, or errors before the analysis and modelling phase. · Ensure robust data quality to minimize potential biases and improve the reliability of FL outcomes. · Implement Data Governance in practice and maintain regulatory compliance. **Preprocessing and Standardization** · Conduct preprocessing to clean and standardize all datasets according to the Common Data Model (CDM) to ensure consistency, completeness and accuracy across integrated datasets, facilitating	· Ensure privacy and data protection during collection and integration. · Prevent unlawful or unfair use of personal data. · Implement GDPR-compliant harmonized anonymization and encryption techniques in each node. · Address legal considerations for cross-border data transfer, if applicable and data-sharing agreements. · Define protocols governing data access and usage. · Implement a risk assessment framework to continuously monitor and mitigate potential threats to data security and compliance. · Revise Data Protection Impact Assessment if needed.	· Inaccurate, inconsistent, or incomplete data from partner nodes; absence of rigorous data validation or accreditation. · Inconsistent preprocessing and standardization practices, incompatible formats, or failure to align on a shared CDM. · Inadequate implementation of PETs (privacy-enhancing technologies), re-identification risks, or missing access controls. · Failure to revise Data Protection Impact Assessments or update risk frameworks as the data landscape evolves.

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Table 1 (*continued*)

Phase and Aim	Key Administrative and Technical Aspects by Phase	Key Ethical and Legal Aspects by Phase	Critical Red Flags
	seamless data interoperability within the FL framework. · Conduct standardization by reducing variability in data formats and structures to increase reliability and comparability of results during model training. · Implement harmonized privacy-enhancing technologies (PETs) and risk assessment methods to prevent potential re-identification of patient data at the federated level. · Implement a structured risk assessment framework to continuously monitor and mitigate potential threats to data security and compliance		
	The data phase concludes with the production of a harmonized, privacy-preserving dataset ready for federated model training, enabling accurate and interoperable analysis across diverse healthcare data sources		
4. Federated learning platform The aim of the phase is to develop and test the platform.	**Deploy FL Platform** · Select or build the FL platform and determine the intended implementation mode (e.g. single-machine simulation, LAN/WAN proof-of-concept, or near-production environment) by: o assessing whether an off-the-shelf framework (e.g. Flower, FedML) suffices or a bespoke solution is needed; o then defining technical requirements, including privacy strategy, architecture, interface set, central-server location and node roles; o and finally identifying the appropriate implementation mode aligned with research goals and potential future deployment. · Configure the operational environment by standardizing OS versions, software stacks, firewall rules, open ports and container runtime (Docker / Kubernetes) and issuing step-by-step node-setup instructions. · Define the supported FL workflow and architecture. Document which topologies the platform will handle (client–server, scatter-and-gather, cyclic weight transfer, peer-to-peer, or cross-site evaluation) and expose the corresponding orchestration templates. · Specify data-partition modes and job types by enabling horizontal and vertical FL, flagging any extra metadata exchange or encryption keys required for vertical joins. · Establish federated network protocols: choose and script VPN set-up for closely governed institutions, or otherwise support gRPC/TCP/HTTPS with TLS certificates signed by the project's certifying authority. · Integrate differential privacy parameters, homomorphic-encryption options, secure aggregation and encrypted model-update channels and surface these as selectable toggles in the job spec. · Create a role-based access model controlling who may submit, cancel or inspect jobs and a scheduling rule for scarce resources (e.g. FIFO with clinician-priority override). · Adopt containerized deployment with mandatory node registration and approval workflows to ensure regulatory compliance, health checks and rolling update support; codify this in Helm charts or equivalent. The registration process should include:	· Ensure user autonomy and establish human oversight mechanisms. · Implement processes for addressing ethical concerns and resolving conflicts. · Identify and mitigate biases in data. · Proactively manage risks to prevent harm. · Plan for potential attacks and system abuse. · Assess patentability of innovations in the technical solution.	· Wrong technology choice (e.g., platform not compatible with privacy or technical requirements), or significant underestimation of customization needs. · Core architecture does not fully implement data privacy strategies. · Failure to provide clear and standardized deployment instructions leads to misconfigured or non-operational nodes. · Platform fails functionality, usability, or security tests with no clear path to remediation. · Lack of systems to monitor platform performance, detect issues, or evaluate impact post-deployment. · Final decision to proceed is based on unclear or subjective criteria, without validated metrics or stakeholder consensus.

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Table 1 (*continued*)

Phase and Aim	Key Administrative and Technical Aspects by Phase	Key Ethical and Legal Aspects by Phase	Critical Red Flags
	o Verification of Data Processing Agreements between participating institutions o GDPR compliance validation o Technical security measures assessment o Incident response procedure coordination o Maintenance of institutional participation registry. **Quality Mechanisms** · Once the platform is set up, conduct initial testing using non-sensitive data to validate core functionalities. · Establish a robust monitoring system to track platform usage, performance and its real-world impact.	**Testing and Verification** Monitor platform usage and performance through optimization loop by iterating on findings and re-running tests until key metrics meet acceptance thresholds, then sign off for full-scale deployment. · Connect the nodes and evaluate the connections and frameworks. · Perform comprehensive testing and verification of the prototype FL platform to assess its functionality, usability and performance across various scenarios and use cases. · Engage stakeholders by inviting clinicians, data stewards and DevOps teams for feedback to identify usability concerns, technical bugs and areas requiring further refinement.	
The FL platform phase concludes with a decision on whether to proceed with full-scale deployment.			
5. Federated learning experiment The aim of the phase is to develop and evaluate algorithm for FL task.	**Task Refinement and Test** · Refine research tasks and objectives. Align project goals and hypotheses with data availability. At this stage, sketch how many sites will participate and how their data will be partitioned. · Safeguard data quality through interdisciplinary collaboration. Data scientists and clinicians jointly verify that each site's dataset meets agreed quality thresholds, confirm consistent labelling and finalize the client-level data distribution plan that will drive the experiment. · Select or design the learning algorithm and training workflow. Decide whether to employ FedAvg, FedOpt, FedProx, or a bespoke method; fix optimizer, learning-rate schedule, round length and validation protocol; and define the server–client update cadence and aggregation rule that will be used throughout. · Before proceeding with full-scale data processing, run pilot tests on a small, representative subset. Use these dry-runs to validate preprocessing pipelines, harmonization techniques, privacy-preserving measures and stress-test the logging/monitoring stack (detecting failed clients, tracking bandwidth and compute loads). · Conduct a FL experiment. This includes implementing tasks, refining models and iteratively assessing performance within the chosen framework: Execute the full FL experiment: 1) Initialize the global model on the central server (a). 2) Distribute weights to participants; each site runs local training tasks, performs any agreed feature-engineering or hyper-parameter refinements and logs training stats (b). 3) Collect and aggregate client updates on the server, completing the a-b-c cycle for every communication round (c). · Iteratively monitor model accuracy, AUC/F1, system latency, per-round bandwidth	· Share task specifications with nodes for review and comparison with original requests. · Require all data providers (local nodes) to accept the task before implementation. · Log approvals locally and centrally. · Promote transparency and accountability in data sharing and research findings.	· Failure to secure data provider (local node) participation, for example because of refusal to accept the task, withdrawal from the collaboration, or failure to obtain data access permission in phase II. · Inadequate data quality or harmonization, which may invalidate the model's reliability or prevent convergence, making the experiment non-viable. · Pilot tests reveal that the model cannot reach predefined performance metrics (e.g., accuracy, fairness, robustness) and there is no clear path to improve, meaning that continuing may not be justifiable. · Key clinical insights are missing or misaligned due to poor collaboration, or outputs lack real-world relevance or clinical validity.

(*continued on next page*)

Table 1 (*continued*)

Phase and Aim	Key Administrative and Technical Aspects by Phase	Key Ethical and Legal Aspects by Phase	Critical Red Flags
	and client availability; trigger alerts for failed or slow clients and adapt learning rates, aggregation weights, or privacy parameters until predefined performance targets are met.		
	Quality and Safety Measures	**The FL experiment phase concludes with a transition decision based on the chosen outcome metrics, determining whether it was successful and should proceed further.**	
	• Implement a robust quality system to ensure accuracy and validate the function and impact of the FL experiment.		
6. Dissemination The aim of the phase is to communicate the results and raise awareness.	• Systematically document and report, results and lessons learned following the FL experiment.	· Finalize project documentation. · Implement a data retention policy. · Establish legal arrangements for IP transfer or licensing if commercialization is pursued. · Establish legal arrangements for algorithm transfer to legal manufacturing process if pursued.	· Project results, processes and decisions are not systematically documented or fail to meet regulatory, ethical, or funder requirements, meaning that the project cannot be validated, reported, or closed properly, thus blocking any future use or commercialization. · Legal pathways for IP or algorithm transfer to a manufacturer are not agreed upon, meaning that the project may not transition from research to development or commercialization. · Public communication reveals controversial results, ethical concerns, or stakeholder dissatisfaction.
	The dissemination phase concludes with a transition decision regarding the next steps: closing the research project, making amendments for further development, or initiating commercialization.		

phases are universally applicable; they collectively represent a comprehensive set of considerations essential for the robust, ethical and legally compliant development of FL systems. Many of these tasks require iterative refinement based on internal key performance indicators (KPIs), evaluation metrics and evolving project needs. This iterative nature emphasizes the importance of flexibility, continuous evaluation and adaptability throughout the project lifecycle. Additionally, while risks associated with each roadmap phase are identified, these should be viewed as indicative rather than exhaustive. They are meant to help researchers and project stakeholders to recognize potential areas of concern and prioritize attention based on the specific context of their project. The relevance and severity of these risks will vary depending on data sensitivity, institutional capacity, jurisdictional scope and stakeholder expectations. It is important to note that each FL project will be shaped by its unique organizational and governance structures; there is no one-size-fits-all model and roles, responsibilities and decision-making processes may differ significantly between projects. Nevertheless, this roadmap provides a generalizable framework and foundational guidance on how such projects might be structured and managed.

Transdisciplinary collaboration is crucial to the success of FL projects in healthcare, as these initiatives span diverse domains, including ethical, legal, technical, administrative and clinical aspects [33,34]. Effective collaboration requires not only deep expertise in individual fields but also the ability to communicate and work across disciplinary boundaries [35]. FL projects, particularly in sensitive domains such as healthcare, require deep, specialized knowledge in machine learning, data governance, cybersecurity, legal frameworks and healthcare ethics and clinical practice. However, these domains should not operate in silos. Effective implementation demands transdisciplinary collaboration, where experts not only contribute their knowledge but also engage in continuous, structured dialogue to align objectives, translate requirements and co-develop solutions.

A key insight from the roadmap's development is that integrating expertise across multiple disciplines in this manner is very challenging because it involves bridging differences in terminology, priorities and methodological approaches. For example, aligning system architecture with ethical, legal and clinical constraints requires mutual understanding and shared decision-making frameworks. Without such coordination, the risk of misalignment increases, potentially compromising both the utility and trustworthiness of the FL system. Thus, the developed roadmap serves both as a practical guide for FL project development and a framework for managing the intricate interdependencies between disciplines. It underscores the need for early and sustained stakeholder engagement, iterative co-design and the establishment of shared governance mechanisms to ensure that the produced FL systems are technically sound, legally compliant, ethically responsible and clinically relevant.

Competence alone is insufficient without shared understanding, mutual respect and a commitment to common goals [36]. Clear guidelines, targeted education and strong motivation are essential to engage all relevant stakeholders, clinicians, data scientists, legal experts and administrators throughout the project lifecycle [37]. Without meaningful collaboration, FL projects risk failure due to misaligned priorities, regulatory missteps, or ethical oversights [33,38]. Embedding transdisciplinary teamwork into both research design and implementation ensures the development of more robust, responsible and sustainable AI solutions in healthcare [39].

Developing healthcare AI that is both trustworthy and sustainable is essential for its successful integration into clinical practice [40,41]. Implementing a structured roadmap in FL projects for healthcare enables innovation while embedding safeguards that protect patient privacy, ensuring fairness and promoting sustainable AI development. Sustainability is not treated as a standalone phase but is embedded across the entire roadmap. In the planning and execution refinement phases, sustainability is addressed through early governance design, funding transition planning and regulatory alignment. During the data and platform phases, sustainability is operationalized through maintainable infrastructure, shared data models, continuous monitoring and legally valid data governance mechanisms. In the FL experiment phase, sustainability is reflected in defined model lifecycle management, performance monitoring and update responsibilities. Finally, the dissemination phase explicitly addresses long-term ownership, intellectual property arrangements and pathways for continued operation, deployment or transfer. This phase-spanning integration ensures that sustainability considerations inform both design-time decisions and post-

Table 2
Ethical guidelines, regulations and laws relevant to FL projects.

Core ethical and legal aspects that should be addressed throughout the project	Relevant ethical guidelines	Relevant EU laws, regulations and guidelines	National laws, regulations and guidelines
- Data protection and privacy - Access to secondary health data - Cybersecurity - AI algorithm manufacturing and market placement - Medical device manufacturing and market placement - Clinical research / research ethics - Intellectual property (IP) - Cross-border data processing - Access to non-personal data for third parties - Conflict of laws of data protection	- Ethical Guidelines for Data Use in Research (EU) - The European Code of Conduct of Research Integrity - Helsinki Declaration - Helsinki Declaration - EU Ethics Guidelines for Trustworthy AI - OECD Principles on AI - UNESCO Recommendation on AI Ethics - IIEEE Ethically Aligned Design - World Health Organization Guidance on Ethics & AI in Health - Good Machine Learning Practice (GMLP): An Essential Guide	- General Data Protection Regulation (GDPR) (EU) 2016/679 - Cybersecurity Act (Regulation (EU) 2019/881) - EU-Level IP Laws: European Patent Convention (EPC), EU Trade Secrets Directive (2016/943), EU Copyright Directive (2001/29/EC) - Regulation (EU) 2017/745 on medical devices - Data Act (in cases involving connected devices and non-personal data access obligations) - Regulation 864/2007 on the law applicable to non-contractual obligations (Rome II) - Regulation (EU) 2017/746 on in vitro diagnostic medical devices - AI Act (EU) 2024/1689 - European Health Data Space Regulation (EU) 2025/327	- National data laws (including access to data for research purposes) and cybersecurity laws and requirements applicable in HealthTech/ Medical R/D and innovation - National medical device laws (i.e. clinical study notification; technical documentation language requirements) - National ethical guidelines and research regulations - National IP laws relating to patents, trade secrets protection and copyright issues

project continuity. By aligning technological progress with ethical and societal values, the new roadmap can serve as a vital tool for building AI systems that are not only effective but also responsible and publicly trusted.

5. Limitations and future directions

This study focuses on the design of a lifecycle-oriented roadmap for FL projects in healthcare rather than the empirical evaluation of a single implementation. Although we incorporated illustrative examples, process-level indicators and sustainability markers, the roadmap has not yet been empirically validated in real-world deployments. As such, the practical feasibility, effectiveness and long-term impact of the roadmap remain to be systematically assessed. Future research should apply and evaluate the roadmap in diverse clinical and organizational contexts, develop quantitative evaluation metrics and assess sustainability outcomes over time.

Methodological limitations should also be noted. The study relied on expert and stakeholder input rather than primary empirical data, which may introduce bias and limit generalizability. Although participants represented five Nordic–Baltic countries, recruitment was limited to individuals connected to a single project potentially limiting the diversity of perspectives. While the final expert panel meeting was conducted face-to-face to enable richer discussion, earlier phases relied on online formats, which may have limited the depth of engagement. Future research should include empirical validation and broader stakeholder engagement to strengthen methodological rigor.

Another limitation is that the roadmap was developed within the context of EU legal and ethical frameworks, which may not fully capture technical and operational challenges outside Europe. While the roadmap offers a broadly applicable structure, its use in other jurisdictions may require adaptation to align with local laws, ethical standards and institutional practices. Researchers and practitioners outside Europe should carefully review and, if necessary, modify the process to ensure compliance with their regional regulatory environments.

Future research should address technical and systemic challenges that impact the scalability and sustainability of FL in healthcare, including improving interoperability between heterogeneous FL frameworks, addressing long-term model maintenance and dataset shift in multi-institution networks and developing open, extensible toolkits for sustainability monitoring within FL pipelines. There is also a need for robust and automated measurement of environmental impact at runtime, along with empirical trials to benchmark environmental and clinical benefits across larger networks. Finally, it would be valuable to investigate incentive structures for data custodians to participate in FL initiatives and conduct policy research aimed at harmonizing cross-border governance for federated AI systems.

6. Conclusions

This work brings together the scattered lessons from early FL projects in healthcare into a structured, lifecycle-oriented roadmap addressing ethical, legal, technical and administrative considerations. The roadmap provides a shared reference point for clinicians, data scientists, IT teams and regulators to support compliant and collaborative development under GDPR and the upcoming EU AI Act. However, the roadmap should be understood as an initial conceptual framework rather than a ready-to-deploy solution, as it assumes transdisciplinary collaboration, adequate infrastructure and baseline technical capacity. Future studies should validate the roadmap in diverse healthcare settings, include sustainability indicators and develop robust data-driven methods to assess environmental impact. The community can move from isolated demos to more reliable and trustworthy technology development processes for AI services in healthcare by addressing these aspects.

Declaration of Generative AI and AI-assisted technologies in the writing process

While preparing this work, the authors used Grammarly and Microsoft Copilot for text editing to improve the manuscript's readability, including spelling and grammar checks. After using these tools, the authors reviewed and edited the content as needed and took full responsibility for the content of the published article.

Ethical approval

Ethical approval was not required for this study.

Patient consent statement

Patient consent was not required as this study did not involve patient data.

CRediT authorship contribution statement

Janne Kommusaar: Writing – original draft, Visualization, Resources, Methodology, Investigation, Conceptualization. **Silja Elunurm:** Writing – original draft, Visualization, Resources, Methodology, Investigation, Conceptualization. **Taridzo Chomutare:** Writing – review & editing, Validation, Software, Resources, Investigation. **Mari Kangasniemi:** Writing – review & editing, Writing – original draft, Visualization, Supervision, Resources, Methodology, Investigation, Funding acquisition, Conceptualization. **Sanna Salanterä:** Writing – review & editing, Writing – original draft, Supervision, Resources, Methodology, Investigation, Conceptualization. **Laura-Maria Peltonen:** Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Software, Resources, Project administration, Methodology, Investigation, Funding acquisition, Conceptualization.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

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