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Design, Development, Integration and Technical Validation of a Large-Scale Digital Health Platform for Remote Monitoring and Management of Patients with Advanced Heart Failure

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Featured Application

The engineering methodology presented in this work can support the development of large-scale digital health platforms for remote patient monitoring and clinical decision support. Although developed for advanced heart failure management, the proposed approach can be applied to other chronic diseases requiring the integration of heterogeneous medical devices, clinical information systems and artificial intelligence services.

Abstract

Digital health solutions increasingly rely on interoperable software platforms that integrate heterogeneous data sources, support remote patient monitoring and deliver clinical decision support while complying with strict security, privacy and regulatory requirements. Numerous studies report the clinical outcomes or analytical capabilities of such systems.

However, the engineering processes leading to their development are rarely described in a systematic manner. This paper presents the design, development, integration and technical validation of the RETENTION digital health platform for the remote monitoring and management of advanced heart failure patients. The platform was developed as a modular software ecosystem integrating mobile and web applications, medical devices, clinical and real-world data repositories, and artificial intelligence services through an HL7 FHIR-centred architecture. The complete engineering lifecycle, from requirements and architecture to software development, integration and validation, is described in this paper. Emphasis is placed on the adoption of interoperability standards, Security and Privacy by Design principles, data management mechanisms and deployment strategies that enable the integration of heterogeneous technologies into a unified platform. By documenting the complete development pathway, this work aims to serve as a guide for the design and implementation of large-scale digital health platforms that support remote patient monitoring and chronic disease management.

Keywords: remote patient monitoring; advanced heart failure; digital health platform; healthcare interoperability; HL7 FHIR; software engineering; real-world data; distributed systems; clinical decision support; telemedicine

1. Introduction

The growing demand for personalised healthcare in chronic diseases and the increasing pressure on healthcare systems has led to the adoption of digital health technologies that supplement conventional clinical practice [1,2]. Remote patient monitoring has proven to be a key component of modern healthcare, enabling the acquisition of physiological measurements, patient-reported outcomes and real-world data outside hospitals [3,4]. These emerging technologies have the potential to improve disease management, support early detection of clinical deterioration and reduce hospitalisations by enabling timely clinical interventions [4,5].

Advanced heart failure (HF) is a chronic disease, particularly suitable for the use of remote technologies [6]. Continuous monitoring of vital signs, reporting of symptoms and treatment adherence are essential for patients with advanced HF [3,6]. Longitudinal monitoring can detect gradual changes much earlier than is possible by conventional clinical practice [3,4]. Many digital health solutions have thus been proposed to facilitate the remote follow-up of HF patients using a combination of connected medical devices, mobile applications and clinical decision support tools [7]. The integration of these individual technologies into operational healthcare platforms, however, is a significant engineering challenge [1,8]. This challenge arises from the need to integrate heterogeneous devices, clinical information systems, advanced analytics and regulatory requirements within a secure and interoperable software ecosystem [9,10].

Recent progress in healthcare interoperability standards, cloud computing and artificial intelligence has enabled the development of sophisticated digital health platforms that can support large-scale remote monitoring programmes [11]. Most published studies, however, focus on clinical outcomes, prediction models or single technology components [4,5]. Little attention is paid to the engineering methodologies necessary to design, implement, integrate and validate full digital health infrastructures [1,8,12]. Therefore, many publications provide only a general overview of architectural decisions, interoperability strategies, software integration processes and security mechanisms that are ultimately responsible for the successful deployment of such platforms in real clinical settings [10,13].

Recent studies show that digital health platforms for chronic disease management are increasingly adopting HL7 FHIR-based interoperability, modular service-oriented architectures and multilayer designs to integrate EHRs, wearable devices, patient-reported data and AI-enabled decision support [14,15]. Despite these advances, recent reviews continue to identify challenges related to semantic misalignment, legacy-system fragmentation, incomplete multimodal integration and the incorporation of patient-generated and contextual data into longitudinal care pathways [16,17]. In parallel, privacy-preserving distributed analytics, including federated learning and related approaches, have received increasing attention as mechanisms for supporting cross-site analysis without centralising sensitive patient data [18,19]. Disease-specific platforms and large-scale pilots have further demonstrated the feasibility of combining remote monitoring, semantic data harmonisation, role-based clinical interfaces and AI services [20,21]. However, comprehensive accounts covering the complete engineering lifecycle—from requirements elicitation and architectural design to interoperability, security and privacy mechanisms, system integration, multi-site deployment and technical validation—remain comparatively limited.

The RETENTION (Heart Failure Patient Management and Interventions using Continuous Patient Monitoring Outside Hospitals and Real-World Data) project aims to facilitate remote monitoring and management of patients with advanced HF [22]. The RETENTION platform combines mobile and web applications, connected medical devices, interoperable clinical information management, distributed analytics and clinical decision support in a modular software architecture that is deployed across multiple healthcare organisations [2]. Particular attention was given to interoperability, security, regulatory compliance and practical integration of heterogeneous technologies into a unified operational platform during the development process [1,10].

Previous work from the RETENTION project has reported specific aspects of the platform's interoperability framework, including the development of the common semantic data model and its mapping to HL7 FHIR resources [23,24]. These studies focused primarily on semantic interoperability and the representation and exchange of heterogeneous healthcare data.

The present work extends beyond this scope by documenting and technically validating the complete engineering lifecycle of the RETENTION platform, from the process of requirements engineering and architectural design to implementation, system integration and technical validation [8,10]. The paper does not focus on clinical outcomes, but on the software engineering decisions, architectural principles and implementation strategies that enabled the creation of a large-scale and regulatory-compliant digital health platform [1,2]. This work aims to guide researchers and developers through the design and deployment of future digital health infrastructures for chronic disease management [9,12,13]. To this end, the paper presents the complete engineering lifecycle together with the lessons learned during the RETENTION project.

This work constitutes a system design, implementation and technical validation study rather than a clinical effectiveness study. Its contribution lies in the systematic engineering and validation of a large-scale, interoperable digital health platform integrating heterogeneous patient-side monitoring technologies, clinical-site infrastructures, FHIR-based data management and distributed analytics across a multi-site deployment. Accordingly, the study evaluates the technical architecture, integration, interoperability, security and privacy mechanisms, deployment and operational validation of the platform, rather than clinical outcomes or the performance of a specific clinical intervention.

2. Materials and Methods

2.1. Requirements Engineering

A structured requirements engineering process was initially followed to translate clinical needs, user expectations and technical constraints into a solid software specification [25,26]. The multidisciplinary nature of remote HF management led to the consideration of the operational, technical and regulatory requirements together with the clinical workflows associated with patient monitoring, for the successful deployment of a large-scale digital health platform [6,27].

A patient-centred approach was adopted, including all stakeholder groups involved in the RETENTION ecosystem (patients, caregivers, clinicians and hospital technical personnel) [28]. Requirements were elicited through a combination of literature review, structured questionnaires, semi-structured interviews and expert discussions at the participating clinical sites [26,29]. This approach helped to ensure that the specification was representative of both end-user expectations and operational constraints related to the integration of the platform into existing clinical settings [30].

The user-needs identification phase involved 163 questionnaires collected by 5 clinical centres, answered by 74 patients, 55 caregivers and 34 clinicians. Patient and caregiver questionnaires were translated and distributed locally, while clinicians completed their corresponding questionnaire online. In parallel, semi-structured interviews were conducted with five hospital IT representatives, one from each clinical centre, to identify constraints related to existing local infrastructure. The elicited information was subsequently reevaluated, through expert discussions and use case scenarios before being translated into functional and non-functional user requirements. The complete requirements engineering artefacts, including stakeholders' questionnaires, interview questions, use case specifications and resulting system requirements, are documented in the publicly available RETENTION requirements deliverable D3.1 [31]. The overall requirements engineering workflow followed during this phase is illustrated in Figure 1.

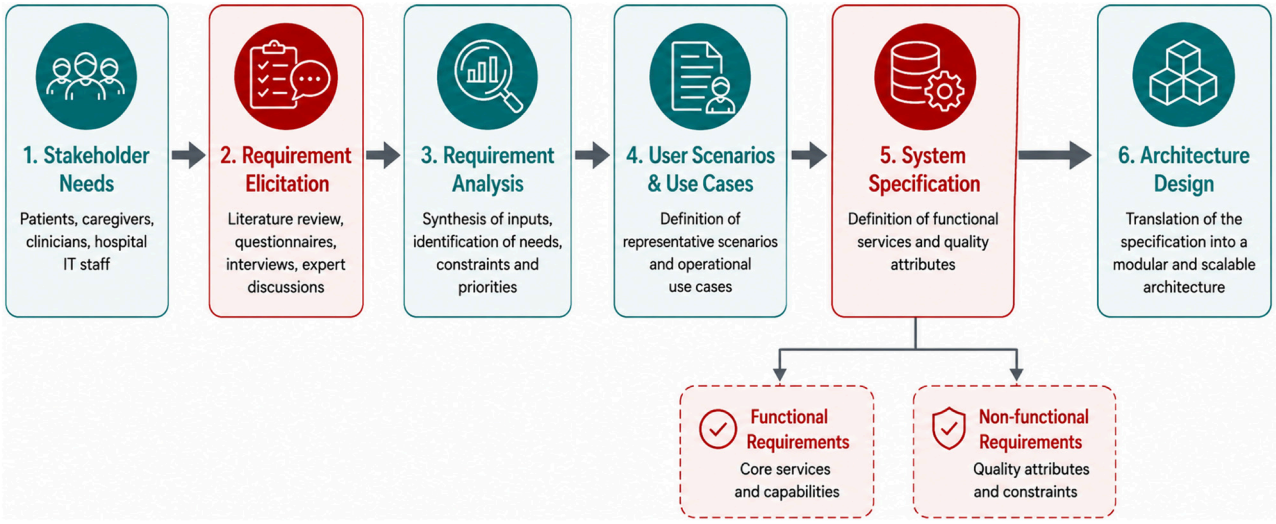


Figure 1. Requirements engineering workflow.

The elicitation process resulted in a set of representative stakeholder use cases that guided the derivation of functional and non-functional requirements and the subsequent architectural design decisions (Table A1).

Findings were subsequently analysed and consolidated into representative user scenarios and operational use cases describing the expected interactions between users and the platform [29]. These use cases provided the foundation for deriving the system specifi-

cation and establishing the interactions between stakeholder needs, functional services and implementation decisions throughout the software development lifecycle [30].

The resulting functional specification defined the platform's core operations: medical device integration, continuous patient monitoring, clinical data visualisation and notification management [32,33]. In parallel, non-functional requirements specified the quality aspects of the implementation, including usability, performance, availability, interoperability, security, privacy and regulatory compliance [34,35]. The full specification of requirements was structured into four domains (clinical, user, technical and regulatory) to support the subsequent design activities [36].

The requirements engineering process laid the foundation for the architectural design activities described in the following section. The adopted approach ensured that every major software component and service addressed specific operational and clinical requirements by maintaining a clear link between stakeholder needs and technical implementation [25,30].

2.2. System Architecture

2.2.1. Architecture Design Methodology

For the platform architecture, an iterative design process was followed, which converted the requirements identified during the requirements engineering phase into a modular and interoperable software solution [37,38]. The architectural design aimed to support continuous remote monitoring of patients with advanced HF while ensuring interoperability, security and compliance with regulatory requirements [39]. The proposed architecture was developed in close collaboration between the technical and clinical partners to fulfil the operational needs of healthcare professionals and the technical constraints associated with deploying the platform across multiple clinical sites [40,41].

A methodology based on a layered architectural approach was followed [42,43]. The system was decomposed into independent components with defined responsibilities and communication capabilities [38]. This separation allowed different development teams to work in parallel, enabling each subsystem to evolve independently [41]. The communication between components was implemented using REST-based interfaces [44,45].

2.2.2. Overall System Architecture

The RETENTION platform was created as a modular software ecosystem enabling continuous remote monitoring of patients with advanced HF and supporting heterogeneous data sources, multiple user groups and distributed clinical sites [46,47]. The design of the architecture aimed to ensure scalability, interoperability and maintainability while allowing independent deployment of software services [48,49].

To meet these requirements, a three-layer architecture was adopted [50]. This architecture consists of the Patient Edge (PE) responsible for patient-side data acquisition, the Clinical Site Backend (CSB) where clinical operations take place, and the Global Insights Cloud (GIC) for centralised analytics, as illustrated in Figure 2. Together, these layers support the complete lifecycle of patient data, from acquisition and local clinical management to large-scale analytics and decision support [47,51].

The PE is the interface between patients and the platform, integrating medical devices, wearable sensors, mobile applications and home gateway services for the continuous acquisition of physiological, behavioural and environmental data [52,53]. This information is securely transferred to the corresponding CSB, where it is merged with clinical data provided by the clinicians [48]. The anonymised data from several CSB instances are then aggregated within the GIC to allow for analytics and model training [51]. This is followed

by the redistribution of machine learning models to the clinical sites at regular intervals for personalised application [54].

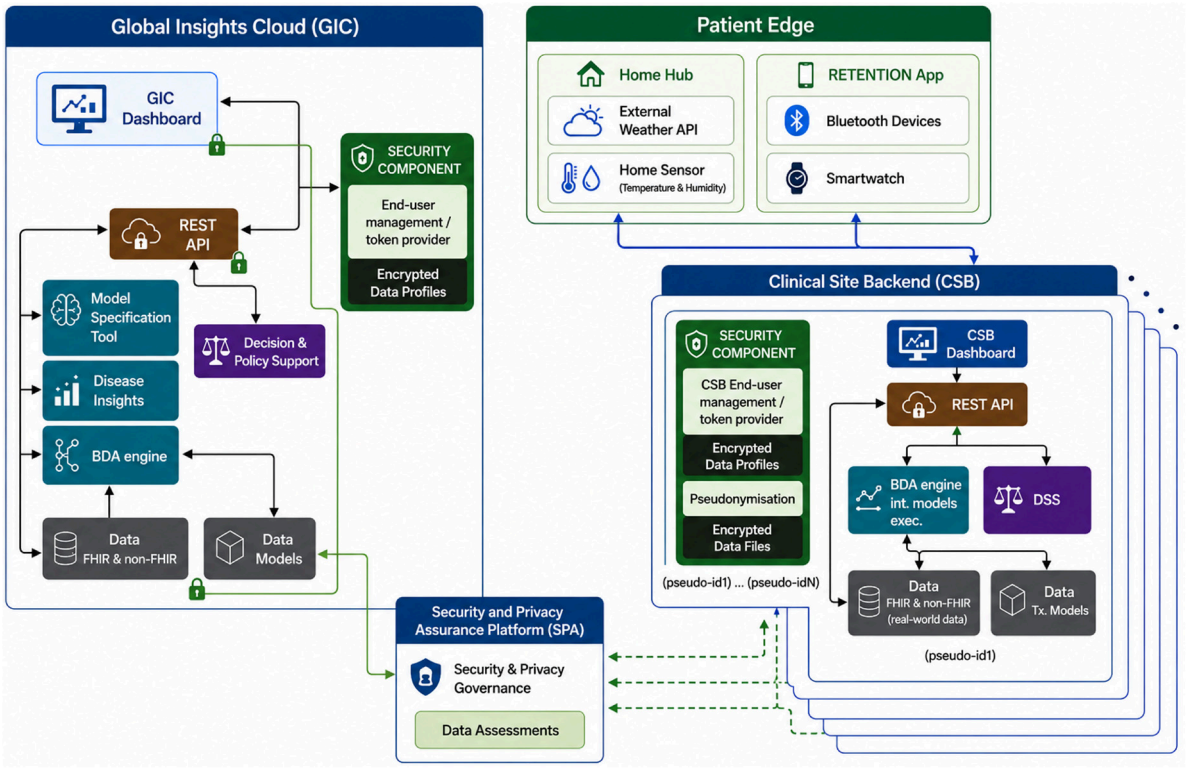


Figure 2. Overall system architecture of the RETENTION platform.

The layered architecture provides several engineering advantages. Clinical data remain owned by each participating healthcare organisation, maintaining local autonomy and compliance with institutional and regulatory requirements. On the other hand, analytics are conducted centrally on anonymised data collected across participating sites [54]. This distributed approach supports scalable deployment and allows for the incorporation of new analytical services without disrupting clinical operations [47,49].

The three-layer organisation was selected to reflect the distinct operational and data-governance responsibilities of the platform, separating patient-side acquisition, site-level clinical operations and notification generation, and cross-site analytics. A fully event-driven architecture was not considered necessary for the intended clinical workflow, as RETENTION was designed as a remote monitoring and decision-support platform rather than an emergency response system [55]. Similarly, a data-mesh approach was not adopted because RETENTION required a common FHIR-centred data model and harmonised interoperability mechanisms across participating sites, while preserving local control of identifiable clinical data [56].

2.2.3. System Components and Data Flow

The modular design of the platform allows each architectural layer to host its own software services and data management mechanisms while exposing standardised interfaces for communication with the other layers [43,57]. Communication between layers is performed through REST-based services, enabling secure data exchange between distributed software modules [41,44].

Data generated at the PE are first acquired by connected medical devices and then transferred to the CSB via a mobile application for clinical use [58,59]. The CSB supports patient monitoring, longitudinal health record visualisations and notification manage-

ment [60]. Anonymised datasets are periodically uploaded to the GIC and integrated across all participating sites to support machine learning model development and advanced analytics [61,62]. The derived models are then deployed back to the CSB, supporting local personalised predictions [61,63].

The platform offers flexibility by separating data acquisition, clinical management and advanced analytics into interoperable architectural layers capable of accommodating future software extensions, additional medical devices and new analytical services with minimal impact on the existing infrastructure [41,43]. This architectural organisation also forms the basis of the unified data management mechanisms discussed in the next section.

2.3. Data Architecture and Management

2.3.1. Unified Data Model

The RETENTION platform integrates heterogeneous information originating from multiple sources, including clinical information systems, connected medical devices, mobile applications, patient-reported outcomes and environmental sensors [64,65]. To enable semantic consistency and interoperability across all software components, a unified data model was adopted to provide a common representation of both clinical and real-world patient data [66,67].

The HL7 FHIR standard [68] was selected as the common interoperability framework for modelling, storing and exchanging healthcare information [69,70]. Standard FHIR resources were complemented with internationally recognised clinical terminologies, including SNOMED CT [71], LOINC [72], ICD-10 [73] and ATC [74], to ensure semantic interoperability and enable consistent interpretation of clinical variables across all participating sites [75,76]. The overall data architecture and the interaction between data sources, repositories and platform services are illustrated in Figure 3.

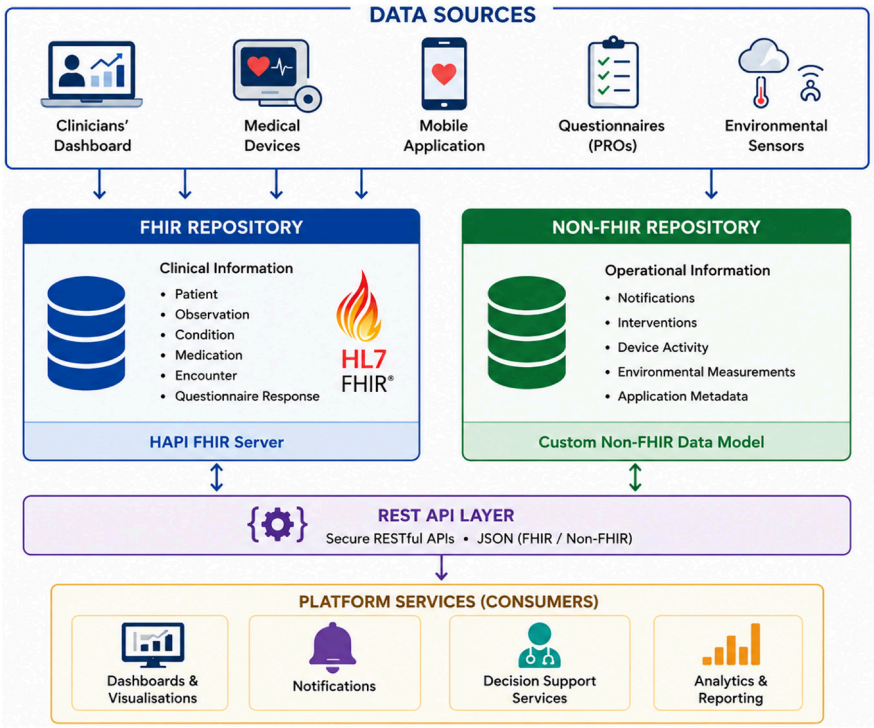


Figure 3. Unified data architecture of the RETENTION platform.

A dedicated RETENTION FHIR Implementation Guide was developed using FHIR Shorthand (FSH) and the SUSHI framework to define project-specific profiles, extensions and implementation rules where standard FHIR resources were insufficient [23,77]. The

Implementation Guide (version 1.0.0), targeting HL7 FHIR R4 (4.0.1), was generated and validated using the FHIR IG Publisher (v1.2.22), with the corresponding quality-assurance report returning zero validation errors. The guide, including the defined profiles, extensions, code systems and implementation examples, was made publicly accessible through the official RETENTION project website [78], enabling external inspection and conformance testing against the defined profiles. Rather than extensively profiling every clinical variable, a selective profiling strategy was adopted, extending only the Patient resource while relying on standard FHIR resources and implementation examples for the remaining entities [23,79]. This approach reduced implementation complexity while maintaining semantic consistency and interoperability across the distributed deployments.

The unified data model was derived from a semantic reference model comprising 444 clinical and contextual variables organised into multiple clinical domains [23]. Each variable was mapped to the most appropriate FHIR resource and, whenever possible, bound to internationally recognised terminology systems. Where no suitable terminology existed, project-specific code systems were introduced to preserve semantic completeness without compromising interoperability [77,80].

The selective profiling strategy was adopted to balance conformance requirements against the complexity and maintainability of a semantic model comprising 444 variables. Dedicated profiles were therefore introduced only where extensions to the base FHIR specification were required, while standard FHIR resources, including Observation, Condition, Encounter, QuestionnaireResponse and MedicationStatement, were represented through predefined implementation examples and terminology mappings [23]. Cross-site consistency was additionally supported by the controlled data-entry pathways of the platform: all participating sites used the same patient mobile application and clinical dashboard, which implemented common mappings to the RETENTION data model and generated FHIR resources according to the Implementation Guide before submission to the site repositories. Consequently, conformance was primarily enforced at the application and implementation level rather than through resource-specific profiles. While this approach reduced profiling and maintenance complexity within the controlled RETENTION deployment, broader integration with independent third-party data producers would require stronger profile-based conformance and validation mechanisms.

Not all information handled by the platform could naturally be represented using healthcare interoperability standards [81,82]. Therefore, operational entities supporting platform functionality, such as notifications, interventions, device activity and platform-specific measurements, were modelled separately using dedicated non-FHIR data structures [69,83]. This separation between clinical and operational information ensured compliance with established healthcare interoperability standards while preserving the flexibility required to support platform-specific services and workflow management.

2.3.2. Data Repositories and Interoperability

To support the different categories of information defined by the unified data model, the RETENTION platform employs two complementary data repositories [48,84]. Clinical information is managed through an HL7 FHIR-compliant repository implemented using a dedicated HAPI FHIR server, which provides standardised storage, retrieval and management of healthcare resources through RESTful services [85]. Operational information that is not naturally represented using FHIR, including notifications, interventions, device activity and platform-specific measurements, is maintained in a separate non-FHIR repository [41]. This dual-repository approach combines standards-based interoperability for clinical information with the flexibility required for efficient platform operation [41,86].

Data exchange between software components is performed through secure RESTful APIs using JSON-encoded messages, providing a uniform communication layer across the platform [87,88]. This service-oriented approach enables software components to exchange information independently of their internal implementation, facilitating modular development and simplifying system integration [41,88]. The same communication mechanisms support interoperability between the distributed CSBs and the GIC, where anonymised datasets are periodically aggregated to support centralised analytics while preserving the federated deployment model adopted by the platform [51,89].

The separation between FHIR and non-FHIR repositories also enables clinical information to remain fully interoperable without constraining platform-specific operational services to healthcare data standards [75,86]. Consequently, the architecture maintains semantic consistency for clinical data while preserving the flexibility required for workflow management, device integration and advanced analytical services [39,75].

Overall, the adopted data architecture combines standardised healthcare information models, modular repository design and interoperable communication mechanisms within a unified framework [84]. This approach enables consistent management of heterogeneous data while supporting scalable deployment, distributed analytics and the platform services presented in the following sections [47,51].

2.4. Platform Implementation

The RETENTION platform was implemented as a collection of interoperable software services distributed across the PE, CSB and GIC. Figure 4 provides an overview of the main platform services and their interactions, which are described in detail in the following subsections. All software services depicted outside the patient-side layer are deployed as containerised services, whereas the patient-side software operates directly on the mobile phone and the Raspberry Pi home gateway.

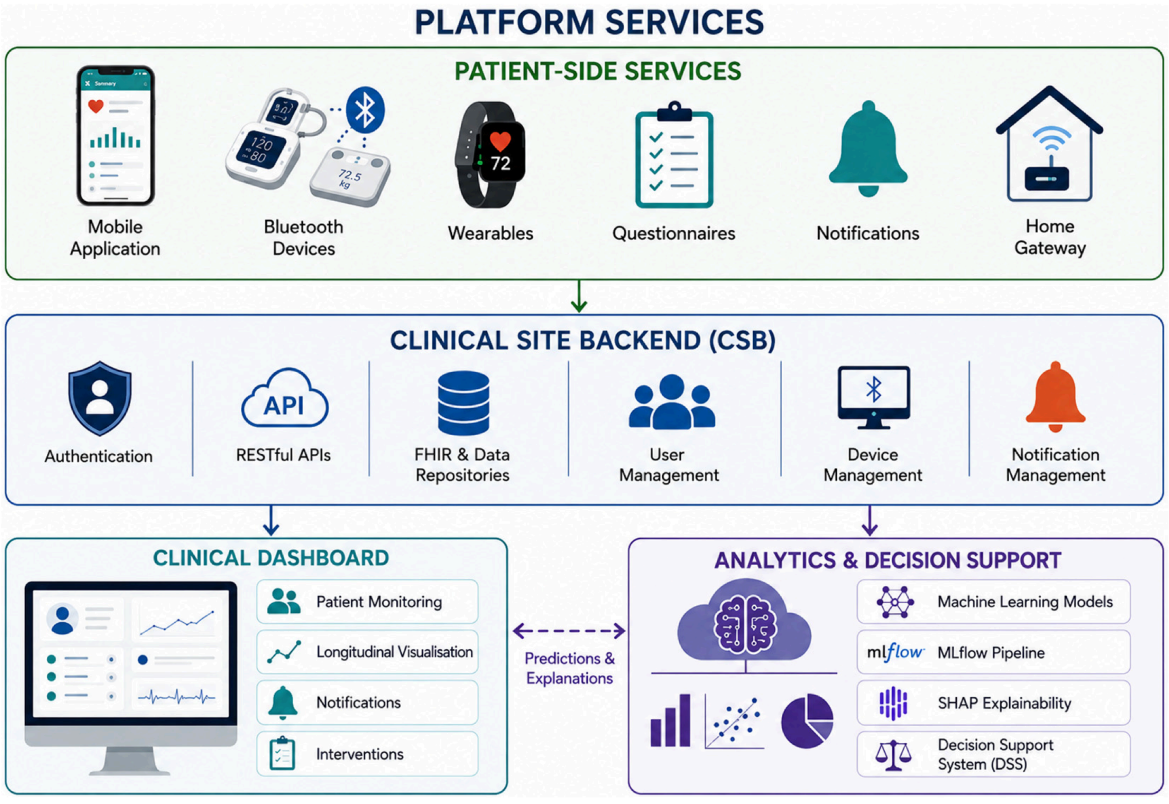


Figure 4. Main software services implemented within the RETENTION platform.

2.4.1. Patient Side Services

The PE layer consists of a mobile application, which integrates medical devices, wearable sensors and patient-reported information to enable continuous home monitoring. The mobile application is the point of contact for patients, allowing the collection of physiological measurements from Bluetooth medical devices and wearables, as well as manual entry of symptom questionnaires and self-reported clinical information, such as medication adherence. Collected measurements are locally validated before being transmitted securely to the CSB, where they are immediately available for clinical assessment [90–92]. This implementation enables continuous collection of patient data with minimal patient intervention and reduced risk of transcription error [3,91].

The patient-side equipment consists of a Samsung Galaxy A03s smartphone (Samsung Electronics Co., Ltd., Suwon, South Korea), Garmin Venu Sq smartwatch (Garmin Ltd., Schaffhausen, Switzerland), OMRON M4 Intelli IT blood pressure monitor, OMRON HN-300T2 Intelli IT weight scale and OMRON P300 Intelli IT pulse oximeter (OMRON Healthcare Co., Ltd., Kyoto, Japan).

A local home gateway consisting of a Raspberry Pi 4 Model B (Raspberry Pi Holdings plc, Cambridge, UK) and a Xiaomi Mijia temperature and humidity sensor (Xiaomi Communications Co., Ltd., Beijing, China) is also utilised. The sensor monitors home conditions, while the OpenWeatherMap API (OpenWeather, https://openweathermap.org/api) provides external environmental conditions based on the patient's postal code [93]. Operational monitoring of the home gateway is supported by an automated inactivity mechanism, which generates a notification for hospital IT personnel when an RPi has not transmitted data for three consecutive days, enabling subsequent troubleshooting. Formal gateway failure-rate and maintenance-intervention statistics were not systematically collected during validation. A smartphone-only approach was not adopted because the RPi supported unattended hourly acquisition of indoor temperature and humidity from the permanently connected home environmental sensor, independently of patient interaction or smartphone availability.

2.4.2. Clinical Services

Healthcare providers access the platform through a web-based clinical dashboard that consolidates patient management, longitudinal monitoring and decision support into one environment. A comprehensive clinical picture is provided by the dashboard, which integrates clinical, physiological, behavioural and environmental data, to offer clinicians a complete view of each patient's health status during the monitoring period. Interactive visualisations allow the investigation of historical measurements, trends and clinically relevant events to aid informed decision-making in the context of routine follow-up [94,95].

The implementation also provides operational services needed for large-scale clinical deployment. These include user and role management, patient enrolment, device assignment, notification management and intervention tracking. The platform generates automated notifications, based on predefined rules. These notifications are displayed on the dashboard, allowing clinicians to quickly identify measurements outside predefined thresholds and take appropriate clinical action [25].

2.4.3. Analytics and Decision Support

Analytical services have been deployed in the GIC, using anonymised datasets collected from all participating clinical sites to build, train and validate machine learning models that support personalised patient management. The analytics infrastructure is an end-to-end machine learning pipeline built on Jupyter Notebooks (Project Jupyter, https://jupyter.org/) and MLflow (https://mlflow.org/), which offers data preprocess-

ing, experiment tracking, model versioning and model deployment capabilities. The trained models are sent to the CSB for personalised application on patients. This enables predictions to be performed locally without having to access patient data stored in a central location.

Model performance was evaluated using predefined validation measures, with model parameters, performance metrics and associated artefacts recorded through the MLflow-based model-management infrastructure, enabling comparison of model runs and supporting subsequent model evaluation. Depending on the prediction task, the recorded evaluation measures included classification and regression metrics such as AUC, confusion matrices, MAE, RMSE and R^2 [96]. The analytics architecture was designed to support an iterative model-development and deployment lifecycle in which trained models are distributed to the clinical sites for local inference. However, automated post-deployment detection of concept drift or site-specific data-distribution shift was not implemented. In a multi-site operational deployment, longitudinal monitoring of input-data distributions and site-specific model performance would therefore be required to identify potential degradation and trigger model re-evaluation and retraining when necessary.

The platform applies explainable AI techniques based on SHapley Additive exPlanations (SHAP) to display the relative contribution of each variable to a given prediction, thus allowing for clinical interpretation of the prediction results [97,98]. The platform includes predictive models as well as a rule-based Decision Support System (DSS) that continuously compares new patient measurements against clinical thresholds and generates notifications whenever abnormalities are detected [3]. The analytics are integrated into the clinical dashboard, providing predictive insights, explainable recommendations and timely notifications to healthcare professionals while preserving the clinician's central role in the final decision-making process [94].

2.5. Security, Privacy and Regulatory Compliance

Security and privacy principles were considered throughout the development lifecycle by adopting a Security and Privacy by Design approach [99,100]. Rather than applying security mechanisms as independent add-on components, they were embedded within the platform architecture to protect sensitive health information throughout data acquisition, storage, processing and exchange. This approach supported the distributed architecture of the RETENTION platform, while ensuring the confidentiality, integrity and availability of clinical and patient-generated data [101,102].

Security and privacy controls were defined according to the risks associated with distributed processing of health data across the RETENTION architecture, including unauthorised access, interception of data in transit, disclosure of identifiable information, re-identification and inappropriate cross-site access [99]. These risks were addressed through authentication and authorisation, role-based access control, secure communications, pseudonymisation, source-side anonymisation and controlled data exchange between the architectural layers [103]. The principal trust boundaries correspond to the Patient Edge–CSB and CSB–GIC interfaces, with identifiable clinical information remaining within the site-level environment and only anonymised data being transferred to the GIC for cross-site analytics.

Access to services on the platform is protected by authentication and role-based authorisation so that users can only access the information and functionality permitted by their assigned role [103,104]. Secure REST APIs form the communication layer between the software components [105]. All interactions are authenticated, authorised and logged to provide traceability across the platform [102,106]. Throughout the project, the API management layer was iteratively improved to increase interoperability, improve validation

processes and enable new services such as secure analytics workflows and controlled access to anonymised datasets within the GIC [99,107].

To facilitate privacy-preserving analytics, all data transmitted from the CSBs to the GIC are anonymised following a defined anonymisation procedure [25,108]. An anonymisation pipeline applies configurable transformation strategies depending on the sensitivity of each data element, including deletion of direct identifiers, generalisation of quasi-identifiers and consistent temporal shifting of dates to preserve the longitudinal relationships whilst preventing re-identification of patients [25]. In addition, k-anonymity validation is performed to verify that anonymised datasets satisfy predefined privacy thresholds while preserving their analytical utility [109]. The principal security, privacy and regulatory mechanisms implemented within the platform are summarised in Table 1.

Table 1. Security and privacy mechanisms implemented within the RETENTION platform.

Architectural Layer	Aspect	Implemented Mechanism
Patient Edge	Unauthorised access and exposure of collected data	Authentication; controlled application access
Patient Edge → CSB	Interception or unauthorised data transmission	Authenticated secure communication; HTTPS/TLS
CSB	Unauthorised access to clinical information	Authentication and authorisation; role-based access control; pseudonymisation
CSB → GIC	Disclosure of identifiable information and re-identification	Source-side anonymisation; data minimisation; secure transfer; re-identification safeguards
GIC	Unauthorised access to aggregated datasets and analytics services	Authentication and authorisation; controlled access; anonymised datasets
Platform-wide	Security incidents and vulnerabilities	Logging and monitoring; security testing; incident-management procedures

In accordance with GDPR terminology, pseudonymisation and anonymisation are treated as distinct processes within the platform. Pseudonymised data remain personal data and are processed within the controlled clinical-site environment, whereas anonymisation is applied before data transfer from the CSB to the GIC [110].

Anonymisation is performed at the source CSB before any data are transferred to the GIC, ensuring that directly identifiable information is not transferred to the central infrastructure. The pipeline periodically processes FHIR and non-FHIR data using predefined anonymisation rules and re-identification safeguards prior to transfer [108,109]. The participating hospitals are responsible for the processing of the raw clinical data within their respective clinical workflows, while the anonymisation pipeline and associated data-handling procedures were reviewed and approved by the RETENTION Data Protection Officer (DPO) with respect to GDPR and applicable national data-protection requirements. Only data satisfying the defined anonymisation criteria are transferred to the GIC for cross-site analytics.

To provide continuous security assurance, a centralised Security and Privacy Assurance (SPA) platform was deployed to continuously monitor the distributed infrastructure, support vulnerability assessment and provide unified reporting for all the platform compo-

nents [102,111]. Penetration testing and mitigation procedures supported security validation activities demonstrating the robustness of the deployed infrastructure and allowing for continuous improvement during the implementation phase [102,103]. In addition, the platform was developed in accordance with the standards of the ISO/IEC 27000 family and the General Data Protection Regulation (GDPR) requirements, thereby supporting both technical and organisational measures for the secure and trustworthy management of sensitive healthcare information [112,113]. Finally, the development of the platform's predictive analytics services considered the emerging requirements of the European Union Artificial Intelligence Act [114], particularly regarding transparency, human oversight and accountability for high-risk AI systems used in healthcare applications.

The RETENTION platform was developed as a research platform for remote patient monitoring and clinical decision support and was not classified as a medical device under Regulation (EU) 2017/745 (MDR) within the scope of the project [115]. Consequently, no MDR risk class or CE marking was assigned to the platform.

2.6. Use of Generative Artificial Intelligence in Figure Preparation

Generative artificial intelligence (GenAI), specifically ChatGPT Images 2.0 (OpenAI, San Francisco, CA, USA), was used as a graphical aid in the preparation of the schematic representations presented in Figures 1 and 3–6. GenAI was used for graphical generation and visual presentation, while the underlying technical content, including the system architecture, components, relationships, terminology and engineering processes represented in the figures, was specified and verified by the authors based on the RETENTION platform. The generated outputs were reviewed and edited by the authors to ensure consistency with the implemented system. GenAI was not used to generate or analyse research data, technical results or scientific findings.

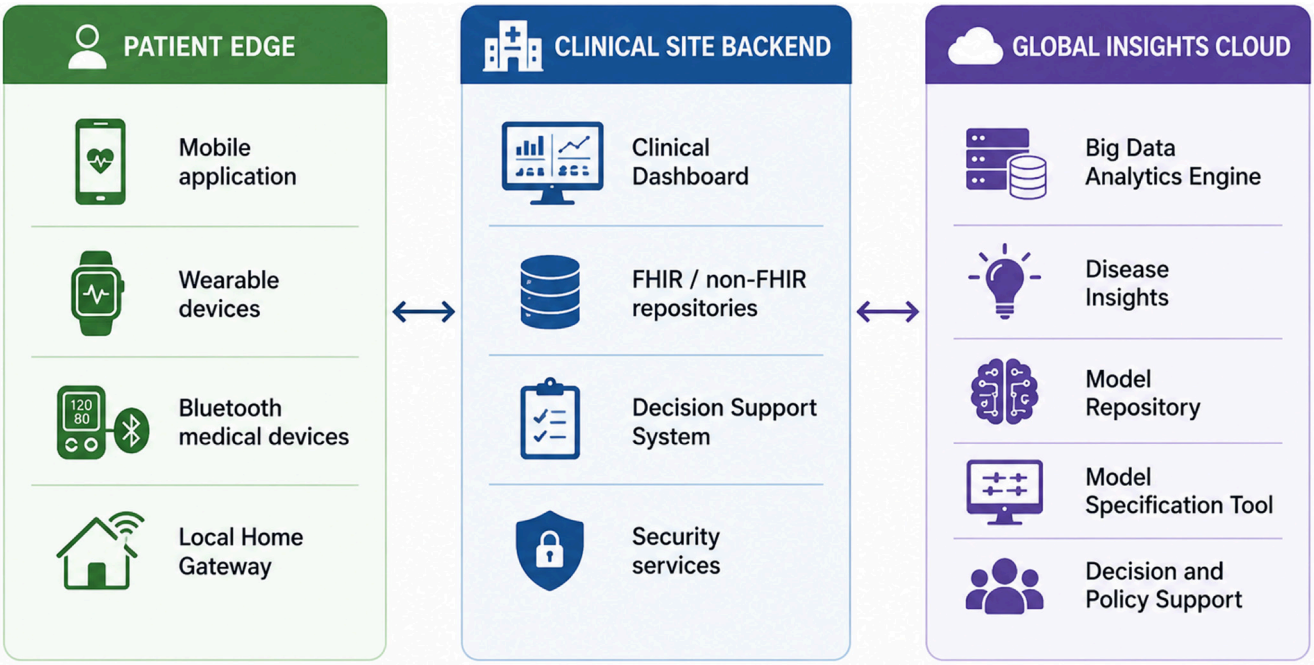


Figure 5. Integrated components of the RETENTION platform.

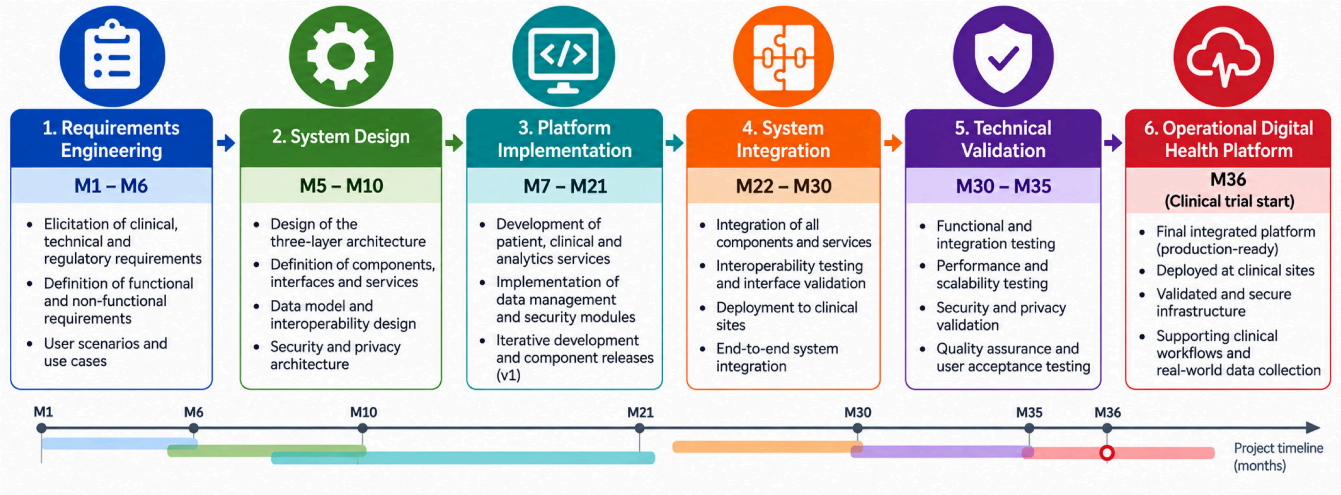


Figure 6. Engineering lifecycle and timeline of the RETENTION digital health platform.

3. Results

The validation presented in this study concerns the technical integration, interoperability, deployment and operation of the platform and does not constitute an evaluation of clinical effectiveness or patient outcomes.

3.1. Integrated Platform Deployment

The engineering activities described in Section 2 resulted in the successful deployment of a fully integrated digital health platform for the remote monitoring and management of patients with advanced heart failure. The final implementation combines patient- and clinician-facing applications, interoperable data management services, analytics components and security mechanisms into a unified software ecosystem capable of supporting continuous data acquisition, clinical monitoring and decision support across geographically distributed clinical sites.

While Figure 4 presented the principal software services and their functional interactions, Figure 5 illustrates their deployment across the three architectural layers of the RETENTION platform and the communication paths between them.

The implemented platform is based on the distributed architecture presented in Section 2.2, which includes individual CSB instances for each of the participating healthcare organisations and a centrally managed GIC that provides shared analytical capabilities. All software components were integrated with standard REST interfaces during deployment to allow seamless communication between the PE, CSB and GIC, while preserving the separation between operational and analytical environments [8,44]. Minor architectural refinements introduced during the integration phase included the deployment of a reverse proxy layer to simplify infrastructure management and the centralisation of the Security and Privacy Assurance platform to optimise computational resources without affecting the architecture of the system.

System integration enabled the complete end-to-end data flow across the distributed platform. Physiological measurements acquired through Bluetooth medical devices, wearable sensors and environmental monitoring systems were successfully transmitted from the PE to the corresponding CSB, where they became immediately available through the clinical dashboard. Anonymised datasets were periodically transferred to the GIC for analytics and machine learning, while trained predictive models were subsequently redistributed to the clinical sites to support local decision support services.

Deployment was based on Docker containers and isolated Docker networks (Docker, Inc., https://www.docker.com/), with the complete set of platform components and their dependencies defined in a common Docker Compose configuration [116]. Deployment-specific parameters were managed through environment (.env) files, while component versioning was used to control software releases and updates throughout the clinical trial. Platform integration, deployment and maintenance were continuously supported through a dedicated project task during the trial period. For data protection and operational recovery, all platform databases were backed up daily; backup copies were retained locally on the hosting infrastructure and automatically transferred to a separate machine. Restoration procedures were also tested successfully to verify that the stored backups could be used for system recovery.

Medical data are stored in pseudonymised form within the CSBs, while internal communication between platform components and databases is restricted through isolated Docker networks. External access to backend services is limited, and the components used by end users communicate with the platform APIs only through the Security Component. This deployment approach strengthens isolation between services, reduces unnecessary exposure of internal databases and supports secure operation of the distributed platform [117].

3.2. Technical Validation Methodology

The integrated platform underwent a comprehensive technical validation process covering both individual software components and the complete distributed infrastructure. Validation activities were conducted throughout the entire implementation lifecycle and included unit testing, integration testing, end-to-end workflow verification, user interface testing, security testing and performance assessment to ensure that all implemented services operated correctly before deployment in the pilot environments. During the implementation process, quality assurance activities were continuously performed, and the issues identified were resolved by iterative refinement of the platform [118]. The principal validation activities performed during the technical evaluation of the platform are summarised in Table 2.

Table 2. Technical validation activities performed during platform integration.

Validation Objective	Aspect
Verification of individual software modules	Unit testing
Validation of communication between platform components	Integration testing
Verification of complete clinical workflows	End-to-end testing
Assessment of application functionality and usability	User interface testing
Verification of authentication, authorisation and secure communication	Security testing
Evaluation of platform responsiveness and stability	Performance testing

Integration testing confirmed the correct interaction between the PE, CSB and GIC, validating the successful exchange of clinical information, real-world data and analytical outputs across the complete software ecosystem. Representative workflows including patient enrolment, device assignment, physiological and environmental data acquisition, secure data transmission, notification generation and analytics execution were executed across the distributed infrastructure. This demonstrated that the integrated platform successfully supports the complete remote monitoring process envisioned within the RETENTION project [119].

Prior to clinical-trial operation, the integrated platform was evaluated in a dedicated virtual hospital environment, enabling end-to-end testing of platform components and

clinical workflows using virtual patients. Subsequently, each of the five participating clinical sites was allocated a dedicated testing period, during which clinicians accessed their respective platform instance, created virtual patients and exercised the implemented functionalities and workflows. This staged validation process enabled technical, integration and workflow-related issues to be identified and addressed before the platform was used to support the clinical trial. No real patients or patient-level clinical data were involved in this technical validation phase.

Beyond the validation activities summarised in Table 2, quantitative evidence was also collected for selected performance and operational aspects of the integrated platform. Stress testing of the FHIR repository and clinical dashboard was performed using a simulated workload substantially exceeding the anticipated project requirements, comprising 16,000 Patients, 12,000 Conditions and approximately 10 million Observations, transferred to the FHIR repository in bundles of 500 resources. The FHIR repository successfully handled the imposed workload, while performance limitations identified in dashboard visualisation under these conditions were subsequently addressed [120]. In addition, continuous uptime monitoring of the five deployed CSB instances showed availability around 99.17% during the monitored period. Security validation included penetration testing, where no critical vulnerabilities were identified. These measurements complement the functional, integration and end-to-end validation activities by providing quantitative evidence of system capacity and operational availability.

Overall, the functional, integration and end-to-end testing activities, together with the quantitative performance and operational assessments, demonstrated the technical readiness of the integrated platform to support the subsequent multi-site clinical trial across the five participating clinical sites [39,118].

4. Discussion

The present study extends our previous RETENTION work on the common semantic model and FHIR-based interoperability [23,24]. While those studies addressed the representation and interoperable exchange of heterogeneous health data, the contribution reported here concerns the integration of these mechanisms within the broader end-to-end platform and their operation alongside patient-side acquisition, clinical services, distributed analytics, security and privacy controls, and multi-site deployment and validation.

The RETENTION project illustrates an engineering process for the design, implementation and technical validation of a large-scale digital health platform able to support continuous remote monitoring of patients with advanced HF. Although several telemonitoring solutions have been proposed in recent years, only a few publications describe in a complete way the technical development process, starting from the requirements elicitation up to the deployment and validation of an operational platform [3,121].

Recent digital health platforms share several characteristics with RETENTION, including the adoption of interoperable data models, distributed or modular architectures, remote data acquisition and AI-supported analytics. However, their technical emphasis and development approaches differ. Some studies primarily address scalable FHIR infrastructures and interoperability [14], while others focus on predictive analytics across decentralised healthcare environments [15], multimodal remote monitoring [16], integration of EHR and wearable data for AI-supported decision making [17], or privacy-preserving federated learning [18]. RETENTION combines these concerns within a single engineering lifecycle, integrating patient-side acquisition, FHIR-based clinical-site infrastructures, cross-site analytics, security and privacy mechanisms, and multi-site deployment and validation. With respect to AI, RETENTION does not introduce a novel learning algorithm; its contribution lies in integrating model development and management into the distributed platform

architecture, with models trained and managed centrally using anonymised cross-site datasets and subsequently deployed to the CSBs for local inference on patient data. SHAP-based explainability is additionally incorporated to support interpretation of individual predictions. This differs, for example, from federated-learning approaches in which model training itself is distributed across participating sites without centralising the underlying datasets [18]. Thus, the principal contribution of RETENTION is the end-to-end integration and operationalisation of interoperable monitoring, distributed analytics and clinical decision-support services rather than advancement of a specific AI technique.

The goal of this work is to provide a comprehensive description of the engineering lifecycle used in the development of the RETENTION platform. One of the main engineering challenges addressed during the development of the platform was the integration of heterogeneous technologies into a unified interoperable ecosystem. Clinical information systems, Bluetooth medical devices, wearable sensors, environmental monitoring systems and advanced analytics components were developed independently, but had to work together seamlessly within a distributed architecture. The modular three-layer architecture, coupled with standards-based interoperability (HL7 FHIR and RESTful services), allowed the integration of these heterogeneous components, while preserving independence between software modules. This architectural approach facilitates future system evolution, allowing new devices, analytical services and software components to be incorporated with minimal modifications to the existing infrastructure [75,122].

Another important architectural decision was to decouple operational clinical services from centralised analytics. The platform maintains the clinical site backend for patient management and clinical workflows, while the global insights cloud runs population-level analytics, balancing local operational autonomy with large-scale data exploitation. A distributed deployment strategy like this also helps to comply with privacy regulations as anonymisation is performed before data leave the clinical environment, and analytical models are redistributed to the clinical sites for local execution [75,123].

The project also highlighted the importance of integrating interoperability and security requirements from the beginning of the development process rather than during system integration. The use of internationally recognised healthcare standards and Security and Privacy by Design principles enabled component integration, reduced implementation complexity and helped to deliver a secure and regulatory-compliant platform suitable for clinical use [69,102]. These engineering practices are generally applicable to future digital health infrastructures which must satisfy technical, organisational and regulatory requirements at the same time.

Despite the successful deployment and validation of the platform, several limitations should be acknowledged. The current implementation was developed in the scope of advanced HF management and supports a predefined set of medical devices and monitoring services. Future extensions are possible due to the modular architecture, but integration of additional clinical domains, devices and hospital information systems requires additional engineering effort and adaptation to local operational requirements. Moreover, although the distributed analytics framework enables scalable model development, the generalisability of predictive models across different healthcare settings is dependent on the availability of appropriate datasets [32,75]. Automated post-deployment monitoring for concept drift and site-specific data-distribution shifts was not incorporated into the current platform. Such mechanisms, together with longitudinal monitoring of model performance and appropriate model re-evaluation and retraining, should therefore be considered in future operational deployments to maintain prediction reliability across sites and over time.

In summary, the RETENTION experience shows that the successful development of large-scale digital health platforms depends not only on advanced analytical algorithms but

also on strong software engineering practices such as requirements engineering, interoperable system architecture, secure data management, modular implementation, and iterative integration and validation [121]. The engineering lessons presented in this work may therefore provide useful guidance for the design and deployment of future interoperable digital health platforms supporting the management of chronic diseases.

5. Conclusions

In this paper, we presented the design, development, integration and technical validation of the RETENTION digital health platform, a large-scale digital health platform supporting the remote monitoring and management of patients with advanced HF. The platform integrates heterogeneous clinical information systems, connected medical devices, patient-facing applications and advanced analytics within a secure, interoperable and distributed architecture designed to support continuous monitoring in real-world clinical settings [3,75].

Beyond describing the final platform, this work documents the complete engineering lifecycle followed during its development, from requirements elicitation and system design to implementation, integration and validation. The adoption of a modular three-layer architecture, standards-based interoperability through HL7 FHIR, Security and Privacy by Design principles and an iterative development methodology enabled the successful deployment of a scalable and regulatory-compliant digital health infrastructure supporting multiple clinical sites and heterogeneous data sources [41,124].

The development process was iterative rather than strictly sequential, with partial overlap between requirements engineering, architecture design, component development, integration and validation activities. Figure 6 summarises the approximate duration and temporal overlap of the principal engineering phases throughout the project.

The experience gained through the RETENTION project highlights that the successful implementation of large-scale digital health platforms depends not only on the integration of advanced digital health technologies, but also on the systematic application of software engineering principles that ensure interoperability, maintainability, security and scalability throughout the development lifecycle [123]. By documenting the engineering decisions and resulting technical solutions, this work provides practical guidance for the design and implementation of future interoperable digital health platforms supporting remote patient monitoring and the management of chronic diseases.

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elicitation, for which informed consent was obtained as documented in the RETENTION requirements deliverable. No additional ethical approval was required for the technical study reported in this manuscript.

Informed Consent Statement: Informed consent was obtained from participants in the anonymous requirements-elicitation questionnaires, as documented in the RETENTION requirements deliverable. This manuscript does not include identifiable patient data.

Data Availability Statement: The manuscript does not include individual-level patient data and reports only technical information related to the design, development, integration and validation of the RETENTION platform. The datasets generated during the RETENTION clinical study are not publicly available due to ethical, privacy and regulatory restrictions. Access to appropriately anonymised data may be considered upon reasonable request to the corresponding author, subject to approval by the RETENTION Data Management Board and the applicable ethical and regulatory requirements.

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Abbreviations

The following abbreviations are used in this manuscript:

CSB	Clinical Site Backend
FHIR	Fast Healthcare Interoperability Resources
GIC	Global Insights Cloud
HF	Heart Failure
HL7	Health Level Seven
PE	Patient Edge

Appendix A

Table A1. Representative stakeholders use cases identified during the requirements elicitation process.

Stakeholder Group—Elicited Need	Derived Requirement—Use Case	Platform Implementation
Patients—routine home monitoring	Daily acquisition and reporting of physiological and symptom data	RETENTION App, Bluetooth devices, Home Gateway
Patients—medication adherence	Recording of scheduled medication intake	RETENTION App
Clinicians—longitudinal patient monitoring	Patient data visualisation and clinical follow-up	CSB Dashboard
Clinicians—identification of clinically relevant events	Notification handling	DSS, notification mechanisms, CSB Dashboard
Clinicians/patients—remote interaction	Patient-clinician interaction and recording of clinical visits	CSB and patient-facing services

Table A1. *Cont.*

Stakeholder Group—Elicited Need	Derived Requirement—Use Case	Platform Implementation
Hospital IT—interoperability with existing information systems	Standards-based exchange of clinical data	REST APIs, HL7 FHIR repository
Hospital IT—protection of clinical information	Authentication, authorisation and controlled data exchange	Security Component
Researchers/data scientists—cross-site analytics	Access to aggregated anonymised information	GIC, BDA Engine

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