



Smart Nano-Sensor Patch for Early Disease Detection with Smartwatch and Cloud Integration

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Executive Summary:

Smart Nano-Sensor Patch for Early Disease Detection

This project presents a comprehensive engineering management plan for the development of a smart nano-sensor patch, a wearable biomedical device for real-time, non-invasive monitoring of biomarkers such as glucose, lactate, and cortisol. Spanning TRL 4 to TRL 7, the project is compliant with ISO13485, GDPR and MHRA requirements to ensure regulatory compliance. Adopting a systems engineering approach, the scheme integrates structured governance, stakeholder alignment and a hybrid Waterfall-Agile methodology suitable for hardware-software co-development. The work has been decomposed through a detailed WBS covering biosensor manufacturing, BLE communications, cloud analytics and mobile app development. A bottom-up cost model with embedded contingencies supports financial planning, enabling estimated savings of up to 30% with cost-optimization strategies. The schedule employs Gantt charting and critical path analysis, while risks are managed using probability-impact matrices and dynamic mitigation registers. The plan includes sustainability (TBL and SDG-aligned), ISO-compliant quality management, ethical governance and formal change control processes. Overall, it defines a robust, scalable roadmap to deliver clinically viable wearable diagnostic systems.

1 Project Scope & Requirements

Project Overview: This project involves the development of a [smart nano-sensor patch that continuously monitors key biomarkers \(e.g. glucose, lactate, cortisol, inflammation indicators\)](#) in a non-invasive manner and streams the data to a paired smartwatch. The smartwatch will analyse data locally using machine learning (ML) algorithms to detect early signs of declining health and sync with a cloud platform for remote monitoring. This section defines the project objectives, rationale, scope limitations, deliverables, requirements, and constraints, ensuring alignment with industry standards and regulatory requirements.

1.1 SMART Project Objectives

The objectives of this project are expressed using S.M.A.R.T. Methodology, ensuring that each goal is specific, measurable, achievable, relevant and time bound. These objectives align with the project's broader innovation agenda and include key pathways such as prototyping, analytics integration, regulatory compliance and stakeholder validation.



Figure 1 Demographic Concept Image of Patch

Table 1 SMART Analysis

GOAL AREA	SPECIFIC	MEASURABLE	ACHIEVABLE	RELEVANT	TIME-BOUND
1. Design & Prototype Multi-Biomarker Patch	Design and develop a functional nano-sensor patch capable of: Real-time monitoring of at least four biomarkers: – Glucose – Lactate – Cortisol – Inflammation proxy (e.g., C-reactive protein) Wireless data transmission to smartwatch via Bluetooth 5.x	Sensor accuracy within $\pm 10\%$ of lab reference values during bench testing	• Utilizes validated electrochemical sensor technology • Leverages low-power Bluetooth SoCs • References proven devices (e.g., FreeStyle Libre CGM) (Kharb et al., 2025)	• Core to enabling real-time, continuous health monitoring • Serves as the foundational hardware for the broader wearable system	Prototype and lab validation to be completed by Q4 2025
2. Integrate Smartwatch Analytics & Alerts	Develop a smartwatch application (Wear OS / watchOS) that: • Receives real-time biomarker data • Implements on-device ML to detect anomalies • Sends alerts for events like hyperglycaemia or stress	Detection accuracy $>90\%$ in simulated glucose/cortisol spikes	• Smartwatch platforms support on-device ML and health APIs • Market trend supports AI-driven, personalized health insights	• Provides autonomous, personalized alerts to the user • Enables proactive intervention in critical biomarker deviations	MVP ready by Q1 2026
3. Ensure Regulatory Compliance for MedTech	Create a comprehensive compliance documentation package including: • ISO 13485 (QMS) • ISO 14971 (Risk Management) • EU MDR 2017/745 • UK MHRA • FDA Class II device requirements (2022)	• Completion of preliminary DHF • Inclusion of risk assessments • Successful audit or external review	• Leverages domain expertise in regulatory compliance • Aligns with ISO 13485-compliant QMS practices	• Compliance is required for CE/UKCA/FDA approvals • FDA mandates special controls for Class II CGM devices	Submission-ready documentation finalized by Q2 2026
4. Validate System & Stakeholder Acceptance	Execute a pilot study with 10–20 volunteers to assess: • Safety and usability of patch + smartwatch • Detection effectiveness in real-world scenarios	• $>80\%$ user satisfaction on comfort/usability • Strong clinical correlation ($r > 0.9$) between patch and fingerstick glucose values	• Collaborate with university or clinical research partner • Trial scale appropriate for early validation	• Demonstrates real-world performance to key stakeholders: – Patients – Clinicians – Investors	Pilot completion by Q3 2026

1.2 Project Justification and Business Case

Healthcare wearable technology is a rapidly expanding field, driven by the increasing demand for continuous health monitoring and early disease detection. By 2024, the [global wearable medical devices market was valued at US\\$91.21 billion](#), which is projected to grow to [US\\$103.04 billion by 2025, showing a CAGR of 17.8%](#) (Fortunate Business Insight, 2025). Within this domain, sensor patches represent a rapidly emerging sub-segment, valued at US\$3.7 billion in 2024, with a projected CAGR of ~42.9% by 2034 (Global Market Insight, 2025). This acceleration is driven by consumer interest in real-time, proactive health management and chronic disease monitoring. The development of smart nano-sensor patches aligns directly with these trends, providing a non-invasive platform for continuous multi-biomarker monitoring. By facilitating physiological data acquisition in real time, the system enhances preventive care and supports early intervention strategies. Early detection of conditions like diabetes, chronic stress and inflammation is of great benefit. For example, alerts arising from increased glucose or cortisol levels may prompt early clinical action. Current tools such as CGM focus on a single biomarker; In contrast, this project offers a multi-analytic approach for more comprehensive health insights. Academic and industry literature increasingly supports multiplexed biosensors that concurrently measure analytes such as glucose and lactate for improved health monitoring (Fortunate Business Insight, 2025).

The proposed patch will target four key biomarkers:

- Glucose – indicator of metabolic activity
- Lactate – reflects tissue oxygenation and metabolic stress
- Cortisol – measures physical stress
- C-reactive protein (or proxy) tracks inflammation and infection

The project addresses key health challenges such as diabetes and sepsis through real-time monitoring while keeping pace with the growing telehealth market and wearable adoption. It also supports the triple bottom line goals by promoting economic viability, social equity and environmental sustainability.

- People: enhancing health outcomes through early intervention
- Planet: Reducing environmental impact using biocompatible and potentially biodegradable materials in disposables

1.3 Scope Description (Inclusions & Exclusions)

Project Scope Inclusions: The project will cover all activities necessary to design, develop, and validate the smart sensor patch system. Major **in-scope elements** include:

Table 2 Scope Description Summary

Workstream	Summary	Key Components / Tasks
Hardware Development	Design nano-sensor patch hardware	Electrochemical biosensor array; Analog front-end (signal conditioning); MCU w/ BLE radio; Rechargeable Li-Po power module; Schematic + PCB design; Prototype fabrication; Bench testing (sensitivity, range, stability)
Firmware & Embedded Software	Develop MCU firmware for data acquisition, BLE, power management.	ADC sampling of electrochemical outputs; BLE 5.x protocol; Power management; Sensor interfaces; Nordic SDK toolchain
Smartwatch App & Algorithms	Companion app for watch/phone with on-device ML and UI	Pairing & live data display; Ondevice ML (anomaly detection/classification); Event alerts (e.g., hypoglycaemia, stress marker patterns); Optional smartphone companion; Secure cloud sync.(Oslo, 2025)

Cloud Infrastructure	Backend for aggregation, storage, dashboards	Secure database; Web dashboard for clinicians/researchers; Telemetry ingestion; Access controls; Encryption; Consent management
Testing & Validation	Electronics, software, and system validation	Unit tests (electronics/firmware/software); Integration tests (patch watch); Validation with simulated sweat/ISF; Supervised human pilot; Evaluate performance vs acceptance criteria (see 1.5) (by Steven Leibson, 2018)
Regulatory Documentation & QMS	Core med-device documentation and lightweight QMS	Requirements spec; Risk management (ISO 14971); Design verification plans; User docs drafts; Design controls under ISO 13485 (inputs/outputs/V&V/reviews)

Scope Exclusions:

Table 3 Scope Exclusion

Exclusion Item	Rationale / Notes
Full Clinical Trials	Large-scale efficacy trials excluded; only small pilot demonstration within project; regulatory-grade clinical studies deferred to commercialization phase.
Mass Manufacturing & Commercial Launch	No full manufacturing operations, validation, supply chain, or marketing; deliverables include design files and a manufacturing plan only
Therapeutic Interventions	Monitoring only; no drug delivery or closed-loop therapy (e.g., insulin pump); no automated treatment actions
Integration with Electronic Health Records (EHR)	No direct EHR integration (HL7/FHIR, national databases) within timeline; additional compliance and agreements out of scope(Gazzarata et al., 2024)
Non-wearable use-cases	No adaptation for non-human or non-wearable formats (implantable, veterinary)

Clarifying these exclusions helps manage stakeholder expectations and concentrate efforts on the core objectives.

1.4 Key Deliverables

The challenge will produce a set of actual deliverables upon finishing touch, which collectively constitute the Project Scope Statement. The fundamental deliverables consist of:

Appendix A Table A1 details the Deliverables span the full lifecycle of the smart nano-sensor patch project, including functional hardware prototypes, embedded and wearable software, cloud infrastructure, validation evidence, technical and regulatory documentation, and project management artifacts. Together, these deliverables demonstrate not only the technical feasibility of the system (through validated prototypes and data platforms), but also its readiness for regulated MedTech development with defined performance benchmarks, compliance documentation, and governance controls.

1.5 Acceptance Criteria

Clear acceptance criteria are defined to decide when the project scope has been satisfactorily completed. These criteria align with the project objectives and deliverables:

Table 4 Acceptance Criteria

Criterion	Acceptance Criteria
Sensor Accuracy and Performance	- Glucose & lactate measurement error < ±15% (ISO 15197 alignment). - Cortisol & inflammation markers: R² > 0.8 vs. reference assays. - Response time ≤ 5 minutes to analyte changes.
Wireless Connectivity and Data Integrity	- Stable BLE within 3 m; >99% packet success rate. - Sensor data update ≥ 1/min/channel.

	• ≤ 1 disconnection/hour; auto-reconnect ≤ 30 s. • Bluetooth 5.x with encryption.
Battery Life	• ≥ 24 hours continuous operation per charge. • Continuous runtime verification under standard use. • Validate low-power features (e.g., ultra-low-power modes of Nordic SoCs).
User Safety and Comfort	• Materials compliant with ISO 10993 for skin contact(Vo & Trinh, 2024). • Pass 24 h skin irritation test on ≥ 5 volunteers. • Device weight < 50 g. • $\geq 80\%$ positive comfort feedback; no adverse reactions or interference.
Alert Efficacy	• Detect simulated anomalies (e.g., induced glucose spikes). • Alert within 5 minutes of crossing clinical thresholds (e.g., glucose > 10 mmol/L). • $\geq 90\%$ detection for critical events with $< 5\%$ false alarms.
Regulatory Pre-Compliance	• Essential documents present: risk analysis, performance verification, design file. • Risk controls implemented for high-risk failure modes (ISO 14971). • Preliminary classification/pathway (e.g., likely MDR Class IIA) with CE/UKCA plan. • Alignment with Section 1.6 expectations.
Stakeholder Approval	• Formal approval by project sponsor and clinical advisor. • Sign-off on final prototype(s). • Validation that deliverables meet scope statement expectations.

1.6 Engineering Requirements & Design Constraints

The development of smart nano-sensor patches is governed by a broad set of engineering requirements and constraints. These requirements translate stakeholder needs, clinical expectations, and regulatory demands into specific, measurable, and verifiable technical specifications. This section details system-level requirements in the hardware, firmware, software, mechanical design, data processing, and regulatory domains.

1.6.1 Functional Requirements (FRs)

Table 5 Functional Requirements

ID	Functionality	Requirement Description	Metric
FR-01	Glucose monitoring	Sensor must detect glucose in 2–20 mmol/L range using electrochemical detection	Accuracy $\pm 15\%$, Update rate: $\geq 1/\text{min}$
FR-02	BLE transmission to smartwatch	Patch must transmit 64-byte packets to paired smartwatch every 60s	BLE 5.0+, RSSI $> -80\text{dBm}$, latency $< 2\text{s}$
FR-03	Edge ML analytics	Smartwatch must process incoming data and trigger alert if thresholds are breached	Alert within 60s of critical threshold breach
FR-04	Battery life	Patch should operate continuously for $\geq 24\text{h}$ on one charge	Tested at 25°C , BLE active 50%, all sensors on
FR-05	Data security	All BLE transmissions must be AES-128 encrypted; cloud sync via TLS 1.3(Sabri et al., 2025)	OWASP IoT Top 10 compliance

1.6.2 Non-Functional Requirements (NFRs)

Table 6 on-Functional Requirements

ID	Category	Requirement
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NFR-01	Usability	Patch should adhere comfortably for ≥8 hours; removal must leave no residue
NFR-02	Interoperability	System must pair with Wear OS ≥2.0 and Apple WatchOS ≥8.0 via standard GATT profile
NFR-03	Reliability	MTBF of patch electronics ≥1000h under nominal use
NFR-04	Maintainability	Firmware must support OTA (over-the-air) updates via smartphone app
NFR-05	Safety	Patch must meet ISO 10993 (biocompatibility) and IEC 60601-1 (electrical safety) (European BioMedical Institute)

1.6.3 Design Constraints

Table 7 Design Constraints

Constraint Type	Description
Physical	Patch dimensions ≤ 5×5 cm, thickness ≤ 2 mm, weight ≤ 50 g
Power	100–200 mAh Li-Po battery, daily wireless charging recommended
Materials	Biocompatible polymer (e.g. PDMS, medical-grade silicone), no latex or nickel
Connectivity	BLE 5.x only, no Wi-Fi/GSM due to size/power constraints
Operating Environment	Temp: 10–40°C, Humidity: 20–80% RH, mild sweat exposure allowed (IPX4 minimum)
Regulatory	Must align with ISO 13485, ISO 14971, ISO 10993, EU MDR 2017/745, MHRA UKCA, FDA Class II rules
Data Privacy	GDPR and HIPAA compliant; no data stored locally on the patch post-session

Ensuring compliance with applicable regulatory and statutory requirements is an important component of the project scope. Early alignment with standards substantially reduces the risks associated with future certification processes and facilitates an easier path to market deployment. To support this, the project will include periodic compliance reviews, including the use of a regulatory checklist to verify that each design output is traceable to relevant sections of applicable standards (for example, ISO 14971, ISO 13485, IEC 60601-1, MDR 2017/745, FDA 510(k) requirements). By incorporating quality assurance and regulatory compliance from the beginning, the development process aims to reduce the potential for costly design modifications during later validation stages.

2 Stakeholder Analysis

Effective delivery of the smart nano-sensor patch project is dependent on sustained, coordinated engagement with a variety of stakeholders. This need is particularly important in the context of the rapidly evolving digital health ecosystem, with the wearable medical device market valued at over US\$120 billion in 2024 and projected to exceed US\$540 billion by 2034. This growth is largely driven by the rising global burden of chronic diseases, widespread consumer adoption of wearable devices, and the continued expansion of remote patient monitoring systems.

2.1 Stakeholder Register

Table 8 presents the major stakeholders, their interests, their influence over the project, and the recommended engagement approach.

Table 8 Stakeholder Register

Stakeholder	Role / Description	Interest	Influence	Recommended Strategy
Project Sponsor (ABC MedTech R&D Director)	Provides funding, direction, and strategic oversight.	Strong interest in innovation, rapid development, and commercial viability.	Very high – controls funding, scope approval, and executive support.	Manage Closely: Bi-weekly progress briefs; quarterly steering meetings; KPI-driven reporting; rapid issue escalation; alignment with commercial objectives.
Project Manager & Engineering Team (University)	Leads design, prototyping, testing, and integration.	High – academic and technical success dependent on outcomes.	Moderate – high execution influence; limited strategic authority.	Manage Closely: Daily stand-ups; clear task ownership; evidence-based conflict resolution; resource support; collaborative culture.
End Users (Patients)	Individuals with diabetes, chronic-stress conditions, metabolic issues, or general health-monitoring needs.	High – desire accuracy, comfort, reliability, and privacy.	Low individually, high collectively – adoption determines market success.	Keep Informed / Involved: User surveys; early prototype trials; expectation management; privacy-first communication(Najla, 2022)
Clinicians & Medical Advisors	Provide clinical guidance and influence patient adoption.	High – focus on data accuracy, workflow fit, safety, and alert reliability.	Moderate – strongly influence trust and clinical acceptance.	Consult / Keep Satisfied: Milestone design reviews; share validation data; integrate feedback into risk management.
Regulatory Bodies (FDA, MHRA, EU Notified Body)	Approve medical-device safety and performance.	Low interest in commercial outcomes; high interest in compliance.	Very high – can approve, delay, or halt market entry.	Keep Satisfied (Compliance-Led): Full adherence to standards; early pre-submission consultations; proactive documentation.
Notified Body / Certification Auditors	Audit QMS and technical documentation for CE/UKCA.	Strong interest in evidence and documentation quality.	High – influence certification timelines.	Keep Satisfied: Gap analyses; mock audits; transparent communication; audit-ready documentation.
Suppliers (Sensors, Electronics, Batteries, Firmware Components)	Provide critical hardware components.	Medium – interested in stable orders and long-term partnerships.	Moderate – delays or quality issues directly affect timelines.	Keep Satisfied: Forecast sharing; relationship management; backup vendors; weekly lead-time tracking.
Smartwatch / Platform Providers (Apple, Google)	Control app-store access and ecosystem compatibility.	Medium – indirect interest in high-quality health apps.	High – can restrict app distribution or technical integration.	Keep Satisfied: Strict adherence to platform rules; developer-program participation; early API testing.
Investors / Funding Agencies	Provide capital or grants to extend development.	High – want milestone achievement, risk reduction, and ROI.	Moderate – influence direction through funding decisions.	Manage Closely (active investors) / Keep Informed (prospects): Milestone updates; demos; commercial-readiness evidence.

2.2 Front-end Stakeholder Network

The front-end stakeholder network defines the critical initial collaboration ecosystem to shape the technical, clinical, regulatory, and commercial feasibility of smart nano-sensor patch systems. It captures key actors across institutional, financial, technological, scientific, marketing, and user domains – reflecting the multi-polar, cross-sectoral structure necessary for disruptive medical device innovation.

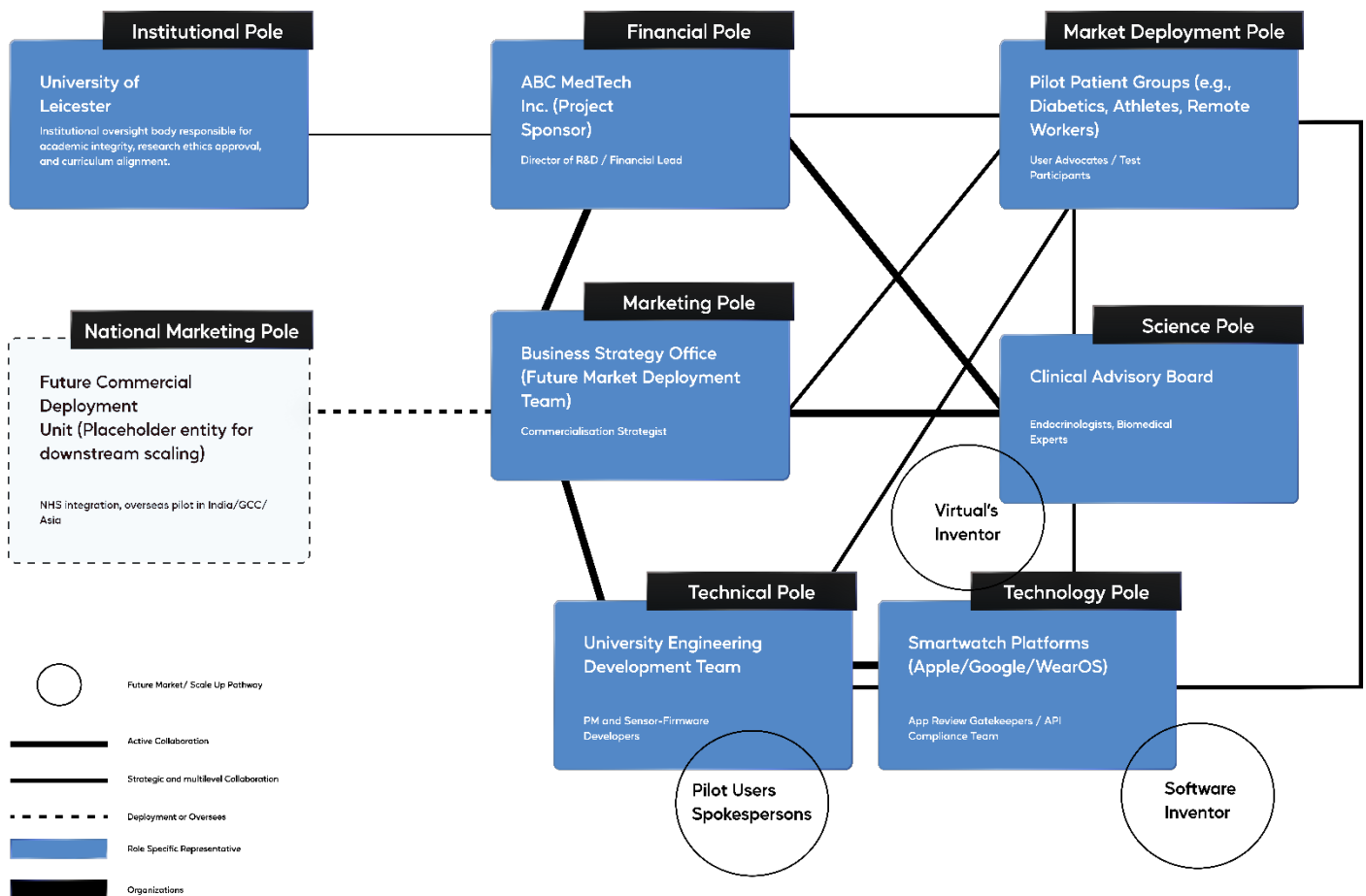


Figure 2 Front End Stakeholder Network

2.3 Stakeholder Synthesis and Analysis Results

This section consolidates multi-dimensional stakeholder data through structured tools stakeholder tables, influence-interest taxonomies, Venn diagrams, and forcefield matrices to gain strategic insights. These frameworks were adapted from public health infrastructure systems but tailored to fit the medical wearable technology context of this project(Franco-Trigo et al., 2020).

2.3.1 Application of Stakeholder Evaluation Table

Stakeholders were systematically evaluated across six key dimensions to assess their relevance, influence, and engagement needs within the context of the project. These dimensions are defined as follows:



Figure 3 Demographic Patch Concept

Table 9 Stakeholder Evaluation Table

Stakeholder	C1 Activity Involvement	C2 Political / Org Power	C3 Support / Threat Potential	C4 Funding Authority	C5 Platform Ownership	C6 End Use Stakeholder
Project Sponsor (ABC MedTech)	■	■	■	■		
University Engineering Team	■		■			
End Users (Patients)	■		■			■
Clinicians / Medical Advisors	■	■	■			■
Regulatory Bodies (FDA, MHRA)		■	■		■	
Notified Body (e.g., BSI)		■	■		■	
Smartwatch Platform Providers		■	■		■	
Academic Supervisors (EG7311 Staff)	■	■	■			
Investors / Grant Bodies (e.g., UKRI)			■	■		
NHS (Future Use / Public Sector)		■		■	■	■ ¹

2.3.2 Influence–Interest Mapping

Table 10 Influence–Interest Mapping

Using PMI's stakeholder quadrant matrix and cross-referencing with power-interest indicators:		
	High Influence	Low Influence
High Interest	Sponsor, Development Team, Supervisors, Clinical Advisors, Investors	End Users (Patients), Pilot Clinicians
Low Interest	Regulators, Platform Providers, Certification Auditors (engaged at cert. stage)	External public (future market observers)

Strategic Interpretation:

- **Manage Closely:** Sponsor, Project Team, Academic Advisors(Latha Thamma reddy, 2023)
- **Keep Satisfied:** MHRA, FDA, Notified Body, Platform Owners
- **Keep Informed:** Clinicians, Patients
- **Monitor:** Indirect audiences, external press, late-phase partners

¹ Legend: ■ = Relevant; NA = Not applicable in current project scope
Shaded cells indicate optional or future-phase linkage, e.g. NHS or global regulators.

2.3.3 Influence–Interest Matrix

Table 11 Influence–Interest Matrix

	Low Influence	High Influence
Low Interest	Smartwatch Platform Providers (Apple, Google) Regulatory Bodies (FDA, MHRA)	Notified Body (e.g., BSI, TÜV) NHS (Future Use)
High Interest	End Users (Patients)	Project Sponsor (ABC MedTech) Engineering Dev Team Clinicians Investors/Grant Bodies

Strategic Notes:

- **Manage Closely:** High interest + high influence → sponsor, dev team, and clinicians receive top engagement.
- **Keep Satisfied:** High influence + low interest → Notified Bodies and regulators (meet compliance expectations).
- **Keep Informed:** High interest + low influence → end users and university mentors (essential for ethics and adoption).
- **Monitor:** Low influence + low interest → smartwatch platform owners (engage only when integration risks emerge).

2.3.4 Stakeholder Engagement Strategy

Context: Effective delivery of a smart nano-sensor patch project requires coordinated engagement with various stakeholders. The wearable medical-device market, projected to exceed USD120 billion in 2024 and exceed USD540 billion by 2034, increases both stakeholder complexity and the risk of misalignment.



Figure 4 Demographic Concept image of Patch with women

STAKEHOLDER PARTICIPATION GOAL

	INFORM	CONSULT	INVOLVE	COLLABORATE	SUPPORT
Description of Participation	Project team shall provide stakeholders with transparent, objective, and concise updates to support their understanding of progress, risks, and scope (Pellegrini & Lovati, 2025).	Project team shall solicit structured feedback on requirements, prototypes, and key decisions, and communicate how this input shapes the project.	Project team shall engage stakeholders in review workshops and validation activities to ensure concerns and preferences are considered in design and decision-making.	Project team shall establish co-design sessions and decision-making forums where stakeholders act as design partners, especially clinicians and end users.	Project team shall offer technical, strategic, or procedural guidance when stakeholders initiate ideas or take leadership (e.g., end users co-leading usability studies).
PROMISE MADE TO STAKEHOLDERS BY PROJECT TEAM	We shall keep you informed through milestone updates, newsletters, and summary reports tailored to your interest level.	We shall listen, document, and acknowledge your input and explain how it influenced system requirements, feature prioritization, or pilot protocols.	We shall collaborate during design reviews, validation testing, and feedback sessions to ensure your insights are reflected and gaps addressed.	We shall treat you as a co-creator our expertise will guide prototype iterations, testing priorities, and real-world deployment planning.	We shall provide support, resources, and access to documentation and technical data as needed to help you lead initiatives that align with project goals.

Table 12 Stakeholder Participation Goal

Effective participation of stakeholders is important for the success of the project. By actively managing relationships and maintaining alignment, the project minimizes risks such as scope creep or loss of support. This inclusive approach reflects best practices in ethical project management. Active engagement ensures that stakeholders feel heard and valued, thereby fostering continued support. In complex MedTech projects, stakeholder analysis and management are not just academic they are essential to delivering a solution that meets both technical goals and stakeholder expectations.

3 Project Organisation & Roles

A Class IIa MedTech project demands a strong governance framework that integrates regulatory oversight with rapid decision-making. We propose a steering committee (including the CEO/founder, CTO, and external clinical and regulatory advisors as sponsor) that meets regularly to review progress, risks, and resource requirements. Below this, a project manager (PM) is given the authority to run day-to-day activities. Functional leads (e.g. engineering leads,

QA/RA leads, clinical leads) report to the PM, but major policy and quality decisions involve the steering committee or executive management to meet ISO13485/21CFR820 requirements(Pacheco et al., 2025a). For example, FDA design-control guidance clearly states that "management with executive responsibility" should determine and document what is required in the quality system. Similarly, ISO13485 mandates top management review and commitment of resources, allowing project governance to be effectively embedded in the QMS. The Governance Board thus ensures alignment with ISO standards and EUMDR 2017/745 (which requires documented decision-making and clinical monitoring) throughout development.

3.1 Project Team Structures

The Smart Nano-Sensor Patch for Early Disease Detection with Smartwatch Integration Project adopts a functional organization model, structured to ensure regulatory compliance, clinical safety, and technological innovation. Below is the role-based organizational chart.

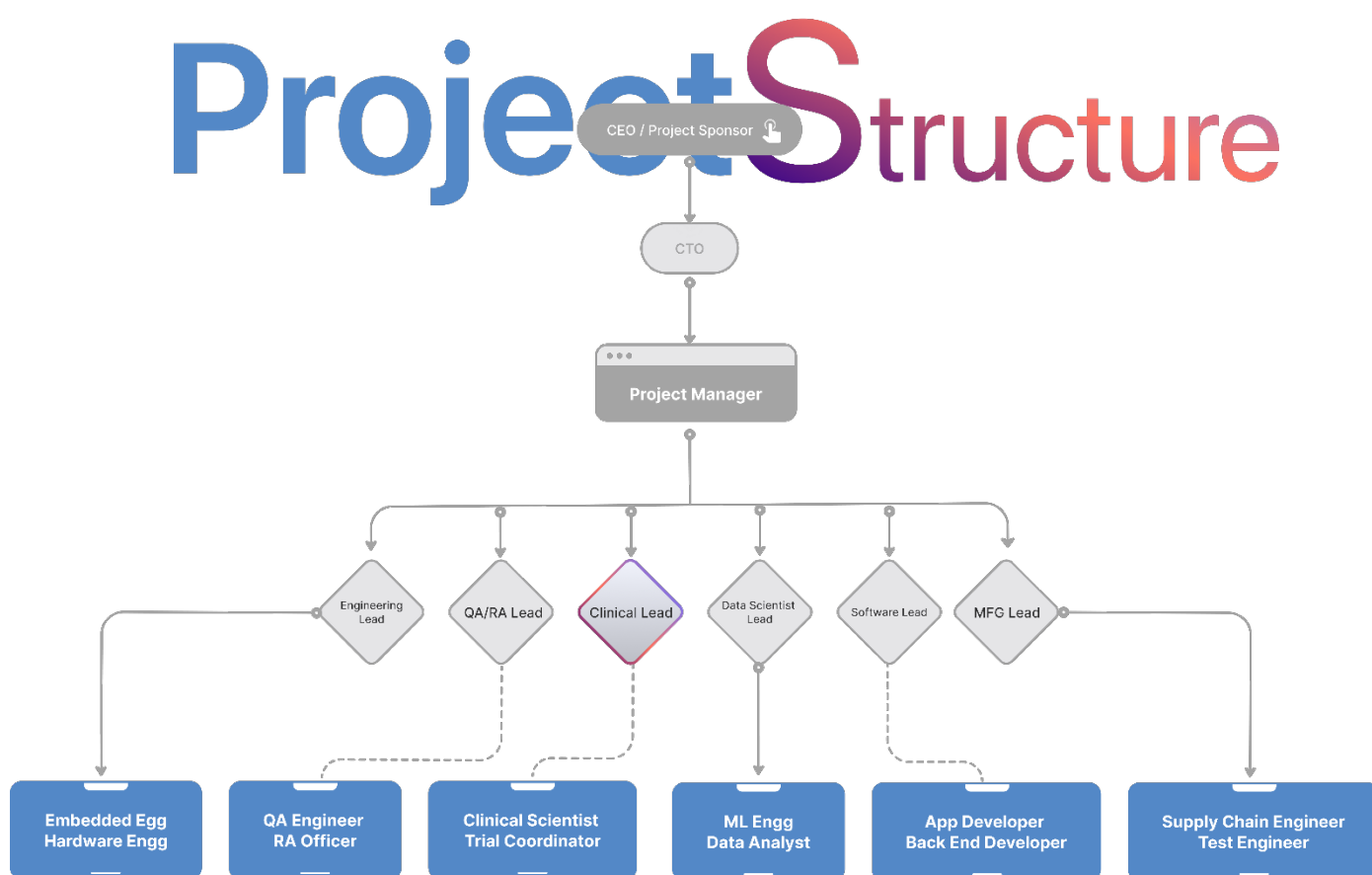


Figure 5 Project Team Structure

Each box represents a team or role; Rows indicate reporting. This reflects industry practices (as in companies like Dexcom or Verily) where product, clinical, quality, and technical leadership collaborate under one PM. (For example, a MedTech QA lead "runs internal audits, leads CAPA, oversees design controls and supplier quality", while a Clinical Scientist "plans and executes clinical investigations".)

3.2 Roles & Responsibilities

The project employs a functionally structured team aligned with ISO13485 and PMBOK guidelines to ensure accountability and clarity of technical compliance. Each role is defined to reflect best practices in regulated MedTech development, supporting parallel hardware, software, regulatory and clinical workflows. The matrix below outlines

individual responsibilities to ensure work ownership, regulatory traceability and effective cross-functional coordination across all project phases.

Table 13 Roles & Responsibilities

Role	Responsibility
Program Manager	- Provides strategic oversight and ensures alignment with business goals and funding milestones. - Approves budgets and high-level resource plans. - Chairs steering committee reviews. - Escalation point for unresolved project issues.
Project Manager (PM)	- Oversees all project planning, WBS tracking, stakeholder reporting, and execution. - Coordinates multidisciplinary team communication (engineering, QA, clinical). - Manages change requests and risk register. - Prepares TRL milestone documentation. - Liaises with the sponsor and regulatory advisors.
Engineering Lead	- Leads hardware/firmware architecture for nano-sensor patch. - Manages embedded systems, PCB design, and power integration. - Coordinates patch-smartwatch BLE communication. - Supports technical file with design verification data.
QA/RA Lead	- Implements ISO 13485 QMS; manages internal audits and CAPA processes(Pacheco et al., 2025b). - Owns CE Mark technical file and FDA 510(k) documentation. - Ensures ISO 14971 risk file traceability across the lifecycle(Jos van Vroonhoven, 2020). - Leads regulatory change control board. ss
Clinical Lead	- Designs study protocols under ISO 14155(Iso). - Coordinates IRB submission, consent documents, and trial sites. - Collects data for performance validation and supports Clinical Evaluation Report (CER).
Data Science Lead	- Designs machine learning algorithms for disease prediction. - Validates models using TRL 6/7 datasets. - Ensures explainability and audit trails for AI inference. - Oversees data pipeline from app to cloud.
Mobile App Lead	- Develops cross-platform mobile UI for patient interface. - Integrates BLE telemetry, analytics, and user alerts. - Ensures GDPR-compliant user data handling and security.
Cloud Backend Lead	- Builds backend for data ingestion, storage, and batch processing. - Implements secure APIs and user authentication. - Deploys model updates and report generation pipelines.
Manufacturing Engineer	- Qualifies suppliers for biosensors, batteries, PCBs. - Designs assembly/test jigs for pilot production. - Documents DFM feedback for v2 iteration.
Test Lead	- Defines unit/integration/system test plans for all hardware and software modules. - Conducts verification activities (per V&V plan). - Logs issues and manages resolution workflows.

3.3 RACI Matrix

	R	Responsible	A	Accountable	C	Consulted	I	Informed	
Project Activity / Deliverable	Project Manager	Engineering Lead	QA/RA Lead	Clinical Lead	Data Scientist	Mobile App Lead	Sponsor / CEO	CTO	Test Lead
Initiate Project & Define Scope	A	C	C	C	C	C	I	R	I
Develop Project Charter	R	C	C	C	C	C	A	C	I
Create Schedule & Resource Plan	A	R	C	C	C	R	I	C	C
Design Biosensor Hardware	C	A	C	C	I	I	I	C	C
Implement BLE Firmware	C	A	C	I	I	I	I	C	R
Develop Mobile App (UX/API)	C	C	C	I	R	A	I	C	I
Cloud Backend & ML Model Integration	I	C	C	C	A	R	I	C	I
Prepare ISO 13485 QMS & Regulatory Docs	C	C	A	C	I	I	I	C	I
Develop Clinical Protocol & Ethics Submission	I	I	C	A	I	I	I	C	I
Conduct Verification & Validation	C	R	A	C	C	R	I	C	A
Prepare Regulatory Submission (CE Mark / FDA)	C	I	A	C	I	I	I	C	I
Execute Pilot Clinical Trial (TRL 7)	I	I	C	A	C	C	I	C	I
Perform Change Control (Design/Regulatory)	A	R	A	C	C	C	I	C	C
Finalize Technical File & Submission	I	C	A	C	I	I	I	C	C
Review & Close Project	A	C	C	C	C	C	R	C	C

Figure 6 RACI Matrix

We define the RACI matrix for key deliverables as follows: The PM is accountable for all ('A'), ensuring overall integration. For each deliverable (rows), exactly one person is responsible ('R'), the others are consulted ('C') or informed ('I'):

In this RACI, the PM is accountable for schedule and scope, the clinical lead is consulted on security/requirements, the embedded engineer leads the hardware functions, the data scientist leads the app/backend software(R), and the RA officer leads the regulatory filings. QA is consulted on all (ensuring quality inspection). As one study notes, both the WBS and its associated responsibility matrix form the basis of "resource allocation [and] responsibility assignment" in project control(Ahmad & Graduate, 2024).

3.4 Leadership & Change Management Approach

3.4.1 Change Management

Subcontractor management controls the participation, delivery quality, and performance of external vendors involved in the project. Vendor selection and qualification depend on defined criteria, such as certification (for example, ISO 13485-certified PCB manufacturer or BLE SoC supplier). Service level agreements (SLAs) outline expectations for deliverables, timelines, technical compliance, and documentation. Progress is tracked through periodic reviews and milestone checks, including sensor prototype delivery and firmware development. Compliance auditing ensures that subcontractors meet regulatory and quality standards, especially for design-related work.

3.4.2 Process Improvement

Process improvement identifies and embeds efficiencies in product development, especially during subsequent iterations and validation. Learned sessions follow key TRL milestones or clinical trials to gain insight. Root Cause Analysis (RCA), using tools such as the 5 Whys or Ishikawa diagrams, examines defects, delays or change rejections. Benchmarking compares project performance to MedTech best practices or peer initiatives. Continuous improvement loops support feedback-driven refinements to firmware, UI, sensor calibration, and documentation workflows. Validated improvements are reflected through updates to version-controlled standard operating procedures (SOPs).

3.4.3 Project Close-Out

Project close-out ensures formal closure through documentation, knowledge transfer and regulatory harmonisation. The final deliverables are reviewed to confirm that all outputs patches, applications, backend systems, and regulatory files are complete and approved. Redeployment of the team occurs after releasing or redeploying resources. DHF, design input/output, test logs and diagnostic data are stored securely. A close-out report summarizes budget, deadline adherence, quality metrics, and deviations.

4 Work Breakdown Structure & Milestones

4.1 WBS Development Approach

A top-down, deliverable-oriented Work Breakdown Structure (WBS) will be employed to organize and manage the project scope, in accordance with PMI and ISO guidelines. At the highest level (Level 1), key deliverables such as project management, patch development, and application development will be identified. These will then be systematically decomposed into Level 2 and Level 3 work packages. ISO21500 emphasizes that the WBS should clearly define all project deliverables and decompose them into manageable components. Similarly, PMI standards describe the WBS as a hierarchical framework that breaks the total scope of work into smaller, more controllable elements, each of which includes specific deliverables. Each work package will be clearly scoped, verified and assigned with its own budget and schedule allocation, as set out in the PMI practice standard for work breakdown structures(Priti et al.).

4.2 Level 1, Level 2, Level 3 WBS



Figure 7 WBS

Figure 4. Illustrative multi-level Work Breakdown Structure (WBS) for the Smart Nano-Sensor Patch project. Level 1 outlines major deliverables, which are systematically decomposed into Level 2 sub-deliverables and Level 3 work packages. This hierarchical structure supports clear scope definition, resource allocation, and schedule planning, in alignment with PMI and ISO 21500 guidelines.

4.3 Work Package Definitions

WP1: Biosensor development

This work package focuses on the design and fabrication of nano-sensor materials. This scope includes researching sensor chemistry, prototyping test chips, and characterizing sensitivity and specificity. It also includes bench-top validation of sensor response to ensure performance benchmarks are met prior to integration with hardware systems.

WP2: Embedded Firmware

This package addresses the development of firmware for the patch's microcontroller and BLE (Bluetooth Low Energy) module. This scope includes programming data acquisition from sensors, implementing signal conditioning and power management, and enabling secure wireless communication with the smartwatch. Hardware-in-the-loop testing will be conducted to verify functional integrity under real-time conditions(Arandia et al., 2023).

WP3: Smartwatch Integration: This work package includes customizing or developing smartwatch firmware and application interfaces to enable seamless reception of patch data. Main functions include BLE pairing, real-time data display, and implementing user alerts.

WP4: Mobile App Development: This package covers the creation of a smartphone or tablet application that serves as the primary patient interface. This scope includes UI/UX design, development of on-device analytics algorithms, data synchronization with the cloud backend, and implementation of dashboards and user notifications.

WP5: Cloud Backend and Analytics: This work package focuses on designing and implementing server-side systems to support secure and scalable data handling. Key tasks include defining the data architecture, developing secure storage and processing pipelines, and creating algorithms for disease detection based on sensor data. Compliance with HIPAA and GDPR standards will be ensured, and end-to-end data flow from sensors to the cloud will be extensively tested.

WP6: Regulatory & Quality Documentation: This package includes the development of necessary documentation and quality systems for regulatory compliance. The scope includes drafting Design History Files (DHF), Device Master Records (DMR) and conducting risk assessment as per ISO14971. This also includes compiling verification and validation plans and preparing submission documents to support CE marking under MDR 2017/745 in line with ISO13485 requirements.

WP7: Clinical Protocols and Trials: This work package addresses the planning and execution of validation studies involving human subjects. Tasks include designing clinical protocols in accordance with ISO14155 and Good Clinical Practice (GCP), obtaining ethical approval and conducting small-scale clinical trials with healthy volunteers. Data collection will focus on validating device performance, security, and usability.

4.4 Key Project Milestones

4.4.1 Key milestones align with technology readiness and regulatory checkpoints:

TRL 5 – Validated Lab Prototype: Completing lab tests on non-GLP integrated prototypes. All critical components (sensors, hardware, software) have been developed and tested at bench scale

TRL 6 – Integrated System Testing: Completion of alpha/beta prototype integration and testing. The patch, watch, and app communicate reliably; Pilot-production prototype built; and verified performance against specifications

TRL 7 – Analytical Validation/Pre-Clinical: Successful validation of full prototype performance using inventoried or animal samples, with documentation of analytical accuracy. Preparation for first-in-human trials (such as IRB submission and FDA pre-IDE meetings) is complete (Jo North, 2024)

Regulatory submission: Submission of CE-marking dossier (or FDA 510(k), if applicable) for Class IIA approval. This includes technical file, clinical assessment report and QMS audit.

Manufacturing preparation: Facility and supply chain qualified under ISO13485, with pilot production operations and validation completed, ready to scale up to market volume.

Initiation of clinical trials: Initiation of limited clinical studies (as per MDR requirements) in the intended patient population.

These milestones include standard MedTech checkpoints. The BARDA TRL specifications provide concrete criteria: e.g. TRL5 is required to "build and test non-GLP prototypes" and TRL6 is required to "integrate and test alpha/beta devices."

Figure 8 Key Project Milestones Illustration

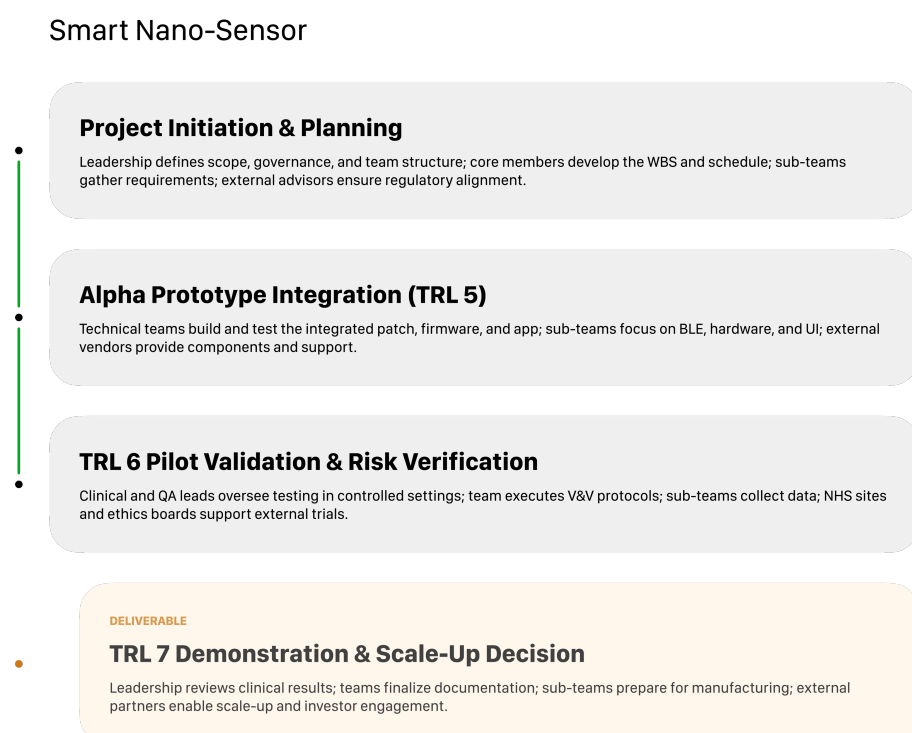


Table 14 Key Project Milestones

Milestone ID	Milestone Description	Project Month	Deliverables / Outcomes
M1	Project Kick-off & Team Mobilization	Month 1	Charter approval, stakeholder alignment, team onboarded
M2	System Requirements Freeze	Month 2	Signed-off PRD, stakeholder sign-off
M3	Prototype Design Freeze (Patch + BLE + App)	Month 4	CAD files, electrical circuit layout, BLE spec, Figma app UI mock-ups
M4	Functional Lab Prototype Tested (TRL 4)	Month 5.5	Lab-tested patch with initial biomarker detection validated
M5	Smartwatch BLE Communication & App Integration	Month 7	Data exchange over BLE, app receives live stream from patch
M6	Integrated Alpha Build (Patch + Smartwatch + App)	Month 9	Fully integrated system, secure data link, alpha test-ready
M7	Ethics & Clinical Safety Approval for TRL6 Testing	Month 10	Approval from MHRA/NHS REC, device risk documentation
M8	Pilot Testing in Controlled Environment (TRL 6 Start)	Month 11	Deployment with 5–10 users, cloud logging, reliability profiling
M9	Design Iteration & App Analytics Improvements	Month 12	Enhanced UX/UI, model accuracy, feedback loop closure
M10	TRL 6 Completion – Demonstrated in Relevant Environment	Month 13.5	Clinical validation, >85% accuracy on live data from real users
M11	TRL 7 Initiation – Operational Demonstration in Real Setting(APRE)	Month 15	Extended testing by partners (clinics, athletes), scalable backend
M12	Final Clinical Report & Go/No-Go Decision for Scaling	Month 17	Full technical/business evaluation for Phase 2 or regulatory prep

5 Project Schedule

5.1 Activity Identification

The project's core development activities span across hardware, firmware, software, cloud, testing and regulatory domains. Each activity plays a specific role in the progression of the system from laboratory prototyping (TRL 5) to clinical validation (TRL 7). Hardware and firmware development form the foundation, which enables real-time data acquisition and transmission. Concurrently, the mobile app and cloud backend ensure data visualization and secure storage. Quality assurance and regulatory documentation underpin compliance and preparation for clinical trials. Pilot testing validates real-world performance, while manufacturing readiness ensures scalability after validation. A summary of these integrated activities is provided in *Appendix Table A2*.

5.2 Precedence Logic & Dependency Mapping

Once project activities are clearly defined, the next step involves mapping their dependencies and establishing a logical sequence for execution. This process is essential for effective project scheduling and resource allocation. The Priority

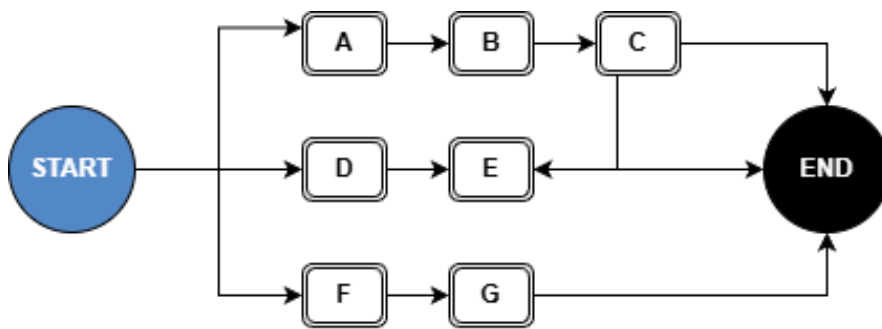


Figure 9 Network Diagram

Diagramming Method (PDM) is used to depict these relationships by connecting tasks using standardized dependency types, namely:

- **Finish-to-Start (FS)** – A successor activity cannot begin until its predecessor has finished.
- **Start-to-Start (SS)** – A successor activity cannot start until its predecessor

activity has started.

- **Finish-to-finish (FF)** – A successor activity cannot finish until its predecessor has finished.

These dependency types determine how the beginning or completion of one activity affects the beginning or completion of another, thereby structuring the project timeline in a logical and manageable way.

Project work package dependencies define a tightly coordinated sequence of tasks, ensuring that critical outputs – such as hardware prototypes, software builds, clinical data, and regulatory submissions – are delivered in the correct order. The initial hardware design feeds into PCB assembly, which in turn enables stable firmware development. Firmware, apps, and cloud systems are developed concurrently, with integration testing serving as a major validation milestone before clinical trials. Clinical trials are dictated by ethics approval and serve as prerequisites for regulatory submissions. In parallel, design freeze triggers manufacturing readiness, ensuring scalable production plans align with regulatory deadlines. These logical relationships help manage schedule risk and maintain milestone integrity. Complete task dependencies and logic links are summarized in Appendix Table A2.

Most project work follows a finish-to-start (FS) logic, ensuring sequential flow – for example, firmware depends on PCB completion, and clinical trials depend on ethics approval. Strategic use of Start-to-Start (SS) and Finish-to-Finish (FF) dependencies compresses the schedule and aligns key milestones, as detailed in Appendix Table A2.(Bedi et al.).

5.3 Network Diagram (AON)

An activity-on-node (AON) network diagram visualizes the project schedule(Grande-González et al., 2025), with each node showing a task and its duration (in months), and arrows indicating finish-to-start (FS) dependencies. The AON diagram maps out key dependencies – for example, hardware must be finished before integration, and ethical approval is required before clinical trials. Parallel streams (for example, firmware and apps) show concurrency through start-to-start logic, while colour coding separates R&D and clinical/regulatory phases. Merged arrows highlight cross-functional dependencies, and node spans support critical path analysis. Aligned with PMI's PDM format and WBS milestones, the diagram enhances coordination by helping teams understand both prerequisites and downstream impacts, enabling clear planning and timeline optimization.

This network shows both sequential dependencies (for example, A → B → D) and concurrent streams (for example, E and development track).

5.3.1 Activity Table

Figure 10 Activity Table

The following table outlines the key tasks, their durations, and dependencies

Task	Activity Description	Duration (mo)	Dependency	Notes
A	Hardware Development	4	—	Starting point of R&D
B	Firmware Development	3	FS → A	Parallel to software
C	App & Cloud Development	3	FS → A	Parallel to firmware
D	Integration & Verification	2	FS → A, B, C	Merge from development tasks

E	Ethics Approval	2	—	Independent of R&D
F	Clinical Trial	3	FS → D, E	Regulatory + device readiness
G	Manufacturing Readiness	2	FS → D	Not on critical path
H	Regulatory Submission	1	FS → F, G	Merged from trial & production
I	Project Completion	0	FS → H	Final milestone

5.3.2 Critical Path Identification

The critical path is defined as the longest-duration sequence of dependent tasks from project start to finish, where any delay will directly postpone the final delivery. From forward and backward pass analysis, the critical path is as follows:

A (4) → D (2) → E (2) → F (3) → H (1) → I (0) = 12 months

All tasks on this path have zero float, meaning they must start, and finish as scheduled to avoid impacting project delivery. Thus, the critical path is:

A → D → E → F → H → I

Table 15 Critical Path Identification

Task ID	Task Name	Critical Path Status	Float Availability	Explanation of Slack / Flexibility
B	Firmware Development	Non-critical	Positive float	Runs concurrently with Hardware Development (A) and merges at Integration (D); early completion provides buffer if A is delayed.
C	App & Cloud Development	Non-critical	Positive float	Executes in parallel with Firmware and Hardware tasks; slack exists if it completes before Integration (D).
G	Manufacturing Readiness	Non-critical	Positive float	Must finish before Regulatory Submission (H), but timing is less critical than Clinical Trial (F), providing scheduling flexibility.

Implications for resource planning: The presence of float in non-critical tasks allows temporary resource reallocation without impacting the overall project duration. For example, personnel assigned to manufacturing readiness (G) can support regulatory submission readiness (H) if critical path pressure increases(Peter Landau, 2025).

5.4 Gantt Chart Strategy

Table X summarizes the Gantt chart implementation strategy using OnlineGantt, detailing setup, tracking, coordination, and alignment with PMI and MedTech project management best practices.

Table 16 Gantt Chart Strategy

Component	Description
Tool Used	The Gantt chart will be developed using OnlineGantt, a web-based platform supporting professional timeline planning, task dependencies, and team collaboration(Richard)
Initial Setup & Baseline	All tasks and milestones from the Work Breakdown Structure (WBS) will be entered into OnlineGantt with specified duration and dependencies (as defined in 5.2). The WBS hierarchy will be reflected in grouped work structures (e.g., hardware, software), and a baseline schedule will be saved to track planned versus actual timelines.

Phase Colouring & Milestones	Project phases will be clearly separated using color-coded stripes: blue for R&D (for example, sensors, firmware, app development), green for verification and validation (for example, systems integration, QA), orange for clinical trials, and purple for regulatory submission and closure. Milestones (for example, "TRL 6 - Prototype Complete") will be marked with diamond symbols.
Progress Tracking & Updates	The project manager will update the Gantt bi-weekly, recording actual dates and task % completion information. Online Gantt automatically recalculates the timeline and highlights deviations. The "Tracking Gantt" view shows actual performance versus a baseline. The critical path is highlighted(Wadhwa Kanika) in red to identify tasks that impact the overall schedule.

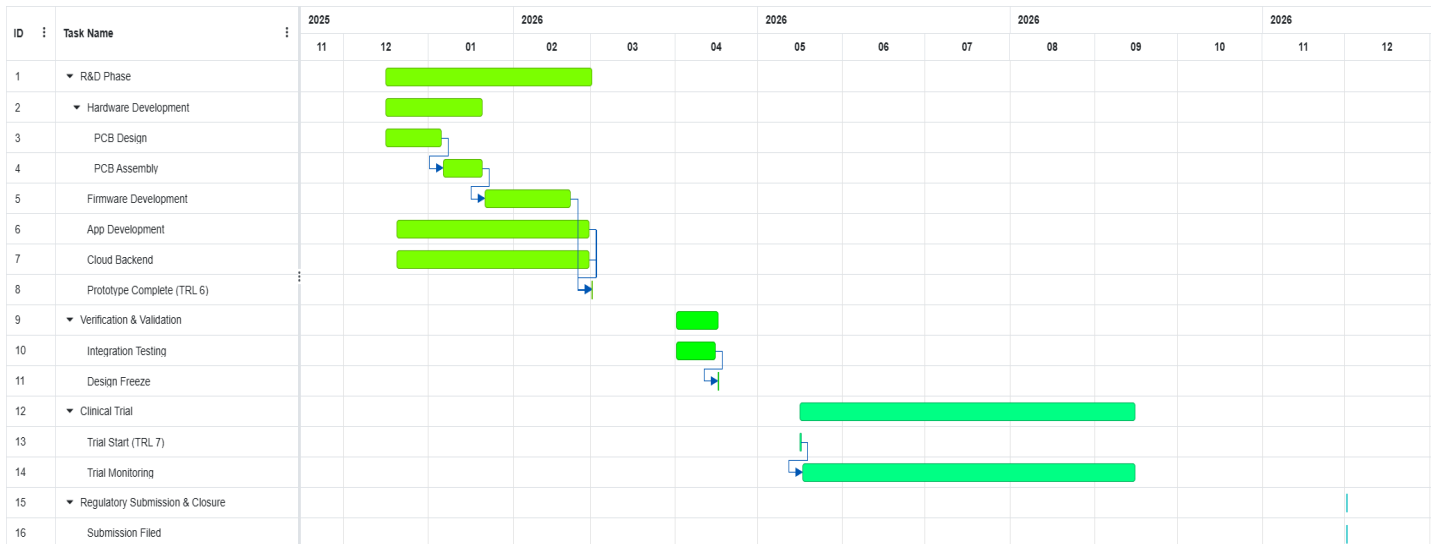


Figure 11 Gantt Chart Project File Snap

Smart Nano-Sensor Project		
Stakeholder Analysis	5 days	
Charter & Scope Documentation	5 days	2
PMP Compilation	10 days	3
WBS and Schedule Baseline	5 days	4
KPI Tracking	180 days	5
Risk Review Cycles	180 days	5
Biomarker Sensor Design	20 days	5
Microfluidic Integration	20 days	8
BLE SoC Configuration	15 days	8
Power Management Design	15 days	8
Flexible PCB Fabrication	20 days	9;10;11
Biocompatibility Testing	20 days	12
Signal Calibration (ADC)	15 days	12
Functional Testing	15 days	12
BLE Data Pairing Protocol	20 days	12
Security Layer Implementation	15 days	16
Real-Time Dashboard Display	15 days	16
Alert Engine for Anomalies	15 days	18
Lightweight Model Deployment	15 days	18
Risk Score Computation	10 days	20
UX/UI Wireframes	20 days	5
User Authentication & Syncing	15 days	22
Biomarker Trends	20 days	23
Report Generator for Clinicians	20 days	24
AWS/GCP Setup & Compliance	20 days	5
Scalable Storage Architecture	20 days	26
Population-Level Insights	25 days	27
Model Retraining Framework	25 days	28
Class II Pre-submission Dossier	30 days	15
EU MDR Class IIa Compliance	20 days	30
ISO 13485 QMS Implementation	20 days	5
Biocompatibility (ISO 10993)	20 days	13
Simulated Wear Testing	25 days	15
Sensor Accuracy Benchmarks	20 days	15
Usability Studies with Wearables	20 days	25
End-User Feedback Loop	20 days	36
Design History File (DHF)	10 days	30
Risk Management File (ISO 14971)	10 days	38
Academic Report Submission	10 days	37;39
Industry Summary for Stakeholders	10 days	40

to address uncertainty.

6 Cost Estimation and Budgeting

6.1 Cost Estimation Methodology

Project costs were estimated using a bottom-up, WBS-based approach, consistent with established project cost management practice. The cost of each work package was determined independently based on the defined scope, material quantity, labour hours, equipment requirements, and applicable unit rates. UK MedTech labour benchmarks (£40-£80/hour) were applied to specialist roles, while material costs were derived from supplier quotations and industry benchmarks. Individual work-package estimates were aggregated into the WBS to generate phase totals and the overall project budget. Parametric and activity-based costing (ABC) investigations were used to validate the estimates. The life-cycle cost perspective ensured inclusion of R&D, validation, regulatory and pilot testing costs(Blessing & Ifeanyi, 2025). All figures are rounded to the nearest £500.

6.2 WBS-Aligned Cost Breakdown

A detailed cost model is provided in *Cost_Model_Patch.xlsx* in *Appendix B Documentation B1* including labour, materials, equipment, and overhead. Table 6-1 summarizes stage-level costs. 10% contingency reserve (WBS 9) is included

Table 17 Phase Level Cost Summary

WBS Phase	Description	Approx. Cost (£)	% of Total
WBS 1 – Project Management & Governance	Initiation, monitoring, closure	£46k	8.20%
WBS 2 – Sensor Patch Development	Sensor design, electronics, prototyping	£164k	29.20%
WBS 3 – Smartwatch Integration	BLE interface, firmware, watch app	£46k	8.20%
WBS 4 – Smartphone Application	UX/UI, feature development	£46k	8.20%
WBS 5 – Cloud & Data Backend	Secure infrastructure, analytics	£49k	8.70%
WBS 6 – Regulatory & Certification	ISO, CE/FDA submission	£90k	16.00%
WBS 7 – Pilot Testing & Validation	TRL 5–6 testing and pilot study	£48k	8.40%
WBS 8 – Documentation & Handover	Technical and academic outputs	£23k	4.10%
WBS 9 – Contingency Reserve	10% risk buffer	£50k	8.90%
Total Project Budget	—	≈£562k	100%

6.3 Material, Labour, and Overhead Models

Materials include sensor substrates, microfluidic layers, BLE modules, batteries, PCBs, and consumables. Off-the-shelf components were preferred to reduce tooling costs. Labor rates reflect UK MedTech benchmarks: biosensor scientists (~£80/hour), regulatory staff (~£70/hour), embedded engineers (~£50-£60/hour), data scientists (~£55/hour), QA managers (~£65/hour), and clinical staff (~£60/hour). Overheads include access to clean rooms, manufacturing facilities, development kits, cloud infrastructure, notified-body fees, and testing equipment. Includes project management overhead of ~10%.

6.4 Software, Licensing, and Cloud Costs

Software cost includes development license, design tools, and analytics library(London Economics, 2022). Cloud infrastructure (~£21k) supporting secure UK/EU-based AWS or GCP services. Analytics and AI functions cost ~£28k, including data-science labour and GPU computations. All systems have been budgeted to support TRL 7 pilot deployment and GDPR compliance.

6.5 Risk-Adjusted Costing and Contingency

A 10% contingency reserve (£50k) has been allocated to address price volatility, regulatory uncertainty and

technical rework. Given the uncertainty inherent in biosensor and regulatory development, this exceeds the benchmark for low-risk construction projects and is only released through formal change control(Zhao et al., 2024).

6.6 Cash Flow Projection

The costs are distributed over an 18-month schedule:

- Months 1-4: Design and Prototyping (~40%)
- Months 5-9: Integration and Alpha Development (~25%)
- Months 10-14: Pilot testing and validation (~20%)
- Months 15-18: Final reporting and handover (~15%)

This phased expenditure aligns with the project milestones and funding gate.

6.7 Cost Reduction Opportunities

Cost efficiency is supported through:

- Initial Planning and Regulatory Engagement
- Agile and Iterative Prototyping
- Design for manufacturability and standard components
- cross-functional collaboration
- Lean Supplier Engagement(Gomaa, 2025)
- Rapid validation and usability testing

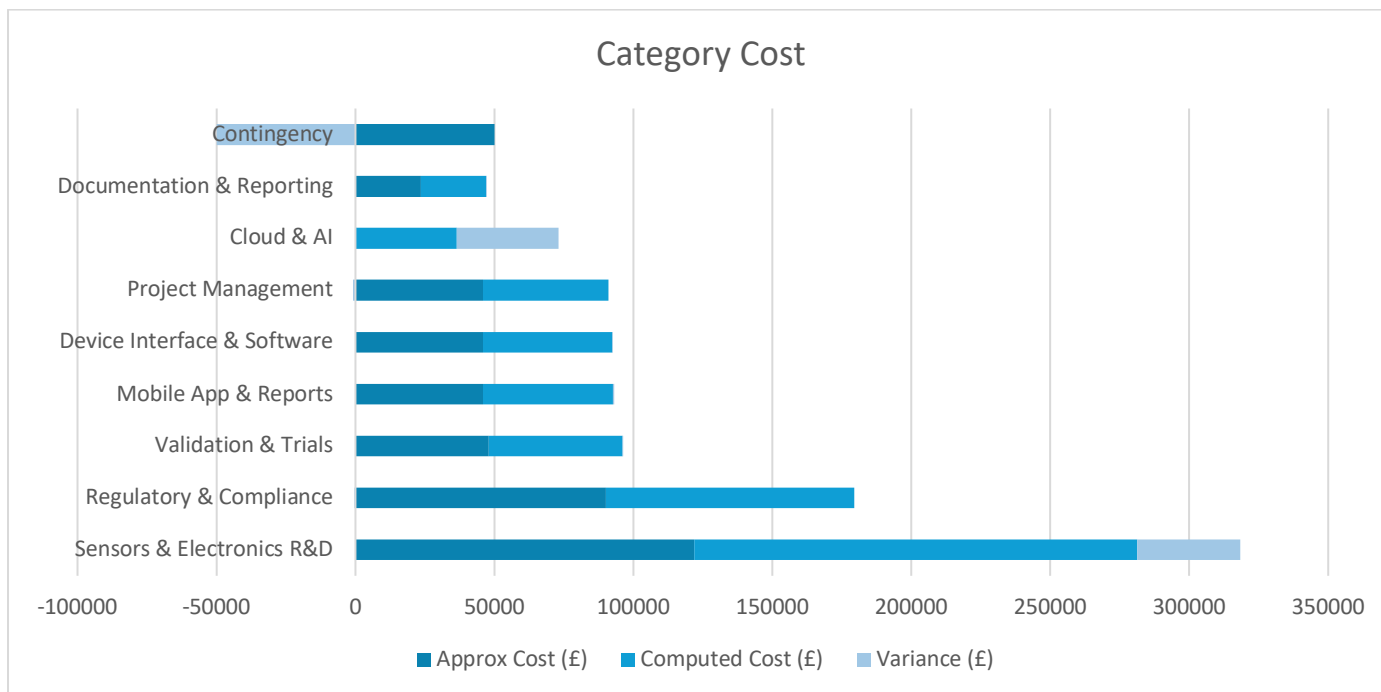
These measures reduce rework and late-stage cost overruns.

Table 18 Cost Reduction Opportunities

Aspect	Baseline Cost	Improved Cost / Savings	% Reduction	Details / Justification
Prototype Unit Material Cost	£60 per patch	£40 per patch	~33%	Cost engineering via DFM, sourcing, lean methods
Cost Savings per Patch	—	£20 saved per unit	—	Material/process optimization
200 Unit Pilot Savings	£12,000 total cost	£8,000 total cost	~33%	£4,000 saved for pilot batch
500 Unit Scale Savings	£30,000 (est. baseline)	20000	~33%	Bulk sourcing, supplier contracts
Sensor Material Bulk Saving	£6,000+ (antibodies)	£3,500–£4,000	~40%	Bulk enzyme/reagent supply for CRP, glucose, lactate sensors
Electronics Cost	£40/module × 200 = £8k	£5/module × 200 = £1k	~88%	Use of COTS BLE modules (e.g., Nordic nRF52) instead of custom dev boards
Manufacturing Efficiency (Labour)	High man-hours	Reduced hours per unit	~20–30%	Lean cell manufacturing, automation (e.g., adhesive application)
Packaging & Waste Reduction	£5/unit	£2–£3/unit	~40%	Eco-friendly, simplified recyclable pouch instead of hard plastic case
Overall Estimated Project Savings	~£25,000–£30,000	~£5,000–£10,000 in pilot stage	20–30%	Cumulative benefit from all strategies (material, sourcing, design)
Long-term Strategic Impact	Higher COGS	Lower cost per unit post-pilot	>30%	Enables scalability, pricing flexibility, improved margins and accessibility
Electronics Cost	£40/module × 200 = £8k	£5/module × 200 = £1k	~88%	Use of COTS BLE modules (e.g., Nordic nRF52) instead of custom dev boards
Manufacturing Efficiency (Labour)	High man-hours	Reduced hours per unit	~20–30%	Lean cell manufacturing, automation (e.g., adhesive application)
Packaging & Waste Reduction	£5/unit	£2–£3/unit	~40%	Eco-friendly, simplified recyclable pouch instead of hard plastic case
Overall Estimated Project Savings	~£25,000–£30,000	~£5,000–£10,000 in pilot stage	20–30%	Cumulative benefit from all strategies (material, sourcing, design)
Long-term Strategic Impact	Higher COGS	Lower cost per unit post-pilot	>30%	Enables scalability, pricing flexibility, improved margins and accessibility

6.8 Total Budget Summary

Table 19 Total Budget Summary



The total estimated cost to deliver the smart nano sensor patch system to TRL 6-7 is ~£562k, including labour, materials, cloud services, regulatory fees and contingency. This budget aligns with comparable mid-scale MedTech proof-of-concept projects and provides a strong foundation for thesis-level development. Expansion beyond TRL 7 will require additional funding for large-scale clinical trials and manufacturing.

The entire cost model is provided in CSV format: [Cost_Model_Patch.xlsx](#) in Appendix B

7 Risk Management

7.1 Risk Management Approach

A structured, ISO14971-aligned risk management process is applied throughout the project lifecycle(Jos van Vroonhoven, 2020). Risks are identified initially and reviewed weekly through a live risk register(ADEBAYO OMOWUNMI TEMITOPE, 2024). The risk analysis follows a probability × impact matrix with color-coded ratings (green/yellow/red). High-severity risks receive immediate mitigation. The PM ensures escalation and periodic review with unresolved risks escalated to senior management. This proactive process supports project flexibility and compliance with recognized MedTech risk standards.

7.2 Risk Identification

The risks were generated from team workshops, prior medical device projects, and industry trend analysis(Suckling et al., 2003). They are grouped by domain:

- Technical – Sensor drift, firmware instability
- Clinical - Skin irritation, non-compliance
- Supply Chain - Component Shortages
- Cyber Security – Breach, Firmware Tampering
- Regulatory – delaying ethics, changing standards
- Schedule - Testing or Integration Overrun

Table 21 Risk Register

ID	Risk Description	Prob	Impact	Score	Rating	Est. Impact	Mitigation Strategy	Owner
R1	Sensor accuracy drift	3	3	9	Medium	£50k, 2 mo	Chemistry improvement, calibration, aging tests	Eng Lead
R2	Battery underperformance	2	4	8	Medium	£40k, 1 mo	Vendor diversification, power optimisation	Eng Lead
R3	Skin irritation	2	3	6	Low	£20k, 1 mo	ISO-tested materials, patch testing	Clinical Lead
R5	Cybersecurity breach	3	5	15	High	£100k, fines	AES-256, secure boot, segmentation	Security Lead
R6	BLE/flex battery shortage	3	4	12	Medium	£60k, 3 mo	Multi-supplier strategy, pre-ordering	Supply Lead
R7	Integration delays	3	3	9	Medium	£20k, 1 mo	Early sprints, CI pipeline, schedule buffer	PM
R9	Regulatory change	2	4	8	Medium	£25k, 3 mo	Continuous monitoring, modular design	QA/RA Lead
R12	Supply cost escalation	3	3	9	Medium	£35k	Fixed contracts, inflation clauses	Finance

7.3 Qualitative Risk Assessment

Each risk is scored using a 5×5 matrix (ISO-aligned).

Table 20 Qualitative Risk Assessment

Score Range	Rating	Response Priority
1–5	Low	Monitor
6–12	Medium	Planned Mitigation
15–25	High	Immediate Action

Probability and impact are rated 1 (low) to 5 (high), customised for project context.

7.4 Quantitative Risk Analysis

High-criticality risks undergo FMEA(Cornelis et al., 2025). Each failure mode is scored by:

- Severity(s)
- event(o)
- investigation(d)

Risk Priority Number (RPN) = S × O × D. RPN >30 indicates design changes or enhanced controls. Monte Carlo simulation was not required; Schedule buffering preferred.

7.5 Risk Register (Excerpt)

7.6 Risk Response Strategies

Table 22 Risk Response Strategies

Strategy	Description	Example
Avoid	Eliminate the risk source	Use pre-certified BLE modules to avoid RF risks
Reduce	Lower probability or impact	Encryption, vendor redundancy, calibration
Transfer	Shift risk externally	Supplier contracts, third-party hosting
Accept	Tolerate with monitoring	Minor non-compliance, low-impact usability issues

7.7 Monitoring and Control

Risk review is embedded into weekly PM routines (Obondi, 2021). Key practices include:

- **Review & Update:** Owners revise ratings and mitigation status.
- **Escalation:** Severe or unresolved risks sent to senior management.
- **Closure:** Closed when resolved or no longer relevant.
- **Communication:** High-risk items reported to stakeholders.

8 Management Plans

8.1 Quality Management Plan (ISO-Compliant)

To ensure that the nano-sensor patches and related systems meet regulatory and user requirements, the project adopts an ISO13485:2016-compliant quality management system (QMS) (Pacheco et al., 2025b). Top management defines quality objectives, allocates resources, and oversees management reviews. Key QMS elements include:

Table 23 Quality Management Plan

QMS Area	Description
Design Control	Maintain Design History File (DHF) and Device Master Record (DMR); document design inputs, outputs, V&V activities.
Risk Management	Apply ISO 14971; maintain Risk Management File with documented hazard controls.
Supplier Quality	Qualify/audit vendors; verify incoming materials meet specifications.
Process & Test Control	Define SOPs, test methods, and acceptance criteria; apply statistical process control.
CAPA	Record non-conformities; conduct root cause analysis; implement and track corrective/preventive actions.

Integration: Reduces schedule delays and rework costs by quickly stopping quality control defects and nonconformities.

8.2 Communication Management Plan

Effective communication is essential to minimize rework and ensure stakeholder alignment.

Table 24 Communication Management Plan

Stakeholder	Information	Channel	Frequency
Core Team	Task status, risks	Teams video calls	Weekly
Steering Committee	Schedule, budget, decisions	Reports	Monthly
Participants	Instructions, feedback	App + Hotline	Ongoing
All Teams	Documents, updates	SharePoint	Continuous
All Stakeholders	Urgent alerts	Slack / Email	As needed

Rationale: This plan reduces communication failure risks by standardizing the frequency, content, and method.

8.3 Change Management Plan

A formal process ensures traceability and control over modifications.

Table 25 Change Management Plan

Change Process Stage	Description
Identification	Anyone may submit a Change Request (CR)
Impact Assessment	Evaluate impact on scope, cost, quality, safety
Approval	Change Control Board (CCB) reviews; major changes go to Steering Committee
Implementation	Update design, regulatory, and test documentation
Verification	Validate outcomes; update DHF and logs

8.4 Integrated Operational Management Strategy

To ensure effective execution of the Smart Patch project, a coordinated set of operational management plans has been established, including procurement, change control, maintainability, configuration, data security, and resource management. The procurement and contracting strategy support supply chain flexibility through ISO13485-certified suppliers, dual-sourcing of critical components, structured contract types, and annual audits (see Appendix A Table A4). A formal change management process ensures that all modifications are controlled and traceable, with steps including impact assessment, approval and validation (see Appendix A Table A5). The sustainability plan applies a triple bottom line (TBL) framework, which integrates environmental, economic and social strategies such as life cycle assessment and ISO14001-compliant sourcing(Nica et al., 2025). To maintain product traceability, the configuration management scheme follows ISO/IEC/IEEE 15288, including version control, baseline identification, audits, and release management (Appendix Table A4). Data security is addressed through a GDPR-aligned data security plan, including AES-256 encryption, role-based access, pseudonymization, and breach response protocols. Finally, the resource management plan ensures timely availability of skilled personnel and laboratory infrastructure through structured role assignments, skills tracking, cross-training, and contingent staffing. Collectively, these interdependent management strategies align with project scope, cost control, regulatory compliance, and risk mitigation objectives.

9 Ethics, Compliance, and Responsibility

9.1 Engineering Ethics: Health, Safety, and Fairness

The project adheres to established engineering ethics, specifically the NSPE Code of Ethics(NSPE, 2021), which emphasises honesty, integrity, and the protection of public health and welfare. Key principles applied include ensuring safety and reliability through rigorous sensor verification(Hayes et al., 2025); maintaining professional competence by working within areas of expertise; avoiding misrepresentation through evidence-based communication; and upholding confidentiality and fairness, especially in handling clinical data and supporting diverse user needs. Inclusive design and strict compliance with regulatory standards further reinforce ethical obligations across development stages.

9.2 Patient Data Privacy and Consent

The project processes sensitive health data and is compliant with UK GDPR, HIPAA (for US contexts), and related data protection laws(Conduah et al., 2025). All measures are in line with the seven GDPR principles prioritizing data minimization, transparency and privacy(UK GDPR, 2023).

Table 26 Patient Data Privacy and Consent

Privacy Measure	Implementation
Informed Consent	Plain-language consent forms integrated into the mobile app; includes data use, retention, and withdrawal terms.
Data Minimisation & Pseudonymisation	Collect only relevant biomarker data; de-identify participant information using pseudonymous IDs.
Encryption & Storage Security	AES-256 for BLE and cloud transmission; TLS for data in transit and at rest.
DPIA	A full Data Protection Impact Assessment is conducted to assess privacy risks and guide mitigation.
Consent Withdrawal	Participants can revoke consent and request data deletion, ensuring control over personal data.

These security measures ensure the ethical handling of participant data and regulatory compliance under GDPR Article 32.

9.3 Regulatory Compliance (Medical Device Classifications)

Under the EU Medical Device Regulation (MDR 2017/745), devices are classified based on risk. Class IIa devices – such as short-term invasive or active devices are considered medium risk and require the implementation of an ISO13485-compliant quality management system, a technical file, clinical assessment and notified body certification prior to CE marking. Post-market surveillance is also mandatory.

- Maintenance of ISO13485 QMS and complete technical documentation
- Conducting clinical assessments and implementing ISO14971 risk management
- Preparing CE or 510(k) submissions, including labelling, EMC and sterilization verification.
- Aligning documentation with EU and US regulatory frameworks for dual market clearance.

9.4 Environmental and Social Responsibility

The project applies the Triple Bottom Line (TBL) framework to integrate economic, social and environmental sustainability principles throughout its lifecycle.

Table 27 Environmental and Social Responsibility

TBL Pillar	Project Strategy
Environmental	Use of biodegradable substrates, near-shored production, recyclable packaging, energy-efficient processes, and end-of-life recycling.
Social	Inclusive design (language, accessibility), engagement with patient groups, equitable employment practices, and local stakeholder involvement.
Economic	Cost-efficient design (e.g., modular architecture), supplier negotiations, and sustainability-aligned pricing to ensure affordability (see Section 6.7).

Additionally, community engagement through pilot studies and forums ensures participatory design and promotes public trust.

9.5 Alignment with UN Sustainable Development Goals (SDGs)

The Smart Patch project supports multiple UN SDGs, strengthening its social value beyond the technical deliverables.

Table 28 Sustainable Development Goals

UN SDG	Project Contribution
Goal 3: Good Health & Well-being	Enhances early disease detection and supports long-term condition management.
Goal 9: Industry, Innovation & Infrastructure	Advances MedTech innovation with integrated digital infrastructure for continuous health monitoring.
Goal 12: Responsible Consumption & Production	Promotes modular design, sustainable materials, and lean manufacturing principles.
Goal 13: Climate Action	Reduces emissions through near-shoring and eco-conscious packaging and production practices.

These alignments demonstrate the project's contribution to the global health, innovation and sustainability agenda.

10 Conclusion:

The Smart Nano-Sensor Patch Project provides an example of how engineering management principles can be applied to accelerate MedTech innovation. Through systematic planning, risk-managed execution, and lifecycle-oriented cost optimization, the project is ready to transition from laboratory prototype to clinical trial (TRL 6-7) within 18 months. Integration of project scope, cost, time, quality and risk within an integrated management plan increases traceability and accountability throughout the lifecycle. The use of lean design, regulatory foresight and stakeholder-driven development further enhances business feasibility and social impact. This comprehensive management strategy not only meets academic and industrial standards but also lays the foundation for future scale, funding, and real-world adoption in health care systems.

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Appendix A

Table A1

Deliverable ID	Title	Description	Success Criteria
D1	Functional Sensor Patch Prototype(s)	One or more prototype units of the nano-sensor patch, integrating sensors, electronics, and BLE communication. Includes physical patch with embedded sensors and Li-Po battery(Sunny et al., 2022).	The prototype continuously measures specified biomarkers and transmits data wirelessly in real time during lab tests.

D2	Smartwatch Application (Beta)	A functioning application installed on a target smartwatch (and optionally a phone), capable of receiving data from the patch, displaying real-time multi-biomarker readings, and generating alerts using an embedded anomaly detection ML model.	The app connects reliably to the patch, visualizes biomarker data, and triggers alerts in ≥90% of simulated abnormal events.
D3	Cloud Data Platform & Dashboard	Cloud-based system comprising a secure API, database for data upload from the smartwatch app, and a web dashboard for authorized users to review trends. Includes data encryption and user authentication for compliance(Elfouly & Alouani, 2025).	Data uploads with accurate timestamps, is securely transmitted, and can be viewed on the dashboard by authenticated users.
D4	Test & Validation Reports	Documentation of testing outcomes: sensor calibration, accuracy vs reference devices (e.g. glucometer), BLE range/stability, battery life, and user feedback from pilot trials. Includes User Acceptance Testing (UAT) report against acceptance criteria (see Section 1.5).	Complete documentation of all test results demonstrating system performance against defined benchmarks.
D5	Technical Documentation Package	Comprehensive documentation for regulatory and development purposes: Requirements Specification, System Architecture, schematics, BOM, firmware source code with annotations, Risk Management File (e.g. FMEA per ISO 14971), and draft Regulatory Submission outline (e.g. device classification rationale, intended use, summary technical documentation as per MDR/FDA).	Full package compiled and structured to support future CE/FDA submissions.
D6	Project Management Artifacts	Project governance materials including Project Management Plan, WBS, Gantt chart, RACI matrix, and Risk Register. Supports academic assessment and internal audit readiness.	All management tools and documents delivered in alignment with project execution and academic best practices.

Table A2

Activity	Description	Key Outputs
Hardware Development	Design and prototyping of the nano-sensor patch including sensor fabrication, PCB layout, power management, and smartwatch interface.	TRL 5–6 lab-ready prototype
Firmware Development	Embedded software for sensor control, power management, and BLE communication. Depends on hardware readiness and iterates alongside testing.	Functional firmware with reliable data transmission
Mobile/Watch App Development	Development of a smartwatch/smartphone app for real-time data visualization and cloud sync. Uses simulated data initially, then real hardware.	User-friendly app displaying real-time health metrics
Cloud Backend Development	Setup of secure cloud infrastructure for storing and analysing patch data, including secure APIs and early detection algorithms.	Encrypted, regulatory-compliant cloud platform

Regulatory Compliance & Docs	Implements ISO 13485 QMS, prepares technical file, risk documentation, and supports CE/FDA submission. Runs from project start to regulatory filing.	CE/FDA submission package and documentation
Clinical Evaluation (Pilot)	Ethics-approved pilot trial with volunteer participants to demonstrate safety and efficacy in real-world use (TRL 7).	Clinical data and user feedback reports
QA & Testing	Verification and validation of all system components including safety, performance, and integration testing. Ensures compliance with standards before trials.	Test reports, V&V documentation
Manufacturing Readiness	Prepares for scalable production: supplier qualification, DFM, and pilot production setup. Ensures smooth TRL 7→8 transition.	Manufacturing plan and supplier agreements

Table A3

Task (Work Package)	Key Dependency (Predecessor → Successor)	Dependency Type
Hardware Design → PCB Assembly	Hardware design must finish before PCB fabrication starts (final schematic needed).	FS
PCB Assembly → Firmware Development	Firmware coding can partially begin earlier, but full integration testing starts after PCB hardware is assembled.	FS (with overlap via SS)
Firmware Dev. → Integration Testing	Firmware (embedded code) must reach a stable build before combined hardware-software integration testing can finish.	FF
App/Cloud Dev. ↔ Firmware Testing	Mobile app and cloud backend can start once system architecture is defined. They progress in parallel (no strict FS), but start-to-start links ensure, for example, cloud analytics begin when app development starts (concurrent R&D).	SS
Integration Testing → Clinical Trial	All system components (hardware, firmware, app, cloud) must be verified together (integration test complete) before beginning a clinical pilot. The device needs to be fully functional and safe for use in trials.	FS
Ethics Approval → Clinical Trial	Ethics committee approval must be obtained before any testing on human subjects begins. The trial can only start after ethics is granted.	FS
Clinical Trial → Regulatory Submission	Clinical data collection (pilot trial) must finish before final regulatory submission. Regulatory filings (e.g. in a CE technical dossier or FDA submission) require evidence from the trial, so submission cannot be completed until the pilot study is done.	FS
Design Freeze → Manufacturing Prep	A stable design (post-verification) is needed before scaling manufacturing. Once the design is frozen and tested, manufacturing process validation and supply chain setup can start.	FS
Regulatory Submission ← Clinical & Manufacturing	<i>(Converging dependency):</i> The final submission milestone depends on both successful clinical results and manufacturing plans. While manufacturing prep can run in parallel, both streams should finish by the submission date (finish-to-finish alignment).	FF

Table A4

TBL Dimension	Strategy
Economic	Cost efficiency, off-the-shelf components, lean design
Social	Inclusive UX, fair labour, participant consent
Environmental	Eco-materials, recyclable packaging, low-energy processes

Sustainability Actions:

- Life Cycle Assessment (LCA) in design
- ISO 14001-compliant suppliers
- Monitor energy and waste KPIs
- Green procurement policies

Integration: Reduces long-term costs and regulatory risk.

Table A5

CM Activity	Description
Planning	Define CM roles, tools (Git, document control)
Identification	Unique IDs for versions; baselines established
Change Control	Linked to Change Management; all updates traceable
Status Accounting	Track state and owner of each configuration item
Audit	Verify physical and functional compliance before major milestones
Release Management	Controlled deployment of approved versions for manufacture and testing

Appendix B

Documentation B1 COST Dashboard B2 Gantt Chart File Gantt Chart Import Excel



Cost_Model_Patch.xlsx



WBS Cost
Dashboard (Interact



MedTech_Project.gantt



SmartPatch%20Schedule.xlsx

Gantt Chart Site Access Link:

<https://www.onlinegantt.com/#/gantt/cloud>

Student Self-reflection on performance

Describe how you have used AT LEAST ONE of the following sources of information to improve this piece of work:

- 1.) (PREFERRED) Feedback from previous assignment(s). This can be from the same module or from a previous module or previous year of study (e.g. comments from 1st year lab formal reports should be used to help improve your 2nd year lab formal reports).
- 2.) The marking criteria or rubric provided for this assignment.
- 3.) The Department Technical Writing Handbook for Students.

The Department Technical Writing Handbook for Students.

Are there any aspects of this work that you would specifically like the marker to comment/or advise on? For example: "I wasn't sure if my figure formatting looked professional and would appreciate feedback on this aspect"

IMPORTANT DECLARATIONS AND REQUIREMENTS

Group Declaration:

We confirm that:

- All factors are fairly awarded
- Required documentation is attached
- All members had opportunity to contribute
- Professional conduct was maintained
- University procedures were followed

Signatures of ALL Group Members:

1. Name: Jagathguru Pazhanivel	ID:249057008	Signature: 	Date: 12/12/2025
2. Name: Nijanthan Udayakumar	ID: 249055249	Signature: 	Date: 12/12/2025
3. Name: Fregin Sherofer Francis	ID: 249050172	Signature: 	Date: 12/12/2025

Module Convenor Use Only:

- Documentation Complete
- Factors Verified
- Procedures Followed
- Approval Granted

Title:	Peer Review and Individual Effort Factors		
Group:	New Group 3		
Date assessed:	12/12/2025		
Group Member and Student ID	Factor	Feedback	Signature
	$0.00 \leq X \leq 1.10$	<i>Group will need to provide a brief justification for the weighting factors awarded.</i>	
Jagathguru Pazhanivel 249057008	1.10	Assumed the leadership role, effectively coordinating meetings, ensuring timely progress, and maintaining high-quality standards across all sections. Their proactive problem-solving and outstanding communication significantly contributed to the project's success. Given these additional responsibilities, a higher weighting of 1.10 is justified.	
Nijanthan Udayakumar 249055249	1.10	Developed a tailored implementation proposal, detailing the integration of Lean methods with smart technologies to address identified inefficiencies.	
Fregin Sherofer Francis 249050172	1.10	Identified potential risks and outlined comprehensive mitigation strategies, ensuring the proposal's feasibility and sustainability.	F. Fregin Sherofer