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Yeonho Yoo, Junseok Lee, Seungwoo Jung, Yunkyung Kang, Dosun Lim, Youngpil Kim, Gyeongsik Yang & Chuck Yoo

Unified Digital Biomarker Platform for Wearable Devices Assuring Integrity, Heterogeneity, and Scalability

Yeonho Yoo[1, +], Junseok Lee[2, +], Seungwoo Jung[2], Yunkyung Kang[2], Dosun Lim[3], Youngpil Kim[4, *], Gyeongsik Yang[2, *], and Chuck Yoo[2, *]

[+]These authors contributed equally to this work
[*]Corresponding authors: ypkim@inu.ac.kr, g_yang@korea.ac.kr, chuckyoo@os.korea.ac.kr
[1]Dongguk University, Department of Computer Science and Artificial Intelligence, Seoul, 04620, South Korea
[2]Korea University, Department of Computer Science and Engineering, Seoul, 02841, South Korea
[3]Korea University, Department of Cardiology, Cardiovascular Center, Korea University Anam Hospital, Korea University College of Medicine, Seoul, 02841, South Korea
[4]Incheon National University, Department of Information and Telecommunication Engineering, Incheon, South Korea

ABSTRACT

This study presents a cloud-based platform for managing personal digital biomarker data collected from wearable and mobile devices. The platform aims to address four essential challenges for personalized healthcare: ensuring data integrity, supporting various biomarker data types, maintaining measurement reliability, and enabling system scalability. To protect data integrity and privacy, the platform uses private blockchain technology. It also supports heterogeneous data formats, such as time-series ECG signals and dietary images, through standardized interfaces. Measurement reliability is ensured by Gaussian mixture model that successfully detect faulty data with 100% recall. In real-world clinical tests with patients, the platform detects all attempts of data tampering and processes diverse biomarker data with an average latency of less than 1.76 s. The platform's scalability maintains stable performance under high data loads, and practical use is demonstrated through integration with our mobile application and biomarker web server. We validate the platform by measuring actual biomarker data from real-world atrial fibrillation patients and demonstrate its capability to securely and efficiently integrate wearable biomarker data for personalized healthcare.

1 Introduction

Digital biomarkers are emerging as essential data in healthcare, providing detailed information about patient health status and treatment outcomes. Various wearable and mobile devices, such as smartphones, smartwatches, and smart rings, can continuously collect biomarker data, including electrocardiograms (ECGs), physical activity, sleep patterns, dietary intake, and vital signs[1]. Accordingly, the digital biomarker market was valued at USD 3.42 billion in 2023 and is projected to grow at an annual rate of 22.7% through 2030[2], reflecting the rapid expansion and clinical relevance of these technologies.

Biomarker data collected through wearable and mobile devices have become important resources in clinical practice and medical research, providing longitudinal information on individual health and enabling personalized care irrespective of location[3–5]. For example, ECG data provide information on cardiac rhythm; physical activity measurements such as step count or movement intensity reflect functional status; sleep data help assess sleep quality; and dietary images captured with smartphones support dietary monitoring and chronic disease management.

To effectively utilize diverse biomarker data, digital biomarker platforms must reliably and efficiently collect, analyze, and facilitate the sharing of this information between patients and healthcare providers. Typically, data are centrally collected and shared, such as through cloud-based systems[6,7]. However, biomarker data are sensitive and come in various formats, posing specific challenges when collected and shared from wearable devices to the cloud. To effectively address these challenges, a digital biomarker platform must satisfy four key requirements: 1) data integrity, 2) support for heterogeneous data formats, 3) measurement reliability, and 4) scalability.

First, data integrity is essential to ensure that biomarker data remain accurate, complete, and unchanged after they are collected in the cloud. Even a single altered value in ECG signals, such as a shift in peak amplitude or a small variation in ST-segment duration, can lead to a different clinical interpretation. For example, changes as small as 0.1 mV in the ST segment can determine whether a recording is interpreted as a normal variant or an acute myocardial infarction[8–10]. Similarly, minor alterations in QT or PR intervals may cause arrhythmias like atrial fibrillation to be misclassified as sinus tachycardia[11]. Thus,

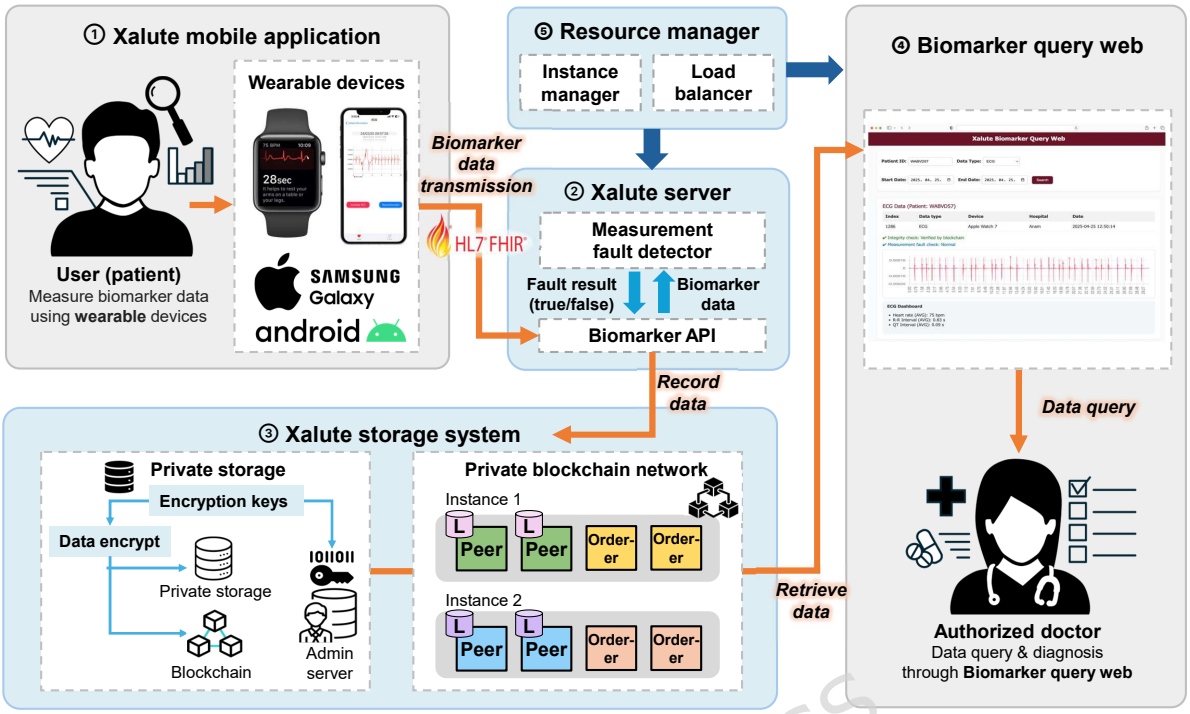


Figure 1. Xalute platform architecture.

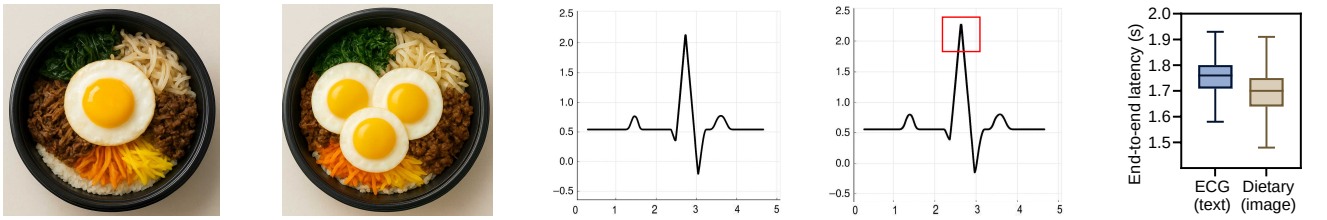
even subtle tampering with biomarker data, particularly in ECG signals, can compromise diagnostic reliability. Furthermore, data integrity can also be compromised by privacy risks. Each individual's ECG waveform contains distinct features that can be used to identify them, similar to a biometric signature[12,13]. This means that any unauthorized access to or extraction of ECG data could threaten the individual's privacy. For this reason, all cyber attacks and unauthorized access must be detectable.

Second, addressing data heterogeneity is vital because biomarker data come in many different formats, such as numerical values, time-series signals, and images. For example, heart rate is recorded as a single numeric value (text), ECG data are collected as continuous time-series signals (text), and dietary intake is captured using the camera of a mobile device (image). Unified handling of different data formats is a prerequisite for enabling cross-modal analysis between different biomarker types such as ECG signals and dietary images. For instance, previous studies have shown that dietary intake can influence cardiac activity, including changes in QT intervals or sympathetic responses[14,15]. By jointly analyzing ECG signals and dietary images, it becomes possible to identify patterns connecting dietary intake to cardiovascular responses. Therefore, supporting heterogeneous biomarker data is essential for integrated analysis and personalized interpretation in digital health systems.

Third, measurement reliability is also crucial because biomarker data collected through wearable and mobile devices are often affected by noise, artifacts, and measurement errors. These issues are common due to user movement, poor sensor contact, or uncontrolled recording conditions. For example, ECG signals recorded from smartwatches frequently contain baseline drift, motion artifacts, or missing segments, which may interfere with rhythm analysis[16]. It is well known that such wearable-derived ECG signals often lack sufficient signal quality for direct clinical use without preprocessing or manual validation[17]. Dietary images may also be blurred, poorly lit, or partially cropped, reducing their usefulness for nutritional evaluation[18].

Such measurement errors can distort downstream analysis and lead to incorrect clinical interpretations. In particular, reviewing thousands of ECG signals manually is not feasible in practice, and undetected artifacts may result in false alarms or missed diagnoses. Therefore, biomarker platforms must include automated mechanisms to detect and filter out unreliable data before it is delivered to clinicians[19]. Ensuring measurement reliability is essential to maintain the accuracy of health insights derived from biomarker data, and to reduce the verification burden on clinicians in real-world applications.

Lastly, scalability is fundamental to handling the increasing volume of biomarker data generated by wearable and mobile devices. Each user can produce multiple biomarker data entries per day, including ECG signals and dietary images. In a deployment involving hundreds or thousands of users, this results in a continuous stream of data that must be processed without delay or failure. During peak usage periods, the platform may need to handle hundreds of simultaneous data transmissions per second. Previous studies have shown that health data platforms using blockchain technologies may experience high failure rates, ranging from 30% to 70%, when handling 100 requests per second. These failures are often caused by limitations in transaction



(a) Dietary: original **(b)** Dietary: tampered **(c)** ECG: original **(d)** ECG: tampered **(e)** End-to-end latency

Figure 2. Data integrity (examples of data tampering in dietary images and ECG signals) and heterogeneity performance (end-to-end latency across different data types).

processing and block validation mechanisms[20–22]. To avoid such issues, a scalable platform must ensure that all data entries are stored successfully and that processing remains stable as traffic increases. This includes maintaining low latency, preventing data loss, and allocating computing resources dynamically in response to system load. If the system does not scale properly, users may experience delayed uploads, incomplete or failed data transfers, and reduced reliability in clinical applications[23]. Therefore, scalability is not only a performance concern but also a fundamental requirement for dependable operation in digital health environments.

However, to our knowledge, existing digital health platforms do not fully satisfy the four essential requirements discussed above. For example, some platforms focus on data collection and user interface design but lack mechanisms to ensure data integrity[24]. Others emphasize secure data handling but do not scale effectively or support multiple types of biomarker data within a unified framework[25] (we will further discuss this in §5). To address these limitations, we present Xalute, a digital biomarker platform that integrates data integrity, heterogeneity, measurement reliability, and scalability into a unified system.

Figure 1 illustrates the overall architecture and workflow of the platform. The Xalute mobile application (①) runs on a user's wearable or mobile device and initiates biomarker data collection, such as ECG signals or dietary images. The collected data are transmitted using the HL7 FHIR standard[26]. The biomarker server (②) receives the data via the Biomarker API. A measurement fault detector is applied to automatically assess the quality of the data and identify potential errors or noise, such as motion artifacts in ECG signals or poor image quality in dietary data. Only data that passes the reliability check is forwarded for storage. The biomarker storage system (③) consists of two layers: a private storage database that holds the raw biomarker data, and a private blockchain network that stores a hash value for each data entry. This structure enables tamper detection by comparing the stored hash values, thereby ensuring data integrity. Also, all data are encrypted and decrypted using encryption keys that are managed by a separate administrative server. The Xalute web server (④) allows authorized clinicians to access, review, and visualize patient biomarker data through the biomarker query web. This server includes a query engine, a blockchain verifier for checking data integrity, a visualizer for time-series and image data, and an interactive biomarker dashboard. A resource manager (⑤) monitors system workloads and dynamically adjusts computing resources based on data traffic. This ensures stable system performance even as the number of users or the volume of incoming data increases.

Together, these components enable Xalute to meet the four challenges described earlier. In the following section, we evaluate the platform's performance in terms of data integrity, heterogeneous data support, measurement reliability, and scalability in real clinical environments, based on data collected from patients with atrial fibrillation.

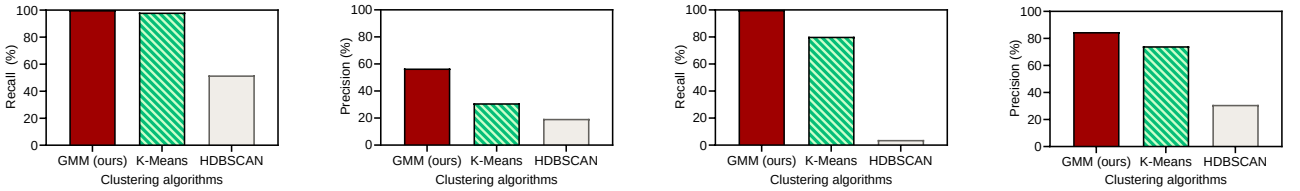
2 Results

We deploy the Xalute platform in a public cloud environment (Google Cloud Platform[27]) and evaluate its performance in a real clinical environment with 100 patients diagnosed with atrial fibrillation, focusing on four key requirements: data integrity, scalability, data heterogeneity, and measurement reliability.

2.1 Data integrity

First, to assess data integrity under conditions of malicious tampering, we deployed the Xalute platform in a real clinical environment and stored a total of 500 biomarker samples, including ECG signals and dietary images collected from patients diagnosed with atrial fibrillation. Subsequently, a subset of these biomarker samples is maliciously tampered with as described below.

Figure 2a–d illustrates representative examples of data tampering. The dietary image is visually altered by increasing the number of eggs from one to three, and the ECG signal is modified by changing a subtle numeric value (a peak value changed from 2.1 to 2.3). We deliberately introduce these subtle yet clinically significant alterations, simulating potential unauthorized data manipulations, such as malicious insider attacks, to evaluate the platform's ability to detect minor but critical



(a) Recall (ECG signal) **(b)** Precision (ECG signal) **(c)** Recall (dietary image) **(d)** Precision (dietary image)

Figure 3. Measurement reliability performance.

data changes. Such minor changes in ECG signals are clinically important because even small alterations in waveform amplitude or morphology can lead clinicians to misinterpret cardiac conditions, potentially affecting treatment decisions[28]. Similarly, visually subtle modifications in dietary images can impair accurate dietary assessments critical for managing chronic diseases[29].

However, it is important to note that the risk of such unauthorized data tampering is highly unlikely by Xalute's security design. Specifically, Xalute employs a blockchain-backed integrity to ensure tampering resistance. Blockchain provides an immutable and tamper-resistant ledger structure, in which recorded information cannot be modified arbitrarily without breaking ledger consistency. This property has been widely discussed as a core security feature of blockchain-based systems[30]. In Xalute, the raw biomarker data are stored in a private database where the SHA-256 hash values of raw data are stored on the blockchain. When the data are retrieved or verified, the hash value is recomputed from the raw biomarker data and compared with the corresponding hash stored on the blockchain. If an attacker attempts to modify the raw biomarker data in the private database, the recomputed hash will no longer match the blockchain-stored hash, and the tampering attempt will be denied. Therefore, data tampering in Xalute would require the attacker to compromise not only the raw biomarker data stored in the private database, but also the corresponding hash value recorded on the blockchain ledger in a consistent manner. Because this requires simultaneous manipulation of both the off-chain data and the blockchain-backed integrity record, any modification of stored data results in a mismatch with the blockchain-recorded hash, making successful data tampering highly unlikely[31].

In addition, biomarker data are protected using encryption, with cryptographic keys strictly managed by a single administrator and stored separately on an isolated server. In addition, all data transmissions are secured using HTTPS protocols. Thus, these comprehensive security mechanisms effectively eliminate realistic opportunities for malicious insider or external attacks. We will explain the security method in detail in §4.5.

In our evaluation, the Xalute platform successfully detects 100% of these simulated tampering attempts (500 out of 500 samples) by comparing newly computed hash values of the modified data against the original hash values stored on the blockchain. These results confirm that the platform reliably identifies unauthorized alterations, ensuring robust protection of clinical biomarker data. Overall, these findings demonstrate that Xalute's two-tiered storage architecture, combining encrypted private storage with blockchain verification, effectively maintains data integrity in clinically realistic scenarios.

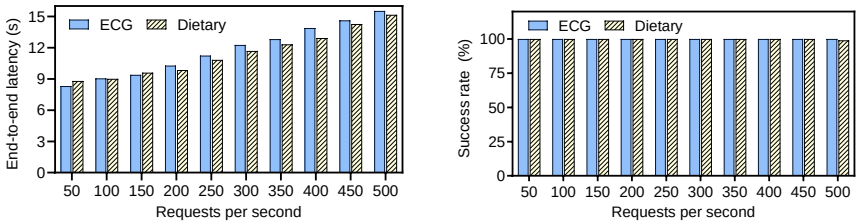
2.2 Data heterogeneity

We next evaluate the Xalute platform's capability to handle heterogeneous biomarker data collected from patients diagnosed with atrial fibrillation (AF). In this experiment, we transmit two heterogeneous types of biomarker data through our biomarker API (Figure 1): ECG signals collected from patients diagnosed with AF, sent as numeric time-series text data, and dietary images included as a representative image-based health data modality, encoded in base64 format. And AF data and dietary images are not correlated.

We measure the end-to-end latency to compare processing overheads between these two data formats. The end-to-end latency is defined as the time elapsed from data transmission from a patient's wearable device to successful storage in both the private storage and the blockchain ledger in the cloud. We measure this latency for a total of 1000 biomarker samples, comprising 500 ECG signals and 500 dietary images.

Figure 2e illustrates the end-to-end latency comparison between ECG and dietary data. Our results demonstrate minimal differences in latency between the texts (ECG) and images (dietary), with an average latency difference of only 3.14%. The overall average latency across all 1000 biomarker samples is 1.76 s, with a variation of 1.5%. This indicates that handling larger and more complex data formats, such as images, introduces negligible overhead within the Xalute platform.

Furthermore, the platform's well-designed chaincode for the Biomarker API and its use of a unified FHIR data format ensure efficiency regardless of data type. As a result, Xalute can seamlessly integrate diverse biomarker modalities without compromising performance, which is essential for real-world deployment where patients generate various types of data.



(a) End-to-end latency **(b)** Success rate

Figure 4. Scalability performance

2.3 Measurement reliability

The Xalute platform includes a measurement fault detector to ensure the reliability of biomarker data measurements from wearable devices. The fault detector utilizes the Gaussian mixture model (GMM) as its core algorithm, chosen for its strong performance in detecting measurement errors across multiple biomarker types. We evaluate the effectiveness of the measurement fault detector by conducting experiments on ECG signals and dietary images, both obtained from real clinical settings involving patients diagnosed with atrial fibrillation. To comprehensively assess performance, we compare the GMM-based fault detector against two alternative clustering algorithms: K-means and hierarchical density-based spatial clustering of applications with noise (HDBSCAN)[32–34]. We use recall and precision, as it is widely adopted in anomaly detection performance assessment[35]. Recall is defined as the ratio of true positives to the sum of true positives and false negatives, where we define normal ECG signals as positive and faulty ECG signals as negative. Precision is defined as the ratio of true positives to the sum of true positives and false positives. Thus, precision complements recall.

We evaluate the measurement fault detector using biomarker data collected from patients. However, wearable ECG acquisition may still be affected by real-world measurement artifacts, such as motion-related disturbances or unstable sensor contact[36]. In our study, these real-world motion artifacts are taken into account within the notion of measurement fault. It is to capture the effect of various artifacts because they can degrade signal quality and reduce measurement reliability. When ECG data were obtained, annotators with experience in ECG analysis reviewed each signal and labeled the presence or absence of these faults in the data. Using these reference annotations, we then evaluate the performance of the measurement fault detector. For ECG signals, we use data measured by patients using wearable devices, which include samples with severe noise caused by poor measurement conditions or interruptions during data measurement. For dietary images, we use real patient data containing images mistakenly captured as non-food items or images that are blurred or shaken due to improper photo capture. These datasets reflect real-world measurement faults, enabling evaluation of the fault detector's performance in identifying corrupted biomarker data in an actual clinical scenario.

Figure 3 compares the recall and precision of GMM, K-means, and HDBSCAN for fault detection on ECG and dietary data collected from patients. Figure 3a illustrates the recall of measurement fault detection on ECG signals. The results show that GMM achieves perfect recall (100%), outperforming K-means (98.2%) by 1.02× and HDBSCAN (51.8%) by 1.93×. Figure 3b presents the precision on ECG signals, with GMM achieving 56.66% precision, outperforming K-means (31.02%) by 1.83× and HDBSCAN (19.47%) by 2.91×. Figure 3c presents recall results for measurement fault detection on dietary images. GMM again leads with 100% recall, outperforming K-means (80.3%) by 1.25× and HDBSCAN (3.9%) by 25.64×. Finally, Figure 3d presents the precision on dietary images, with GMM reaching 84.75% precision, outperforming K-means (74.25%) by 1.14× and HDBSCAN (30.94%) by 2.74×.

2.4 Scalability

We evaluate the scalability of the Xalute platform by measuring end-to-end latency and success rate as the number of data requests per second (RPS) increases in a real clinical environment with patients diagnosed with atrial fibrillation. End-to-end latency is defined as the time elapsed from data transmission by the patient's wearable device until the data are securely stored in both private cloud storage and the blockchain ledger. Success rate refers to the proportion of data entries successfully committed to the blockchain at each request load level. The experiment presents performance results across a range of request rates, from 50 up to 500 RPS. Given that each user transmits one ECG measurement every 30 s (i.e., 1/30 requests per second), the RPS range of 50 to 500 is equivalent to 1,500 to 15,000 concurrent users. So, the maximum testing load of 500 RPS corresponds to up to 15,000 concurrent users.

Figure 4a shows the end-to-end latency when transmitting ECG signals and dietary images, with request rates increasing from 50 to 500 RPS. As a result, the latency remains on the order of only tens of seconds even under the highest loads. At 500 RPS, the system processes incoming data with an average latency of 15.5 s for ECG text entries and 15.2 s for dietary image entries, representing only about a 1.8× increase compared to the latency at 50 RPS.

Regarding the success rate, Figure 4b shows that even at 500 RPS, 99% of data samples are successfully recorded, with only three dietary images failing to commit to the blockchain. All ECG data entries are logged without any loss. At lower throughput levels (below 400 RPS), the transaction success rate is 100%.

3 Discussion

Our study demonstrates a novel integration of multiple critical capabilities in a unified digital biomarker platform. Specifically, we prove Xalute can ensure data integrity through blockchain verification, support heterogeneous biomarker modalities under a unified format, and maintain measurement reliability using a GMM-based fault detector—an approach that in our evaluation captured 100% of introduced measurement faults, outperforming alternative clustering algorithms—all while scaling to high data volumes in a cloud environment. In a real-world deployment involving atrial fibrillation patients, the platform detected all instances of data tampering (100% of alterations), integrated diverse data types (e.g., ECG signals and dietary images) with negligible performance overhead, and sustained stable operation even under heavy usage loads. These results suggest that Xalute can effectively overcome the quality issues often seen in digital health data, enabling more reliable and comprehensive biomarker monitoring for clinical care and research.

The clinical relevance of this unified platform is evident in its ability to securely manage real-world data streams from wearable and mobile devices in everyday patient care. For atrial fibrillation patients, continuous ECG monitoring via smartwatches combined with contextual data such as dietary intake offers a richer picture of patient health. Xalute's architecture ensures that such multi-source biomarker data can be collected and transmitted in real time without compromising integrity or privacy. Authorized clinicians can access the integrated data through a web-based dashboard, allowing them to efficiently monitor patients' cardiac rhythms alongside lifestyle factors, all within a single platform. By assuring that each data point is verifiably authentic and promptly available, Xalute addresses key barriers in remote monitoring and telehealth, potentially improving the management of chronic conditions through timely, data-driven interventions. It also aligns with the growing emphasis on using real-world digital biomarkers in clinical decision-making and research, where data trustworthiness and scalability are paramount.

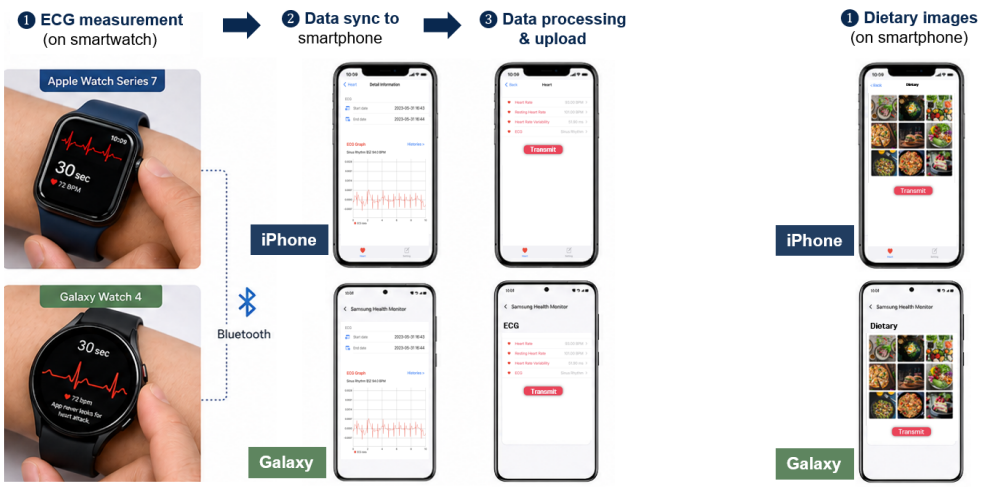
Despite these promising results, our platform has certain limitations in its current implementation and evaluation that present clear and achievable directions for future development. First, while we validated Xalute using two biomarker types (ECG signals and dietary images) and targeted a specific clinical population (atrial fibrillation patients), the platform is designed with a flexible, modular architecture capable of seamlessly integrating additional biomarker types such as continuous activity metrics, blood pressure measurements, and other sensor-based data. This inherent flexibility ensures that expanding to cover a broader array of biomarkers will be straightforward and technically feasible.

Second, while our current security approach—using encryption and a permissioned blockchain—places responsibility on managing cryptographic keys and regulatory compliance, these are widely recognized practices in cloud and healthcare IT industries. Proven solutions and standardized best practices already exist to manage these requirements efficiently, significantly mitigating associated risks and simplifying the path to larger-scale deployment.

Third, interoperability with existing health IT systems was beyond the scope of our current evaluation; however, we strategically adopted widely accepted standards such as HL7 FHIR from the outset. Leveraging such standards positions Xalute well to integrate smoothly into existing clinical workflows and data ecosystems, avoiding the creation of new data silos. Subsequent development efforts will specifically address seamless integration with electronic health records and other external digital health platforms, further enhancing the practical applicability and value of our unified digital biomarker platform.

Finally, although this study uses real patient data, its primary objective is to develop and validate the wearable device–based biomarker data acquisition and management platform, rather than to directly demonstrate improvements in clinical outcomes or clinician decision-making. Xalute is designed to support the collection of biomarker data outside the hospital environment and to help clinicians with reliable access to patient-generated biomarker data. Therefore, the key contribution of this study lies in establishing a technical foundation for reliable patient monitoring and remote clinical assessment. In the future, clinical studies are needed to evaluate whether the proposed platform improves clinician decision-making, and clinical outcomes compared with existing clinical workflows.

While the current evaluation has identified clear areas for expansion, these limitations are inherently addressable due to the platform's modularity, adherence to industry standards, and robust foundational technologies. Our key area for future work is the incorporation of artificial intelligence (AI) and advanced analytics into the platform. By applying machine learning algorithms to the securely aggregated biomarker dataset, Xalute could assist clinicians with early detection of arrhythmias or other critical conditions and enable personalized treatment recommendations. Indeed, we plan to develop an AI-driven diagnostic module that leverages the high-quality data ensured by Xalute to deliver enhanced clinical decision support.



(a) ECG signals **(b)** Dietary images

Figure 5. Workflows for acquiring ECG signals and dietary images.

4 Methods

4.1 Participants and environment

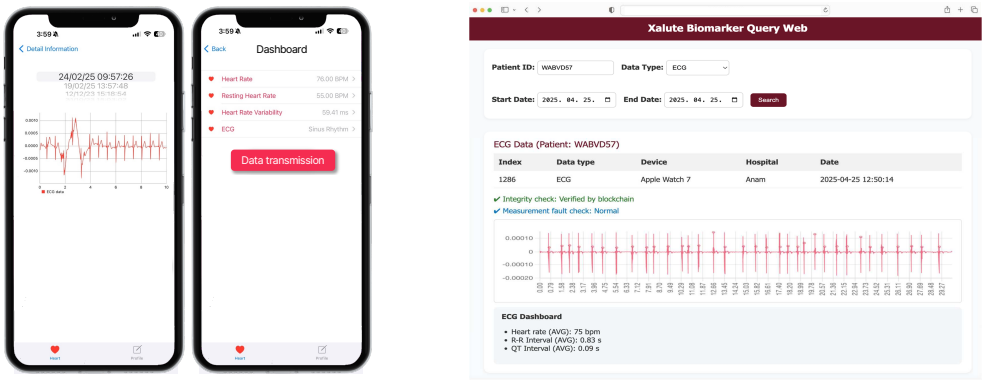
Participants. We enrolled 100 patients diagnosed with atrial fibrillation at Korea University Anam Hospital between July 24, 2023, and July 23, 2024. All participants had a confirmed diagnosis of atrial fibrillation and the ability to use wearable devices, and they provided written informed consent prior to participation. The study was approved by the institutional review board (IRB) of Korea University Anam Hospital (approval number: 2023AN0319). All methods were carried out in accordance with relevant guidelines and regulations.

Device and platform environment. For the wearable device, we use Apple Watch Series 7 (watchOS 8.7) and Samsung Galaxy Watch 4 (Wear OS 5) to collect ECG data from patients. Each smartwatch is paired with its companion smartphone (iPhone 7 Plus with iOS 15.8.2 or Galaxy S21 5G with Android 14, respectively). Single-lead ECG data are collected by placing a finger on the Digital Crown (Apple Watch) or on the sensor button (Galaxy Watch) as in Figure 5a (①). The ECG data are collected at device-specific sampling rates: 512 Hz for the Apple Watch and 500 Hz for the Galaxy Watch [35, 36]. The recorded ECG data are transferred to the paired smartphone via Bluetooth 5.0. The Xalute app, running on the smartphone, utilizes Apple HealthKit (version 15.4) on iOS and the Samsung Health Data SDK (version 1.4.1) on Android to receive the ECG data from the watch. Then, the Xalute app transmits the ECG data to the Xalute biomarker server through a FHIR-based API over HTTPS. The backend infrastructure, including the Xalute biomarker server and blockchain network, was hosted on the Google Cloud Platform[27], utilizing e2-standard-4 virtual machine instances, each equipped with 4 vCPUs and 16 GB of memory. For dietary images, the dietary image is captured via the smartphone camera. They are Base64-encoded. The Xalute app transmits to the Xalute biomarker server as the ECG data via the FHIR-based API over HTTPS.

Data collection procedures. Figure 5 illustrates the end-to-end workflow of ECG data collection. ECG data were collected twice from each patient with atrial fibrillation—once before and once after the atrial fibrillation surgery. Patients were guided by medical staff to properly use the device to ensure data quality. During each data collection session, a single-lead ECG was recorded for 30 seconds while patients were in a supine position. The ECG data are synchronized with the Xalute app on the paired smartphone as in Figure 5a (②). After the patient taps the transmit button in the Xalute app, the ECG data are transmitted to the Xalute biomarker server (Figure 5a (③)). For dietary images, users capture food images before and after their meal directly within the Xalute app. They then tap the transmit button to send the captured images as in Figure 5b (①).

4.2 Xalute mobile application

The Xalute mobile application is integrated with wearable devices and transmits heterogeneous biomarker data, along with user information, to the Xalute biomarker server using the HL7 FHIR standard[26], which provides a unified format. ECG data captured by wearable devices is transmitted as text-based numeric time-series data, while dietary images from the mobile are encoded in Base64 format and sent to the server as image data. For ECG, the user initiates the on-demand single-lead ECG recording on the watch (30-second recording on Apple Watch), and the recorded signal is synchronized to the companion smartphone application. The mobile application transmits it through an HL7 FHIR-based interface to the Xalute server. Furthermore, we develop a mobile application compatible with both iOS and Android operating systems. Since different devices may produce



(a) Mobile application screenshots **(b)** Biomarker query web screenshot

Figure 6. Xalute mobile application and biomarker query web.

distinct data formats even for the same biomarker type, the system is designed to accommodate such heterogeneity.

Also, the application enables continuous collection, secure transmission, and immediate visualization of biomarker data from wearable devices. Figure 6a displays screenshots of the mobile application interface. As patients measure their biomarker data using smart devices such as smartwatches, the mobile application automatically synchronizes this data, allowing users to review measurements via the mobile application interface and securely transmit the data to the server.

Upon arrival at the server, the data are processed by the biomarker API. The original biomarker data are securely stored in a private database, while cryptographic hash values are concurrently recorded on a private blockchain ledger to ensure data integrity. Thus, all biomarker data types follow this consistent process.

4.3 Biomarker query web

To provide authorized clinicians with comprehensive access to patient biomarker data, we develop the biomarker query web. This web service enables clinicians to query, review, and visualize biomarker data collected from patients' wearable devices and securely stored within the Xalute platform. Figure 6b shows a screenshot of the Xalute query web. The architecture of the Xalute query web is composed of four integral components as follows.

Query engine. The query engine provides a flexible and performant mechanism for querying patient biomarker data stored in the biomarker storage system. It supports multi-parameter searches including patient identifiers, biomarker types, and date filters, enabling clinicians to retrieve specific data subsets relevant to their diagnostic or research needs.

Blockchain verifier. To guarantee data integrity, the blockchain verifier component cross-checks hash values of biomarker data entries against records stored on the private blockchain network. This process enables tamper detection by verifying that the data presented to clinicians has not been altered since initial storage. The verifier provides real-time feedback on data integrity status within the user interface. Only data that has successfully passed blockchain verification is presented.

Biomarker visualizer. This component provides advanced visualization capabilities for time-series and image-based biomarker data. It supports multi-scale zooming, annotation, and comparative visualization to assist clinicians in detecting subtle anomalies or patterns within ECG waveforms, dietary images, or other biomarker modalities. The visualizer is built to handle high-frequency data streams while maintaining responsiveness.

Biomarker dashboard. The biomarker dashboard delivers an interactive summary view of biomarker metrics, highlighting key trends, statistics, and alerts relevant to patient health status. It aggregates data from multiple biomarker sources and presents them in an intuitive format, facilitating rapid clinical interpretation and longitudinal monitoring. The dashboard further supports customization, allowing clinicians to tailor displayed metrics according to clinical priorities.

4.4 Blockchain network

To ensure data integrity, Xalute deploys its blockchain network using Hyperledger Fabric, a permissioned blockchain framework designed for securely recording data transactions. The blockchain network consists of peer nodes and orderer nodes. Each peer node maintains a ledger, executes chaincode (smart contracts), and endorses and commits transactions. Orderer nodes collect endorsed transactions, order them into blocks, and distribute these blocks to peer nodes. Data transactions are executed within a dedicated private channel, enabling confidential data sharing among authorized participants via separate ledgers.

In the Xalute platform, the blockchain network configuration comprises four peer nodes distributed across two separate cloud instances, along with three orderer nodes operating within a single channel. The orderer nodes employ the Raft consensus algorithm to ensure efficient and reliable transaction ordering and overall network stability[37]. Two peer nodes and two orderer

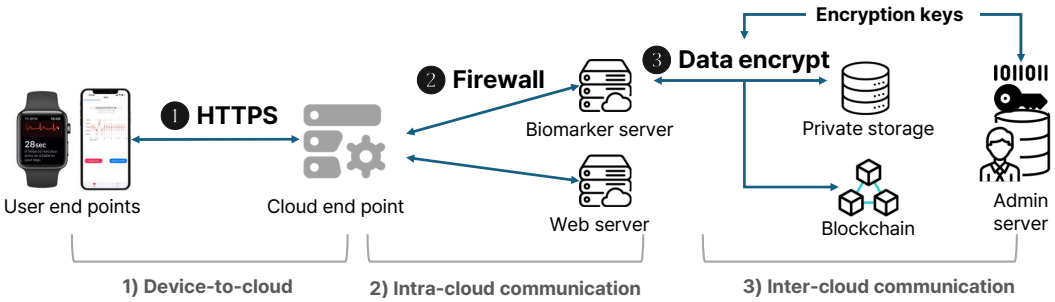


Figure 7. Xalute security architecture.

nodes run on one cloud instance, while the remaining nodes run on another instance. This design enables continuous network operation even if one instance experiences failure.

The biomarker transaction process proceeds as follows: when biomarker data and associated metadata (e.g., patient identifiers) are received, the biomarker server submits a transaction proposal to the required peer nodes for endorsement. After endorsement, the orderer nodes package endorsed transactions into blocks and distribute these blocks to peer nodes. Each peer node then validates and commits the blocks to its local ledger. All data access operations, including data retrieval, modifications, and additions, are logged and securely recorded on the blockchain ledger, providing comprehensive auditability and traceability.

For each biomarker data entry, a hash value is computed using the SHA-256 algorithm and recorded on the blockchain ledger rather than storing the entire raw data. Because the size of raw biomarker data typically exceeds the storage capacity of the blockchain, raw data are securely stored in a private database as proposed in Dai et al.[31]. When data are accessed, the system recomputes the SHA-256 hash from the stored raw data and compares it with the hash recorded on the blockchain ledger. A matching hash confirms data integrity, enabling immediate detection of any unauthorized or accidental modifications[38]. This two-tier storage and verification approach efficiently ensures biomarker data reliability and security without overwhelming the blockchain's storage capabilities.

4.5 Security

To protect Xalute from malicious attacks, we focus on external threats across three primary attack surfaces: 1) device-to-cloud communication, 2) intra-cloud communication, and 3) inter-cloud communication. Device-to-cloud communication refers to network traffic exchanged between user endpoints (e.g., wearable devices, smartphones, and web browsers) and the cloud endpoint. Intra-cloud communication covers data transfers between cloud servers within the same cloud environment hosting Xalute platform components. Inter-cloud communication involves data exchange between different infrastructures (e.g., regions) where Xalute services are deployed. The cloud infrastructure surface encompasses all underlying physical and virtual resources, such as compute nodes, storage systems, virtual machines, and associated management interfaces.

To mitigate risks associated with these attack surfaces, we implement a layered security approach, as summarized in Figure 7. First, device-to-cloud communication is secured using HTTPS with TLS 1.3, ensuring strong symmetric encryption for all network traffic. Even if an attacker intercepts packets, the content remains encrypted and unreadable, effectively protecting data in transit[39].

Second, intra-cloud communication is protected by a firewall that enforces a strict default-deny policy, blocking all unauthorized inbound traffic. This helps prevent unauthorized access and mitigates the risk of data interception or injection within the internal cloud environment[40]. In addition, we use a virtual private cloud (VPC) that provides an isolated network environment that securely connects internal Xalute components[41].

Finally, to protect the cloud infrastructure and data at rest, we adopt distributed encryption. Biomarker data are encrypted and stored on one server, while the corresponding encryption keys are securely managed on a separate, isolated server. This key–data separation significantly reduces the impact of potential breaches and supports enhanced data security and regulatory compliance.

4.6 Measurement fault detector

To identify measurement faults in data collected from wearable devices, we implement a fault detection method addressing the significant noise commonly present in real-world biomarker data. We compare three clustering algorithms, K-means, HDBSCAN, and GMM.

To optimize these algorithms for detecting faults, we use two publicly available datasets: one for ECG analysis and another for dietary images. The PTB-XL dataset comprises 21799 clinical 12-lead ECG records, each 10 seconds long, from 18869 patients (52% male, 48% female) ranging from 0 to 95 years old[42]. We use data sampled at 500 Hz and utilize predefined

Table 1. Comparison of platforms across four key aspects in digital biomarker platforms

Digital biomarker platform	Integrity	Heterogeneity	Measurement reliability	Scalability
Winslow et al.[24]	X	X	X	X
Ichikawa et al.[25]	O (Hyperledger Fabric)	X	X	X
Griggs et al.[45]	O (Ethereum)	X	X	X
Ranjan et al.[46]	X	X	X	O (Kafka)
Dhruva et al.[47]	X	O (text, image)	X	X
Kim et al.[48]	O (Ethereum)	X	X	X
Ali et al.[49]	O (Hyperledger Fabric)	X	X	X
Salari et al.[50]	X	X	X	X
Ait et al.[51]	O (Ethereum)	X	X	X
Rashid et al.[52]	O (Hyperledger Fabric)	X	X	X
Baraeinjad et al.[53]	X	X	X	X
Aalami et al.[54]	X	O (text, image)	X	X
Sun et al.[55]	X	X	X	O (cloud)
Ford et al.[56]	X	X	X	X
Nipu et al.[57]	X	X	X	X
Ours: Xalute	**O**	**O**	**O**	**O**

training, validation, and test splits provided by the dataset organizers. The Food-101 dataset contains 101000 images across 101 food categories, with 750 images per category for training and 250 for validation[43].

For both GMM and K-means, we set the number of clusters to five, with one cluster for normal data and four for abnormal data. Training is performed over ten iterations with a learning rate of 1e-4. Min-max normalization scales the ECG data within the range from -1 to 1. For HDBSCAN, it does not require pre-specification of cluster numbers. Finally, we train separate models for each biomarker type, independently applying each algorithm to the ECG and image datasets. Based on the experiment results, we select GMM as the core algorithm due to its superior capability to accurately detect faults.

4.7 Resource manager

Xalute maintains scalability to efficiently process increasing biomarker data requests from wearable and mobile devices. High volumes of simultaneous data retrieval or storage can cause delays due to system bottlenecks, impacting responsiveness[44]. To address this, Xalute employs horizontal scaling through two distinct components: 1) an instance manager and 2) a load balancer.

First, the instance manager dynamically adjusts the number of active server instances based on system demand. For example, if the biomarker server experiences a sudden surge in ECG data submissions, the instance manager reactively provisions additional server instances to handle the increased workload. When demand decreases, excess instances are removed to optimize resource usage. By continuously monitoring workload metrics, the instance manager ensures sufficient resource capacity to maintain responsiveness during traffic spikes.

Second, the load balancer efficiently distributes incoming user requests across available server instances. When a new request arrives, the load balancer evaluates the current workload of each instance and forwards the request to the instance handling the fewest requests. For example, when multiple wearable devices simultaneously submit ECG biomarker data, the load balancer distributes these requests evenly among biomarker server instances. This balanced distribution minimizes response latency, maximizes throughput, and provides clinicians and patients with a seamless experience.

Furthermore, the system proactively monitors the RPS of biomarker transactions to determine when to scale out. When the RPS exceeds the threshold of 100, empirically identified through extensive performance testing as the maximum sustainable load per server instance, additional instances are provisioned. This proactive scaling strategy ensures consistent performance and scalability, even during periods of intensive biomarker data submissions or batch uploads.

5 Related work

To evaluate the completeness of existing digital biomarker platforms, we survey prior studies and platforms to assess whether they satisfy the four key requirements: integrity, heterogeneity, measurement reliability, and scalability, as summarized in Table 1.

Several studies support data integrity using blockchain. Griggs et al.[45], Kim et al.[48], and Ali et al.[49] deploy the public blockchain (e.g., Ethereum), while Ichikawa et al.[25], Ait et al.[51], and Rashid et al.[52] use the permissioned blockchain (e.g., Hyperledger Fabric). Xalute adopts Hyperledger Fabric, leveraging its permissioned architecture to enhance privacy by allowing only authorized entities to access the data. Furthermore, Xalute integrates a private database and data encryption to provide an additional layer of protection for sensitive biomarker data.

For data heterogeneity, Aalami et al.[54] and Dhruva et al.[47] support various data types, including text-based biomarkers (e.g., ECG, heart rate, and weights) and image-based data (e.g., body shape images and MRI). However, other platforms support only text-based or image-based biomarkers, but not both. On the other hand, our platform supports both text-based and image-based biomarkers, such as ECG and dietary images.

Measurement reliability is largely overlooked in existing platforms; none of the surveyed platforms incorporates mechanisms for fault detection. Xalute introduces a measurement fault detection model that accurately identifies incorrectly measured data, thereby enhancing the robustness of collected data.

Regarding scalability, Ranjan et al.[46] employ Apache Kafka as part of a streaming data architecture to handle large volumes of continuous health sensor data (e.g., heart rate). Kafka's high-throughput message queue system enables efficient real-time data processing, contributing to the scalability of their platform. Sun et al.[55], on the other hand, leverage cloud services such as DynamoDB and Lambda, which provide autoscaling for increasing traffic. Their system benefits from the elasticity of cloud services, allowing it to effectively accommodate increases in the number of users or request volume without performance degradation. Xalute also deploys a resource manager, composed of an instance manager and a load balancer, to dynamically scale resources horizontally. In summary, Xalute is the first platform that comprehensively satisfies all four key requirements: integrity, heterogeneity, measurement reliability, and scalability.

6 Conclusion

This study presents Xalute, a digital biomarker platform that securely and efficiently manages diverse biomarker data collected from wearable and mobile devices. The platform successfully addresses key challenges, including data integrity, data heterogeneity, measurement reliability, and scalability. By combining private blockchain technology with resource scaling and measurement fault detection mechanisms, Xalute ensures trustworthy and high-quality biomarker data for clinical use. Our clinical evaluations with real-world patients demonstrate the platform's ability to detect data tampering, process various biomarker types with low latency, and maintain stable performance under high data loads. Integration with wearable devices and a biomarker query web confirms its practical applicability for patient monitoring. Future work will focus on developing a diagnostic system using AI techniques to assist in early and accurate disease diagnosis based on securely collected biomarker data.

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Corresponding authors: Youngpil Kim, Gyeongsik Yang, and Chuck Yoo.

Author contributions statement

C.Y. designed the architecture. Y.Y. and J.L. conceived the experiments. Y.Y., J.L., S.J., and Y.K. conducted the clinical evaluation and data collection. Y.Y., J.L., S.J., Y.K. and C.Y. analyzed the results. Y.Y., J.L., S.J., Y.K., D.L., Y.P., G.Y., and C.Y. wrote the manuscript. All authors reviewed the manuscript.

Data availability

The datasets generated during and/or analyzed during the current study are not publicly available due to containing information that could compromise the privacy of research participants but are available from the corresponding author on reasonable request.

Additional information

Competing interests: The authors declare no competing interests.

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