# Clerky – Full Business Model (October 2025)

## The Why – The Problem, Market Gap, and Context

Healthcare professionals are under increasing pressure to deliver safe, efficient, and guideline-compliant care while navigating overwhelming documentation demands. Current Clinical Decision Support Systems (CDSS) such as Epic, Oracle Cerner, or UpToDate primarily provide either narrow rule-based alerts or reference search tools. None combine real-time documentation feedback, guideline adherence analysis, and automatic audit readiness within the same workflow. This leads to missed safety steps, inconsistent record keeping, and medico-legal exposure.

The market is evolving rapidly: generative AI is being embedded in EHRs (e.g. Epic’s GPT-4 integration, Oracle’s voice-enabled ‘Agentic AI’), and standalone AI tools are entering clinical practice. However, most still focus on administrative or single-modality functions—note generation, imaging triage, or predictive analytics. There remains a significant gap for an AI tool that actively checks documentation against evidence-based guidance in real time and assists clinicians in aligning care with national standards. This is where Clerky fits: as a trust-preserving, clinician-supporting AI built around safety, auditability, and regulatory compliance.

## The What – The Solution

Clerky is an AI-powered clinical co-pilot that reviews consultation notes and transcripts against national medical guidelines (e.g. NICE, RCOG, BJOG, and specialty colleges). It identifies missing documentation, cross-references relevant recommendations, and provides evidence-backed suggestions to improve completeness and compliance.

Core features include:  
• Real-time guideline adherence scoring and feedback.  
• Automatic generation of audit-ready documentation.  
• Guideline citation for every recommendation.  
• Intelligent anonymisation to protect patient data.  
• Multi-model AI pipeline (DeepSeek → Mistral → Anthropic → OpenAI → Gemini) for cost-efficient accuracy.  
• FHIR-based interoperability with NHS systems to ensure scalable deployment.

In short, Clerky doesn’t replace the clinician—it supports them. It acts as an always-on, evidence-based assistant that ensures care decisions are properly justified and recorded in line with clinical governance expectations.

## The Who – Target Market and Evidence of Demand

Clerky’s primary users are clinicians—doctors, midwives, and nurse practitioners—who want faster, more reliable, and defensible documentation. Secondary users include governance leads, quality improvement teams, and medico-legal bodies who need consistent audit trails and safety assurance.

The NHS faces ongoing 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[[1]](#footnote-1). Audit backlogs and retrospective reviews waste thousands of clinician hours annually. Clerky directly addresses these pain points by embedding guidance and audit tools into everyday documentation workflows.

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

## The How – Development, Regulation, and Implementation Plan

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| Phase | Objective | Timeline | Estimated Cost |
| Phase 1 | Build pilotable NHS-ready prototype with FHIR integration via NHS Developer Sandbox (documentation support only, non-SaMD). Develop MHRA-compliant 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 |  |

The prototype will be developed and validated within the NHS Developer Sandbox, demonstrating FHIR-compliant data handling and interoperability. ISO 62304 principles will be adopted from inception to streamline future SaMD certification. A light ISO 13485 QMS, DCB 0129/0160 safety case, and Data Protection Impact Assessment will be completed prior to pilot.

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

Subsequently, the pilot validation will be submitted for peer-reviewed journal publications and a marketing strategy developed around the possible entry-points into clinical use (single-user, Royal College endorsement, departmental adoption, widened use-case pilots within other specialties and explore options in other markets.

## The How – Business Model and Revenue Strategy

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 the size and complexity of deployment:

Individual licence – possibly with freemium approach (first week/month free, first 10 uses free etc…)

Small department pilot (e.g. maternity triage)

Full hospital trust deployment

Multi-trust or regional licence: enterprise agreement based on user volume.

Future revenue streams include:  
• Analytics dashboards for governance teams.  
• Training and education modules for trusts / Royal Colleges / medical schools.  
• Insurer and medico-legal risk scoring partnerships.  
The model prioritises predictable annual revenue, high margins, and low variable costs due to Clerky’s multi-provider AI cost optimization.

## Financials – Early Projections and Market Potential

UK CDSS market value (2025): approx. £500 million, growing at 9–10% CAGR. Global market projected at $3.9 billion by 2030[[2]](#footnote-2).

The NHS digital transformation agenda prioritises AI that improves safety and productivity, aligning directly with Clerky’s value proposition[[3]](#footnote-3).

Revenue projections:  
• Year 1: 5–10 sites → ~£200k.  
• Year 2: 20+ sites → ~£1M.  
• Year 3: 50+ sites → £2–3M ARR.

Funding requirements:  
• Short-term: £250k SEIS/EIS round for development and pilot execution.  
• Medium-term: £1M seed round to achieve UKCA certification and early NHS scaling.  
• Long-term: Series A (£3–5M) for national expansion and international adaptation.

## Risks & Mitigations

• AI accuracy and hallucination – mitigated via model cross-checking, limited output scope, and human-in-loop validation.  
• Data privacy – ensured through client-side anonymisation and DTAC & GDPR-compliant hosting.  
• Regulatory delay – mitigated by early MHRA consultation and ISO 13485 readiness.  
• Clinician adoption – addressed via co-design, NHS Clinical Entrepreneur Programme endorsement, and demonstrable time savings.  
• Financial runway – controlled through phased fundraising and lean cloud infrastructure.

1. “Of several factors that might improve awareness of and adherence to clinical practice guidelines, **access to relevant guidelines at the point of care (in EMR)** was most highly rated — **87 % of physicians** responding (45 % “agree” + 42 % “strongly agree”) selected that option.  
   🔗 > Qumseya, B. et al., *Barriers to Clinical Practice Guideline Implementation Among Physicians: A Physician Survey*, International Journal of General Medicine, 2019. [tandfonline.com](https://www.tandfonline.com/doi/full/10.2147/IJGM.S333501?utm_source=chatgpt.com) [↑](#footnote-ref-1)
2.  **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](https://www.marketsandmarkets.com/Market-Reports/clinical-decision-support-systems-market-18085342.html?utm_source=chatgpt.com)

    **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](https://www.grandviewresearch.com/horizon/outlook/clinical-decision-support-systems-market/uk?utm_source=chatgpt.com)

    **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)](https://www.grandviewresearch.com/industry-analysis/clinical-decision-support-system-market?utm_source=chatgpt.com) [↑](#footnote-ref-2)
3. “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](https://transform.england.nhs.uk/key-tools-and-info/digital-productivity/?utm_source=chatgpt.com)

   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](https://digital-transformation.hee.nhs.uk/news/nhs-long-term-workforce-plan-puts-digital-at-the-forefront?utm_source=chatgpt.com)

   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](https://transform.england.nhs.uk/ai-lab/?utm_source=chatgpt.com) [↑](#footnote-ref-3)