Business Case

Executive Summary:

clerky is an innovative AI-driven platform designed to revolutionize clinical consultations in healthcare settings. Developed by a practicing NHS obstetrician & gynaecologist, the platform addresses critical challenges in real-time guideline adherence and clinical documentation. By leveraging advanced AI technology, *clerky* enables healthcare professionals to focus more on patient care while reducing documentation burden and mitigating negligence risks.

Aim and Project Definition:

clerky's mission is to transform clinical practice by combining AI-powered documentation with intelligent decision support, enabling healthcare professionals to maximize their time with patients. Our working prototype demonstrates core capabilities including real-time consultation transcription, automated clinical issue identification, guideline integration, and EHR-compatible note generation.

The next development phase will focus on optimizing our AI engine to deliver rapid, reliable clinical decision support while maintaining the highest standards of accuracy and safety. Key deliverables encompass:

- Enhanced operational prototype
- Expanded clinical workflow algorithms
- Seamless EHR integration

Given the NHS's current operational pressures, *clerky* would hope to devier both productivity gains and cost reduction. With obstetric negligence claims alone consuming £1.6 billion (~ 1%) of the NHS budget in 2023/24, our initial focus on maternity services presents a compelling opportunity to demonstrate significant ROI. By ensuring consistent guideline adherence, streamlining documentation, and supporting clinical decision-making, *clerky* directly addresses key drivers of negligence claims while enhancing operational efficiency

Problem Statement:

The healthcare sector is rapidly evolving towards AI integration, creating a time-sensitive opportunity for market leadership. While current competitors exist, their offerings are limited in scope:

- Medwise.ai primarily functions as a specialized medical search engine, lacking comprehensive clinical decision support
- Microsoft's Nuance, despite marketing claims about AI capabilities, remains focused on basic transcription and note generation

- No current solution offers Clerky's integrated approach to real-time clinical guidance and documentation

This first-mover advantage presents a critical but narrowing window of opportunity. The market gap will attract competition as AI technology matures, making swift execution essential to establish market leadership.

UK and EU markets present specific regulatory challenges, as Clerky will likely be classified as a higher-class medical device, likely 2a at least. However, this challenge can be strategically addressed through:

1. Leveraging the UK government's commitment to AI investment (and potential regulatory reforms which may follow)
2. Pursuing parallel development in markets with established regulatory frameworks but faster approval pathways, such as:
    - United States (FDA Digital Health Software Precertification Program)
    - Australia (TGA Digital Health Applications Framework)
    - New Zealand (Medicines and Medical Devices Safety Authority)

Advantages of *clerky*

- *Ease of use:* Web-based, reducing the barriers to use as this doesn't require installation, users can try easily and see the benefits
- *Ease of input:* agnostic regarding input (voice / type / copy-paste)
- *Bespoke:* (can be personalised to the clinician's field and trust by focusing the guidelines on particular libraries of guidance)
- *Up to date:* Rather than trying to *de novo* create algorithms from the body of medical literature, as the defunct *Babylon Health* attempted, *clerky* already identifies the appropriate clinical guideline for the scenario and provides them to the user
- *Safety:* Promotes adherence to up-to-date clinical guidelines, reducing uncertainty, adverse events and both the human and financial cost of clinical negligence.
- *Simple:* Simplifies workflows by automating routine tasks and providing interactive decision support and aiming to integrate with existing EHRs

Disadvantages/Limitations:

- Requires significant initial investment for development and user training.
- Early-stage prototype requires further validation for broader deployment.
- Regulatory compliance required

Financial Assessment to Bring to Clinical Use:

- *Likely costs:* Development, implementation and marketing costs are highly subjective and beyond my competency to estimate with any degree of confidence.
- *Potential Savings:* First to the user in both time and reduce workplace stress, overtime the productivity gains and reduce negligence costs anticipated to accrue to the health system are significant..

View on Marketing the Project: *Target Audience:* Primary users include NHS clinicians, particularly in Obstetrics & Gynaecology, with potential expansion to midwives, nurses, and HCAs/MCAs. Long-term scalability includes other medical specialties.

Market Entry Strategy:

1. Pilot implementation in high-priority clinical areas such as maternity triage.
2. Stakeholder engagement with NHS trusts and professional organizations.
3. Adoption of a tiered subscription model, including freemium options for initial use.

Strategy to Launch:

- *Phase 1:* Enhance prototype with user feedback
- *Phase 2:* Develop technological infrastructure
- *Phase 3:* Launch a fully operational platform with pilot sites

Summary: *clerky* represents a transformative solution to longstanding challenges in clinical consultations. By integrating AI-driven transcription, real-time guideline adherence, and seamless documentation, it enhances both clinician efficiency and patient outcomes. Aligned with NHS priorities such as digital transformation and sustainability, *clerky* is poised to deliver significant benefits across the healthcare ecosystem. Through strategic investment and stakeholder collaboration, this project has the potential to scale nationally, driving innovation and excellence in healthcare delivery.