

PRODUCT REQUIREMENTS DOCUMENT

# HealthGuard AI

## Generative Health Diagnosis Platform

Version 1.0 | Concept Stage | April 2025

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# 1. Executive Summary

HealthGuard AI is a generative AI-powered health monitoring platform that continuously analyzes user health data to proactively detect early signs of disease. Unlike reactive healthcare tools that respond to symptoms after the fact, HealthGuard operates as a persistent health intelligence layer — integrating wearables, EHRs, biometric measurements, and genetic profiles to generate personalized health predictions and actionable recommendations.

The core insight: most preventable health conditions are preceded by detectable signals that patients and even clinicians miss because data is fragmented across devices, systems, and time. HealthGuard unifies this data and applies generative AI to surface those signals early.

## Stage Note

This is a concept-stage PRD. All metrics are projected targets based on market research and competitive analysis. Clinical validation and regulatory review are required before any health claims can be made publicly.

## 2. Problem Statement

### 2.1 The P0 Problem

Healthcare is fundamentally reactive. Patients visit doctors when symptoms emerge — often after conditions have already progressed. Meanwhile, the average person generates enormous amounts of health-relevant data daily (heart rate, sleep, steps, glucose, stress markers) that goes entirely unanalyzed in any meaningful clinical context.

### 2.2 User Pain Points

- Fragmented health data across Apple Watch, Fitbit, hospital EHR systems, lab results, and apps — none of which communicate with each other
- No intelligent synthesis layer that connects patterns across time and data sources
- Low-trust, high-friction doctor visits where context is lost between appointments
- Rising healthcare costs making preventive care economically inaccessible
- Patients with chronic conditions spend years managing symptoms that could have been caught earlier

### 2.3 Market Evidence

- 61% of preventable hospitalizations involve conditions that showed early biomarker signals 6+ months prior
- Wearable device market projected to reach \$380B by 2028
- AI health diagnostic market growing at 45% CAGR

- Apple Health, Fitbit/Google, and ChatGPT entering this space — but none offering unified, proactive, personalized early detection

## 3. User Research & Personas

### 3.1 Primary Persona: Minnie

Attribute	Detail
Age / Role	40 years old, Bank Manager
Location	Denver, Colorado
Education	MBA
Income	\$120,000/year
Health Context	Blurred vision, frequent urination, circulation issues, unexplained weight loss
1-Month Goal	Clarity on symptoms, focus on health
1-Year Goal	Have a diagnosis, be fit
5-Year Goal	Living a healthy, carefree life
Personal Goal	Hike a 14er
Pain Point	Quality of life affected by undiagnosed conditions; 3-month specialist wait times

#### Persona Quote

"I just want clarity on what's happening with my body — and I want it now, not after a 3-month wait for a specialist."

### 3.2 Empathy Map

#### Thinks & Feels

- Positive but anxious, hopeful for solution, curious yet skeptical
- Concerned about insurance implications of a diagnosis

#### Hears

- Word of mouth recommendations from friends and family
- Positive testimonials about health apps and wearables

#### Does

- Downloads health apps, inputs health data, symptoms, and medical history
- Tracks her health metrics, engages with real-time monitoring features

## Elements of Value (Bain Framework)

- Functional: Saves time, simplifies, reduces risk, organizes, integrates, informs
- Emotional: Reduces anxiety, wellness value, therapeutic value, provides access
- Life Changing: Provides hope

## 4. Market & Competitive Analysis

Competitor	Strength	Gap HealthGuard Exploits
Apple Health + Watch	Strong wearable ecosystem	No AI diagnosis layer; siloed data; no EHR integration
Fitbit / Google	Large user base	Fitness tracking only — no disease detection
ChatGPT	Accessible AI	No health data integration; not clinically grounded
DxGPT / Doctronic	Clinical NLP	Point-in-time only — no continuous monitoring
Garmin	Fitness tracking	Consumer fitness focus; no disease detection
HealthGuard AI	Unified AI health layer	Wearables + EHR + genetics + continuous monitoring + predictions

## 5. Product Goals & Success Metrics

### 5.1 Primary Objective

Reduce time-to-diagnosis for preventable chronic conditions by enabling early detection through continuous AI-powered health monitoring.

### 5.2 OKRs

- O1 — Drive user health outcomes: 30% of users who receive early detection alerts receive confirmed diagnoses within 90 days
- O2 — Build trust and engagement: DAU/MAU ratio > 40% (daily health check habit)
- O3 — Clinical validation: Partner with 3 healthcare systems for a data validation study

## 5.3 KPIs

Metric	Definition	Target
Early Detection Rate	% of users with flagged conditions confirmed by physician	≥ 25%
User Retention (90-day)	% users still active at day 90	≥ 55%
Data Integration Coverage	% of users with 3+ connected data sources	≥ 60%
Provider Collaboration Rate	% of AI alerts shared with healthcare provider	≥ 30%
CSAT	User satisfaction score	≥ 4.2 / 5.0
False Positive Rate	AI alerts not confirmed clinically	≤ 15%

## 6. Feature Architecture

### Epic 1: Health Monitoring & Tracking

- Symptoms Tracker — Log and track symptoms over time with AI pattern detection
- Early Detection Engine — AI analysis of health signals for anomaly detection and risk flagging
- Inputting Health Records — Manual and automated EHR import via FHIR API

### Epic 2: Data Integration

- Wearable Device Integration — Apple Watch (HealthKit), Fitbit, Oura Ring, Garmin, Whoop
- Hospital System Integration — HL7 FHIR API for EHR connectivity
- Bluetooth Vital Sign Devices — Glucose monitors, blood pressure monitors

### Epic 3: User Experience

- User Interface — Clean, accessible health timeline dashboard
- Profile Creation & Customization — Medical history, medications, allergies, health goals
- Accessibility — WCAG 2.1 compliance, screen reader support, multi-language

### Epic 4: Security & Support

- Data Encryption — End-to-end encryption for all health data at rest and in transit
- Compliance & Standards — HIPAA, GDPR, FDA SaMD positioning
- Data Backup and Recovery — Encrypted backup, automated disaster recovery

- Educational Resources — Condition libraries, health literacy content
- Customer Support — AI-assisted 24/7 support with human escalation

## 7. Feature Prioritization

### 7.1 Impact / Effort Matrix

Feature	Quadrant	Quarter
Symptoms Tracker	High Impact / Low Effort	Q1 — Ship First
Health Records Input	High Impact / Low Effort	Q1 — Ship First
Early Detection Engine (MVP)	High Impact / Low Effort	Q1 — Ship First
Wearable Device Integration	High Impact / High Effort	Q3 — Big Bet
Hospital System Integration	High Impact / High Effort	Q3 — Big Bet
Security Infrastructure	High Impact / High Effort	Q2 — Plan Ahead
Educational Resources	Low Impact / Low Effort	Q4 — Fill-in

### 7.2 Quarterly Roadmap

Epic	Q1	Q2	Q3	Q4
User Experience	UI + Profile Creation	Accessibility V1	UI Refinement	—
Security	Data Encryption	Compliance + Backup	Customer Support	Educational Resources
Health Monitoring	Symptoms Tracker	Early Detection	Early Detection V2	Health Records
Data Integration	—	—	Wearable Integration	EHR Access

## 8. Technical Architecture (PM-Level)

### 8.1 Data Ingestion

- Wearable APIs: Apple HealthKit, Google Fit, Fitbit API, Garmin Connect, Oura API
- EHR Integration: HL7 FHIR API for hospital system connectivity
- Manual Input: Symptoms logger, medical history forms, lab result upload
- Lab/Biometric Devices: Bluetooth integration for glucose monitors, BP monitors

## 8.2 AI/ML Layer

- Anomaly Detection Model: Trained on longitudinal health time-series data to identify deviations from user-specific baselines
- Risk Stratification Engine: Classifies users by disease risk category using multi-modal health signals
- Generative AI Layer: Produces plain-language health summaries and personalized recommendations
- Guardrail: All AI outputs framed as 'health insights, not medical diagnoses' — users always directed to consult healthcare providers

## 8.3 Proposed Technology Stack

Layer	Technology
Frontend	React Native (iOS + Android) + React (Web)
Backend	Node.js + Python (ML services)
Database	PostgreSQL (health records) + MongoDB (sensor data)
ML Framework	TensorFlow / PyTorch
Cloud	AWS HealthLake (HIPAA-compliant storage)
AI APIs	OpenAI API / Anthropic API for generative summaries

# 9. Compliance Architecture

### Critical Requirement

All compliance requirements must be reviewed with qualified legal counsel before any user data is collected or processed. This PRD is a product design document, not legal advice.

- HIPAA: PHI encryption at rest and in transit for all US users; BAA agreements with all data processors
- GDPR: Explicit consent mechanisms, right to deletion, data processing agreements for EU users
- FDA SaMD: MVP positioned as wellness monitoring tool, not Class II medical device — avoids specific disease claims in v1
- Zero-knowledge architecture for genetic data — never stored in identifiable form

## 10. Risks & Mitigations

Risk	Impact	Likelihood	Mitigation
False positive alerts causing anxiety	High	Medium	3+ signal confirmation before alert; 'not a diagnosis' framing always shown
FDA reclassification as medical device	High	Low	Avoid specific disease claims; position as wellness monitoring
Data breach of sensitive health data	Critical	Low	End-to-end encryption; SOC 2 Type II; zero-knowledge genetic data
User distrust of AI health recommendations	Medium	High	Transparent AI explanations; always recommend physician consultation
Wearable data quality gaps	Medium	Medium	Graceful degradation — insights scale with available data

## 11. Core User Stories

ID	User Story	Acceptance Criteria	Priority
US-01	As a user, I want to connect my Apple Watch so HealthGuard can monitor my vitals continuously	Watch data syncs within 5 min; HR, steps, sleep shown on dashboard	Must-Have
US-02	As a user, I want to log symptoms daily so the AI can detect patterns over time	Symptom log saved with timestamp; AI shows trends after 7 days	Must-Have
US-03	As a user, I want an early detection alert when my data suggests health risk	Push notification with plain-language explanation and next step	Must-Have
US-04	As a user, I want my AI health summary shareable with my doctor	One-tap PDF export with all data sources cited	Should-Have
US-05	As a user, I want my data completely private and under my control	Deletion removes all records within 24 hours; no third-party data selling	Must-Have

## 12. Revenue Model

Stream	Model	Target
Consumer Subscriptions	Standard (\$9.99/mo), Premium (\$24.99/mo)	Primary revenue

Stream	Model	Target
B2B Corporate Wellness	Per-employee annual license	Secondary
Healthcare System Partnerships	Data partnership + integration fees	Long-term
Insurance Partnerships	Preventive care program integrations	Future scope

## 13. Open Questions

- Should the MVP target iOS-only or cross-platform from day one?
- What is the minimum number of data sources required to generate a meaningful early detection signal?
- How do we maintain the regulatory line between 'wellness insights' and 'medical advice' across different markets?
- What clinical partnerships are needed to validate the early detection model before public launch?

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