Proposal for UK Technology Leadership & Digital Health Readiness

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Executive Summary

Keza Studio is pleased to present this proposal to support SureReach Ltd's expansion into the United Kingdom healthcare market.

Having reviewed SureReach Ltd's objectives and discussed your ambitions for entering the UK digital health ecosystem, we believe the greatest value we can provide is not simply as a technology consultancy, but as your UK technology leadership partner.

Our role will be to bridge the gap between your existing development capability and the unique technical, regulatory and operational requirements of delivering digital healthcare solutions within the NHS and wider UK healthcare sector.

This will include assessing whether any current or planned SureReach Ltd functionality may fall within the UK medical-device regulatory framework overseen by the Medicines and Healthcare products Regulatory Agency (MHRA), particularly where software or AI functionality performs, supports or influences a medical purpose.

Where this is applicable, we will help SureReach Ltd establish its initial regulatory position, understand the likely technical and engineering implications, identify the documentation and evidence that may be required, and develop a practical roadmap for progressing toward UK market readiness.

Rather than replacing your existing engineering team, we will provide the strategic technical leadership, governance and UK healthcare expertise required to ensure the platform is secure, scalable, appropriately governed and ready for successful UK deployment.

This proposal therefore outlines a phased engagement beginning with a comprehensive UK Technical & Digital Health Readiness Assessment, followed by an ongoing Fractional CTO / UK Technical Lead service to guide technology strategy, coordinate engineering delivery and support SureReach Ltd’s commercial growth in the UK.

Objectives

The engagement is designed to help SureReach Ltd:

- Successfully establish its UK technology operation.
- Accelerate entry into the NHS and wider UK healthcare market.
- Align the platform with UK regulatory, clinical-safety, information-governance and security expectations.
- Establish an initial MHRA / Software as a Medical Device regulatory position where applicable.
- Identify the technical, product and engineering implications of any applicable medical-device requirements.
- Improve software quality, scalability and operational resilience.
- Establish a mature engineering and deployment capability.
- Establish robust CI/CD, release-management and production-governance processes.
- Provide experienced UK technical leadership without the immediate need for a full-time CTO.
- Maximise the effectiveness of SureReach Ltd's existing development team.
- Establish a prioritised roadmap for progressing from the current platform to UK market readiness.

Our Approach

We recommend a two-phase engagement.

Phase 1 – UK Technical & Digital Health Readiness Assessment

Duration: 4–6 weeks

This initial phase provides a comprehensive review of SureReach Ltd's technology platform, engineering capability and operational readiness for the UK healthcare market.

The objective is not simply to identify problems, but to give SureReach a clear understanding of:

- where the platform is today;
- where it needs to be for the UK;
- what the major technical, regulatory and operational gaps are;
- what needs to happen first;
- which activities can be undertaken by the existing development team;
- which activities require specialist external support;
- and the likely investment and delivery roadmap required.

Technical Architecture Review

We will conduct an independent assessment of the current platform architecture, including:

- Overall application architecture
- Cloud infrastructure
- Hosting environment

- Data architecture
- API strategy
- Scalability
- Performance
- Reliability
- Disaster recovery capability

The review will establish whether the current architecture provides a suitable foundation for UK deployment and identify areas requiring remediation or redesign.

Where the existing development team has already undertaken infrastructure or scalability modelling, we will review and validate that work rather than unnecessarily recreating it, and extend it to address UK-specific requirements where appropriate.

Engineering Review

Working alongside SureReach Ltd's existing development team, we will assess:

- Development processes
- Source-control strategy
- Code quality
- Coding standards
- Technical debt
- Test coverage
- Documentation
- Team structure
- Engineering workflows
- Technical ownership
- Release processes
- Development and production access
- Dependency management
- Change-control processes

Our objective is to understand both the technical state of the platform and the capability of the existing engineering organisation.

The resulting recommendations will be designed to strengthen and coordinate the existing team rather than replace it.

Security Assessment

The security review will include:

- Identity and access management

- Infrastructure security
- Application security
- Secrets management
- Vulnerability management
- Logging and monitoring
- Backup strategy
- Security governance
- Privileged access
- Data encryption
- API security
- Production access controls
- Incident-management processes

The review will also identify any work required to prepare for:

- Cyber Essentials Plus
- NHS Data Security and Protection Toolkit
- NHS procurement expectations
- Appropriate penetration testing
- Security assurance expected of healthcare technology suppliers

Security findings will be incorporated into the overall technical roadmap and prioritised according to their impact on UK deployment.

Deployment & DevOps Assessment

A key focus of the engagement will be helping SureReach Ltd establish a robust, repeatable and secure deployment pipeline that supports rapid product development while maintaining the reliability, traceability and governance expected within healthcare environments.

We will review the current software delivery lifecycle and make recommendations covering:

- Source control and branching strategy
- Continuous Integration (CI)
- Continuous Delivery / Continuous Deployment (CD)
- Automated testing
- Release management
- Development, Test, UAT and Production environments
- Infrastructure as Code
- Configuration management
- Secrets management
- Deployment approvals and governance
- Software versioning
- Release traceability
- Rollback and recovery procedures
- Monitoring, logging and observability

- Production support processes
- Incident management
- Backup and disaster recovery

Our objective is to establish a modern DevOps capability that enables confident, repeatable and auditable deployments while reducing operational risk.

This becomes particularly important if any part of the SureReach Ltd platform falls within medical-device regulation, because changes to safety-relevant software must be appropriately controlled, tested, documented and traceable.

The deployment pipeline will therefore be designed not simply for development speed, but to provide the foundations for the level of engineering governance expected within regulated healthcare environments.

UK Healthcare Readiness

We will evaluate SureReach Ltd's readiness against UK healthcare expectations, including:

- NHS interoperability requirements
- Clinical safety processes
- DCB0129 applicability
- DCB0160 deployment considerations
- Information governance
- UK data-protection requirements
- Healthcare hosting considerations
- NHS procurement and assurance expectations
- DSP Toolkit readiness
- Cyber Essentials Plus readiness
- Accessibility considerations
- Future NHS integration opportunities
- Security governance

This workstream will establish a practical view of what SureReach Ltd needs to demonstrate when engaging NHS organisations and other UK healthcare partners.

MHRA & Medical Device Regulatory Readiness

Where applicable, we will assess whether SureReach Ltd's current or planned functionality may fall within the UK medical-device regulatory framework overseen by the MHRA.

As part of this assessment, we will:

- Review the platform's **intended purpose**, target users, clinical context and intended claims.

- Assess whether relevant functionality may constitute **Software as a Medical Device (SaMD)** and identify the likely classification direction.
- Review the implications of clinical decision-support, monitoring, alerting and AI functionality where applicable.
- Assess the current availability of supporting technical evidence, including software requirements, architecture, risk management, testing, traceability, cybersecurity, usability and change control.
- Identify the engineering and documentation gaps that would need to be addressed as part of any future regulatory programme.
- Identify where specialist medical-device regulatory support or conformity-assessment expertise will be required.

Deliverables will include:

- Draft Intended Purpose Statement
- Initial MHRA / SaMD Regulatory Readiness Assessment
- Indicative qualification/classification position
- Regulatory & Technical Documentation Gap Analysis
- Recommended regulatory and engineering roadmap

The objective of this phase is to establish a **clear initial regulatory position and practical roadmap**. It does not include formal regulatory advice, MHRA registration, conformity assessment or delivery of a complete Class IIa/Class IIb certification programme. Where these are required, they will be separately scoped with appropriately qualified specialists.

AI Governance (where applicable)

Where AI capabilities form part of the platform, we will review:

- AI governance
- Model management
- Model versioning
- Model change control
- Clinical risk
- Transparency
- Auditability
- Data provenance
- Human oversight
- Responsible AI practices
- Testing and validation
- Monitoring of model performance
- Potential MHRA implications where AI functionality has a medical purpose

Particular attention will be given to how changes to models are governed where those changes could affect clinical outputs.

Phase 1 Deliverables

At the conclusion of the assessment, SureReach Ltd will receive:

- **Technical Due Diligence Report**
- **Architecture Review**
- **Engineering Maturity Assessment**
- **Security Assessment**
- **Deployment Pipeline Improvement Plan**
- **UK Healthcare Readiness Assessment**
- **MHRA / Software as a Medical Device Regulatory Readiness & Gap Assessment**
- **Draft Intended Purpose & Regulatory Positioning Summary**
- **Indicative Medical Device Qualification / Classification Rationale,** subject to specialist confirmation where required
- **Regulatory & Clinical Safety Evidence / Documentation Gap Matrix**
- **MHRA / NHS Market-Readiness Roadmap**
- **Prioritised Technical Roadmap**
- **Technical & Regulatory Risk Register**
- **Recommended Delivery Plan**
- **Indicative Implementation Budget**

The MHRA / NHS Market-Readiness Roadmap will clearly identify:

- what needs to happen;
- why it needs to happen;
- the recommended sequence;
- dependencies;
- responsible parties;
- which work can be delivered internally;
- which work requires Keza Studio;
- which activities require specialist regulatory or clinical expertise;
- and indicative implementation effort.

Phase 1 Deliverables

The **£7,500 Phase 1 fixed fee** covers regulatory scoping, readiness assessment, gap analysis and roadmap development as described above.

The purpose of Phase 1 is to determine the appropriate regulatory direction and give SureReach Ltd a clear understanding of the work required.

It does **not** include delivery of an end-to-end Class IIa or Class IIb medical-device certification or conformity-assessment programme.

Where required, the following would be separately scoped:

- Full medical-device technical documentation programme
- Class IIa / Class IIb conformity assessment
- Approved Body engagement and fees
- MHRA fees
- Formal regulatory/legal opinions
- Implementation and certification of an ISO 13485 Quality Management System
- Full clinical evaluation programmes
- Clinical investigations
- UK Responsible Person services
- Formal medical-device registration or regulatory submissions
- Specialist regulatory consultancy
- Independent clinical-safety services
- Specialist testing or certification

Where these activities are required, Keza Studio can help SureReach Ltd **coordinate the programme and technical workstreams**, working alongside appropriately qualified regulatory, clinical, quality and conformity-assessment specialists.

Phase 2 – Fractional CTO / UK Technical Lead

Following completion of the assessment, Keza Studio will provide ongoing strategic technology leadership for SureReach Ltd's UK operations.

This service is designed to complement and coordinate your existing development team rather than replace it.

Our role is to provide experienced technology leadership, ensure delivery aligns with UK healthcare expectations and establish the engineering governance required as the business grows.

Technology Strategy

We will:

- Own and maintain the UK technology roadmap.
- Define technical strategy.
- Review architecture decisions.
- Ensure scalability.
- Support product planning.
- Guide technology investment decisions.
- Balance commercial priorities with technical delivery.
- Coordinate technical priorities arising from UK healthcare and regulatory requirements.
- Ensure that regulatory considerations are incorporated into product and technology decisions where applicable.

Engineering Leadership

We will work closely with SureReach Ltd's existing engineering team by:

- Coordinating development activities.
- Defining sprint priorities.
- Reviewing technical designs.
- Conducting architecture reviews.
- Supporting code-quality initiatives.
- Managing technical risks.
- Providing technical mentoring where appropriate.
- Establishing engineering standards.
- Improving documentation.
- Coordinating remediation work.
- Acting as the technical bridge between management and engineering.

This enables SureReach Ltd's existing developers to remain focused on delivery while benefiting from experienced UK technical leadership.

DevOps & Platform Engineering

Keza Studio will help establish and continuously improve a modern engineering delivery capability, including:

- CI/CD pipeline implementation and optimisation
- Automated testing strategy
- Release governance
- Infrastructure as Code
- Environment management
- Cloud architecture optimisation
- Platform monitoring and alerting
- Operational resilience
- High-availability planning
- Incident-management processes
- Release traceability
- Rollback processes
- Production-change governance

The goal is to create an engineering platform capable of supporting rapid product evolution while maintaining the reliability, control and traceability expected within healthcare environments.

UK Healthcare Technology Leadership

We will provide ongoing guidance across:

- NHS digital and technology standards
- NHS procurement readiness
- Clinical-safety processes
- DCB0129
- DSP Toolkit readiness
- Cyber Essentials Plus preparation
- Information governance
- Healthcare interoperability
- Security governance
- MHRA / SaMD regulatory roadmap coordination where applicable

Regulatory Delivery Coordination

Where Phase 1 identifies an applicable medical-device pathway, the Fractional CTO role can coordinate the **technology workstreams required to support that pathway**.

Keza Studio will not act as an Approved Body or replace specialist regulatory, quality or clinical-safety professionals.

Our role will be to ensure the engineering organisation can actually deliver the technical evidence and controls required by the agreed regulatory strategy.

This can include:

- Translating regulatory requirements into engineering work packages.
- Coordinating technical contributions to medical-device technical documentation.
- Establishing requirements traceability.
- Strengthening software design documentation.
- Establishing appropriate design and change controls.
- Improving testing and validation evidence.
- Establishing release evidence and version traceability.
- Coordinating risk-management activities with engineering.
- Improving cybersecurity processes.
- Establishing technical processes supporting post-market monitoring.
- Coordinating implementation planning for relevant quality-management requirements.
- Working alongside SureReach Ltd's appointed regulatory specialists.
- Working alongside the Clinical Safety Officer.
- Supporting technical preparation for MHRA registration or conformity-assessment activities led by the appropriate specialists.

This allows SureReach Ltd to have a **single UK technical leader coordinating its engineering team, NHS-readiness programme and medical-device technology workstreams**.

Stakeholder Engagement

Keza Studio will act as SureReach Ltd's UK technical representative by:

- Attending customer meetings.
- Supporting NHS engagements.
- Working alongside implementation partners.
- Supporting procurement activities.
- Providing technical input into bids and proposals.
- Representing the technology function during commercial discussions.

Product & Technology Governance

We will establish governance processes covering:

- Technical decision-making
- Risk management
- Architecture governance
- Change control
- Technical reporting
- Engineering KPIs
- Delivery planning
- Roadmap management
- Release governance
- Regulatory-impact assessment for material product changes where applicable

Monthly reporting will provide executive visibility of technology progress, risks, regulatory dependencies and priorities.

Benefits to SureReach Ltd

This engagement provides SureReach Ltd with:

- Experienced UK technology leadership.
- A trusted strategic technology partner.
- Independent architectural oversight.
- Better utilisation of the existing development team.
- Improved engineering governance.
- Faster UK market readiness.
- Robust deployment and release processes.

- Reduced delivery risk.
- Improved software quality.
- Greater confidence when engaging NHS organisations.
- Early identification of MHRA / medical-device obligations before they become late-stage delivery blockers.
- A clear separation between NHS, clinical-safety and medical-device requirements.
- A structured path from the current platform toward UK market readiness.
- A technical leader capable of coordinating SureReach Ltd's existing developers with UK regulatory, clinical and commercial stakeholders.

Commercial Proposal

Phase 1

UK Technical & Digital Health Readiness Assessment

Duration: **4-6 weeks**
Fixed Fee: **£7,500**

Includes the workshops, assessments, documentation and executive reporting described within the Phase 1 scope, including:

- technical architecture assessment;
- engineering assessment;
- security assessment;
- deployment and DevOps assessment;
- UK healthcare-readiness assessment;
- initial MHRA / SaMD regulatory-readiness assessment;
- intended-purpose work;
- initial qualification/classification analysis;
- regulatory documentation gap analysis;
- clinical-safety / regulatory evidence mapping;
- prioritised roadmap;
- risk register;
- recommended delivery plan;
- and indicative implementation budget.

Exclusions / Separately Scoped Activities

The Phase 1 fixed fee does not include:

- Formal medical-device certification or conformity assessment
- Delivery of a complete Class IIa / Class IIb certification programme
- Approved Body fees
- MHRA fees
- Formal legal opinions

- ISO 13485 certification
- Full implementation of a Quality Management System
- Full clinical evaluation or clinical-investigation programmes
- UK Responsible Person services
- Formal regulatory submissions
- Formal MHRA registration
- Specialist independent clinical-safety services

Where these become necessary, Keza Studio will identify them during Phase 1 and provide recommendations regarding the appropriate specialist resources and next steps.

Phase 2

Fractional CTO / UK Technical Lead

Recommended engagement: **2 days per week**

Typical allocation:

- Technology leadership
- Engineering coordination
- Architecture governance
- DevOps and deployment governance
- Stakeholder engagement
- Technical reporting
- UK healthcare technology leadership
- Regulatory delivery coordination where applicable

Monthly Fee: **£800 per month**

The Fractional CTO engagement will be reviewed periodically with SureReach Ltd to ensure the level of support remains appropriate as the UK operation develops.

Additional Consultancy

Specialist consultancy outside the agreed engagement may be provided on a day-rate or separately agreed project basis where required.

Depending on the findings from Phase 1, this could include engagement or coordination of specialist:

- Medical-device regulatory expertise
- Quality-management expertise
- Clinical-safety expertise

- Clinical-evidence expertise
- Cybersecurity testing
- Penetration testing
- Accessibility testing
- Interoperability expertise
- Approved Body / conformity-assessment support

Any additional work will be discussed and agreed with SureReach Ltd before commencement.

Why Keza Studio?

Keza Studio combines extensive software engineering leadership with practical experience delivering secure, scalable digital solutions within regulated environments.

Our focus is not simply delivering technology, it is ensuring technology supports business growth, operational excellence and successful market adoption.

For SureReach Ltd, this means bringing together technology strategy, engineering leadership, deployment maturity, UK healthcare readiness and regulatory coordination into one coherent programme.

Rather than replacing the development capability SureReach Ltd has already established, we will help strengthen it, coordinate it and provide the UK technical leadership required to navigate the next stage of the company's growth.

By acting as SureReach Ltd's UK technology leadership partner, we will help establish the governance, engineering capability, regulatory readiness and deployment maturity required to scale confidently into the UK healthcare market.

Next Steps

Upon acceptance of this proposal, we will:

1. Confirm project scope, product boundaries and timelines.
2. Schedule stakeholder and technical workshops.
3. Conduct an intended-purpose and UK regulatory-scoping workshop.
4. Commence the Technical & Digital Health Readiness Assessment.
5. Review the platform, architecture, security, engineering and deployment capability.
6. Establish the initial MHRA / medical-device regulatory position where applicable.
7. Produce the assessment reports, MHRA/SaMD readiness outputs and strategic roadmap.
8. Present findings and priorities to SureReach Ltd leadership.
9. Agree any separately scoped specialist regulatory work required.

10. Transition into the ongoing Fractional CTO / UK Technical Lead engagement.

We look forward to supporting SureReach Ltd as a long-term strategic technology partner and helping establish a **successful, secure, scalable and appropriately governed presence within the UK healthcare sector**.