Clerky – First Draft Business Case

Introducing Clerky: The AI platform making healthcare safer, smarter, scalable.

Clerky is an AI-powered clinical platform that helps clinicians deliver safer, more consistent care by checking documentation against best-practice medical guidelines in real time. It ensures every care plan is evidence-based, compliant, and clearly recorded – supporting clinicians, strengthening governance, and driving measurable improvements in quality, consistency and efficiency across health systems.

Developed by an NHS Obstetrics and Gynaecology Consultant, supported by the NHS Clinical Entrepreneur Programme, Clerky addresses one of healthcare's biggest challenges: bridging the gap between best practice and real-world delivery.

> "I built Clerky because I need it." *– Dr Ian Nouvel, Founder and CEO, Clerky*
> **NHS Obstetrics and Gynaecology Consultant**

The Elevator Pitch

What if a doctor could, at the press of a button, check whether a patient's care plan was truly the right one?

Clerky empowers clinicians to achieve excellence in every consultation, raising the standard of care and helping them deliver their best every time. Perfect care every time might be impossible – after all, every patient is unique – but with **Clerky**, clinicians can get much closer.

Clerky is an AI-powered platform that instantly checks whether all the key questions have been asked, investigations ordered, and options discussed – by seamlessly referencing the most relevant medical guidelines.

Right now, medical guidelines are notoriously hard to find, read, and apply in real time. Clerky solves that by making best-practice guidelines, as chosen by the user, instantly accessible, improving both safety and consistency of care – while automatically updating clinical documentation.

We've already built a working prototype, clerkyAI.health, and filed a patent. The next steps are regulatory approval, UI optimisation, and clinical pilots.

With the right investment and team, Clerky has the potential to transform clinical decision-making across every specialty – and become a global healthcare standard.

The Why – The Problem, Market Gap, and Context

We need to do better. Most doctors recognise the gap between the care they aspire to deliver and the care they can deliver in reality. That gap causes avoidable harm – and clinicians, providers and health systems are urgently searching for ways to bridge it.

Short on time, resources and staff, doctors face immense internal pressures – exhaustion and burnout – and external ones from patients, governance bodies, insurers and courts.

The result?

➢ Between 8% and 12% of NHS patients experience preventable harm, costing £2.1 billion per year in direct care costs (BMJ Quality & Safety, 2022).
➢ The NHS also faces an estimated £58 billion in outstanding negligence liabilities (NHS Resolution Annual Report, 2025).

In 2022, the NHS embraced the concept of *Get It Right First Time* (GIRFT). **Clerky** is a fast, reliable and intelligent way to check that we're *getting it GIRFT*.

Clerky is an **AI-enhanced Clinical Decision Support System (CDSS)** that helps clinicians optimize each encounter. Its scope extends far beyond single consultations – it can review care plans across an entire system, spotting trends and risks before they escalate, shifting healthcare from reactive to preventative.

Competitors

Current market-leading CDSS platforms – Epic, Oracle Cerner and UpToDate – primarily provide either narrow, rule-based alerts or reference search tools. None currently combine **real-time documentation feedback, guideline adherence analysis, and automatic audit readiness** within a single workflow.

In a high-pressure, low-resource clinical environment, this gap leads to missed safety steps, inconsistent record keeping, and increased medico-legal exposure.

The market is evolving rapidly. Generative AI is being integrated into Electronic Health Records (EHRs) – for example, Epic's GPT-4 integration and Oracle's voice-enabled "Agentic AI" – and standalone AI tools are entering clinical practice. Yet most still focus on single-modality or administrative functions such as note generation, imaging triage or predictive analytics.

The closest competitors are **iatroX**, **Dyna AI**, and **UpToDate Expert AI**:

- *iatroX* provides CDSS via chat-based guideline referencing – yet its outputs are declarative and reasoning opaque.

- *Dyna AI* and *UpToDate Expert AI* offer AI-generated answers to clinical questions – but their reasoning remains opaque and their interaction is detached from the clinician's documentation workflow.

There remains a clear gap for an AI tool that **actively checks clinical documentation against evidence-based guidance in real time**, supporting clinicians in aligning care with national standards.

Clerky fills that gap – a trust-preserving, clinician-supporting AI built around safety, auditability and regulatory compliance.

The What – Clerky's Solution

Clerky is an AI-powered clinical platform that reviews *care as written* – the clinician's own consultation notes – against the most relevant medical guidelines.

The user (or their department) selects which guidelines to apply, creating a personalised library of best practice so they're always *GIRFT* – drawing from international, national, local and departmental standards.

Clerky identifies missing documentation, cross-references relevant recommendations, and provides evidence-backed suggestions to improve completeness, compliance and safety.

Core Features

- ➢ **Real-time guideline adherence scoring and feedback**
- ➢ **Automatic generation of audit-ready documentation**
- ➢ **Evidence citation for every recommendation**
- ➢ **Intelligent anonymisation to protect patient data**

➢ **Multi-model AI pipeline** – (Mistral, Anthropic, OpenAI, DeepSeek,and Gemini – to balance accuracy, cost and performance)

In short, Clerky doesn't replace the clinician – it supports them. It acts as an always-on, evidence-based assistant that ensures every care decision is justified, traceable and aligned with clinical governance expectations.

The Who – Target Market and Evidence of Demand

The Who – Users and Market Need

Primary users: Clinicians. While doctors are likely to be the most impactful users, we anticipate that allied health professionals—including midwives, nurses, physiotherapists, and others increasingly practising autonomously—will also benefit greatly. Clerky empowers all clinicians to deliver faster, more reliable, and defensible care through accurate, evidence-based documentation.

Secondary users: Clinical governance leads, quality improvement teams, and medico-legal bodies who require consistent audit trails and safety assurance.

The NHS continues to face critical challenges in documentation quality, litigation costs and workforce efficiency.

- **87% of clinicians** report that easier access to guidelines at the point of care would improve adherence.

- There are **over 100,000 NHS vacancies**, and **one in three doctors** report burnout. Tools that reduce cognitive load and documentation time are no longer optional – they're essential.

- Audit backlogs and retrospective reviews consume **thousands of clinician hours** every year.

Clerky directly addresses these pain points by embedding guidance, quality assurance and audit functionality seamlessly into everyday documentation workflows.

Where to start - The Case for Maternity Care

If there's one NHS specialty that truly needs **Clerky**, it's maternity care. Here, it can support safer decisions, clearer documentation and better outcomes for mothers and babies.

> "We spend more on the cost of harm, when we could be spending more on prevention." – _James Titcombe,_ _bereaved father and patient safety campaigner, Baby Lifeline Charity_

In 2022–23, the NHS spent approximately **£2.6 billion** on clinical negligence claims.[1]
Although **obstetrics** accounts for only **12.8%** of all claims, it represents **56.7%** of the total value of payouts.[2]

Repeated investigations into failures of maternity care have blighted the NHS – _Ockenden, East Kent, Morecambe Bay, Nottingham_ – and now a new **national inquiry** led by **Baroness Amos** is examining 14 further hospital trusts.

As Bill Kirkup, author of the _East Kent Report_, warned:

> "It is too late to pretend that this is just another one-off, isolated failure. If we do not begin to tackle this differently, there will be more."

Our early engagement with **clinical safety leads** and **NHS Clinical Entrepreneur Programme** mentors has confirmed strong interest in a pilot for **maternity** – an environment where real-time documentation accuracy is both high-impact and measurable.

Maternity is the perfect test bed for Clerky's capabilities: it involves high volumes, time-sensitive decisions, and well-defined national standards such as _Saving Babies' Lives_ and _Ockenden_ recommendations. A pilot here would generate quantifiable improvements in documentation completeness, safety compliance and governance efficiency – creating an evidence base for broader rollout across other NHS specialties.

Clerky's modular design naturally supports expansion across hospitals and specialties. Each individual clinician or team can tailor the platform by selecting the specific guidelines they wish to apply, creating a personalised library of best practice. Following a successful roll-out, we anticipate rapid adoption in other

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[1] https://njslaw.co.uk/blog/nhs-spends-double-the-amount-on-maternity-payouts
[2] NHS Resolution, 2025

high-risk areas such as Emergency Medicine, as well as high-throughput settings like General Practice, where efficiency and guideline adherence are equally critical.

The How – Development, Regulation, and Implementation Plan

We have held **preliminary discussions** with the software development team at **Cambridge-based EG Technology** to scope potential collaboration – exploring costs, timelines and milestones for taking Clerky from prototype to pilot and beyond.

These discussions have not yet resulted in a formal agreement but have informed a clear and achievable development pathway.

Development Roadmap

Phase	Objective	Timeline	Estimated Cost
Phase 1	Build pilotable NHS-ready prototype with FHIR integration via NHS Developer Sandbox . Develop MHRA-compliant Software as Medical Device (SaMD) version (Class IIa) following ISO 62304 processes and UKCA readiness.	4–6 months	£300–600k
Phase 2	Pilot: undertake staged pilot assessment of use in NHS antenatal clinic and triage maternity settings with partner organization(s)	+6 months	—
Phase 3	Analyse results, publish, build marketing strategy, explore other markets incl overseas	+3 months	

Technical and Regulatory Foundations

The prototype will be developed and validated within the **NHS Developer Sandbox**, demonstrating **FHIR-compliant** data handling and interoperability.

ISO 62304 (software development guidelines) will be embedded from inception to streamline future SaMD certification.

A **ISO 13485** quality management system, **DCB 0129/0160 safety case**, and **Data Protection Impact Assessment (DPIA)** will be completed prior to piloting.

Pilot and Scaling Plan

The initial pilot, in **NHS obstetric clinics and maternity triage units**, will assess real-time AI guideline feedback and documentation improvements over an **8–12 week** period.
Following successful validation, **Clerky** will scale through **NHS innovation networks** to reach additional trusts.

Pilot results will be prepared for **peer-reviewed publication**, while a targeted **marketing and adoption strategy** will be developed. This will explore multiple entry routes into clinical use – from single-user access and **Royal College endorsement**, to departmental adoption, wider specialty pilots, and eventual **international expansion**.

The How – Business Model and Revenue Strategy

Initial customers are likely to be individual clinicians – doctors who want to improve the quality, safety and efficiency of their own care.

The long-term strategy is to scale through **medical departments**, then **hospitals**, **trusts**, **regions**, and eventually the **NHS itself**.

Simultaneously, Clerky can be licensed to other **national or international** healthcare systems and regulatory bodies.

Commercial Model

Clerky will operate as a **B2B SaaS product**, licensed to individuals, NHS trusts, healthcare organisations and insurers.
Pricing will follow a **tiered subscription model** aligned with deployment size and complexity:

- **Individual licence** – potentially with a freemium model (e.g. first week or first 10 uses free)

- **Small-department pilot** – such as an obstetrics & gynecology unit
- **Full hospital trust deployment**
- **Multi-trust or regional licence** – enterprise agreements based on user volume

Future Revenue Streams

- **Analytics dashboards** for clinical governance and quality teams
- **Training and education modules** for trusts, Royal Colleges and medical schools
- **Insurer and medico-legal partnerships** for risk scoring and mitigation

This model prioritises **predictable annual revenue**, **high margins**, and **low variable costs**, supported by Clerky's **multi-provider AI cost optimisation pipeline**.

Financials – Early Projections and Market Potential

The **UK Clinical Decision Support System (CDSS)** market is valued at approximately **£500 million in 2025**, with a projected **9–10% compound annual growth rate (CAGR)**. Globally, the market is expected to reach **$3.9 billion by 2030**[3].

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[3] 🎬 **Global Market Size**
The global *Clinical Decision Support Systems (CDSS)* market was valued at **USD 2.46 billion in 2025** and is projected to reach **USD 3.89 billion by 2030**, growing at a **compound annual growth rate (CAGR) of 9.6 %**.
🔗 MarketsandMarkets – Clinical Decision Support Systems Market Report
🎬 **UK Market Projection**
The UK *Clinical Decision Support Systems* market is expected to reach **USD 634.9 million by 2030**, with a **CAGR of around 10 % (2025–2030)**, reflecting strong adoption within NHS digital transformation programmes.
🔗 Grand View Research – UK Clinical Decision Support Systems Market Outlook
🎬 **Alternative Global Estimate (Higher Forecast Range)**
Grand View Research also reports that the global CDSS market could reach **USD 10.71 billion by 2030**, up from **USD 5.79 billion in 2024**, at a **CAGR of 11.0 %**.
🔗 Grand View Research – Global Clinical Decision Support Systems Market Analysis (2024–2030)

The **NHS digital transformation agenda** prioritises AI solutions that enhance safety and productivity – aligning directly with **Clerky's** value proposition[4].

Revenue Projections

- **Year 1:** 5–10 pilot or early adopter sites → ~£200k

- **Year 2:** 20+ sites → ~£1 million

- **Year 3:** 50+ sites → ~£2–3 million annual recurring revenue (ARR)

Funding Requirements

- **Short term:** £250k SEIS/EIS round to complete development and execute pilot

- **Medium term:** £1 million seed round to achieve **UKCA certification** and early NHS scaling

- **Long term: Series A (£3–5 million)** for national expansion and international adaptation

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Risks & Mitigations

- **AI accuracy and hallucination** – mitigated through **model cross-checking**, **limited output scope**, and **human-in-loop validation** to ensure reliability

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[4] "Digital productivity means working smarter, not harder. Our Digital Productivity programme aims to accelerate the adoption of evidence-based digital tools to improve productivity across the NHS … and lower costs, reduce waste, and increase patient and staff satisfaction." NHS Transformation Directorate

Also, the NHS's **Long Term Workforce Plan** explicitly states that **AI and technological innovations** will be instrumental in freeing up staff time and improving the efficiency of services. digital-transformation.hee.nhs.uk

And officially: the NHS has established the **NHS AI Lab** to accelerate "the safe adoption of artificial intelligence in health and care," indicating institutional commitment to AI-enabled transformation. NHS Transformation Directorate

and safety.

- **Data privacy** – protected by **client-side anonymisation** and **DTAC** and **GDPR-compliant** cloud hosting.

- **Regulatory delay** – reduced by **early MHRA engagement**, **ISO 13485 readiness**, and proactive **SaMD classification planning**.

- **Clinician adoption** – supported through **co-design with end-users**, **NHS Clinical Entrepreneur Programme endorsement**, and evidence of **demonstrable time savings**.

- **Financial runway** – managed via **phased fundraising**, **lean operational costs**, and **scalable cloud infrastructure**.

Overall risk level: *Moderate and well controlled through early regulatory planning, clinician co-design, and proactive governance alignment.*

Next Steps & Investment

Clerky is now ready to move from prototype to pilot.
The next 12 months will focus on delivering an NHS-ready, FHIR-integrated version of the platform, completing regulatory preparation, and running a maternity triage pilot to demonstrate measurable safety and efficiency gains.

*We are seeking **£250 SEIS/EIS investment** to:*

- Finalise the pilotable prototype and complete NHS Developer Sandbox validation

- Conduct the initial **8–12 week pilot** in maternity triage and antenatal clinic settings

- Prepare MHRA submission materials and establish ISO 13485 quality management

- Strengthen the core team and engage pilot partners

This will position Clerky for a **£1 million seed round** in 2026 to achieve **UKCA certification**, early NHS adoption, and publication of clinical and economic impact data.

Beyond the UK, Clerky's model has clear international potential wherever healthcare systems seek safer, more efficient, evidence-based care.

We are now inviting conversations with investors, NHS innovation leads, and clinical partners who share our vision of using AI to make best-practice medicine truly achievable – every time, for every patient.

> **"Our health service is being held back by creaking, outdated technology … It is time for an upgrade."** Wes Streeting, Secretary of State for Health and Social Care, Liverpool, 13 June 2024.

Dr Ian Nouvel
Founder & CEO, Clerky
Clinician–technologist with decades of frontline experience in medicine, coding and quantitative finance – building AI tools that make best-practice care scalable, reliable and safe.

Hannah Nouvel
Co-Founder & Head of Strategy, Clerky
Marketing professional skilled in storytelling, networking and partnership development – building Clerky's profile and relationships across healthcare and innovation networks.

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