ChatGPT

Clerky – Business Case and Investor Pitch (2025)

The Why (Problem, Market Gap, Competitor Summary)

Healthcare providers face intense pressure to deliver **evidence-based care** yet often lack real-time support to ensure clinical **notes and decisions adhere to guidelines**. Studies show major barriers to guideline adherence include the complexity of guideline documents and time constraints during clinical work [1]. In fact, **65% of physicians cite lack of time** as a reason for not following guidelines, and **87% say easier access to relevant guidelines at the point of care would improve adherence】[1][2]. Currently, clinicians rely on memory or manual lookup (e.g. lengthy PDF guidelines or tools like UpToDate) – a** reactive, inefficient approach **that leads to missed steps, inconsistent documentation, and avoidable errors. Quality assurance teams typically review cases *after the fact* through labor-intensive audits, meaning systemic gaps may go unnoticed until patient safety events occur. This *market gap* is clear: healthcare needs a proactive, integrated solution that** brings guideline knowledge and auditing into the clinical workflow in real time**.

Competitor Summary: Traditional clinical decision support systems (CDSS) and EHR-embedded alerts exist, but they are often limited to narrow functions (e.g. medication checks) and do not comprehensively check documentation against guidelines. Manual audits and training programs are the primary way hospitals address guideline compliance today, resulting in delayed feedback and variability in care. No major incumbent currently offers an AI-driven tool that **scores clinical documentation for guideline adherence** and gives instant feedback. Indirect competitors include generic documentation assistants (e.g. transcription services) which **lack quality-checking**, and static guideline reference apps which require users to stop and search. Clerky's innovation is to fill this gap by providing **real-time, automated guideline adherence checking and documentation coaching** – moving healthcare from **retrospective audits to point-of-care intervention**.

The What (Solution – Clerky's Capabilities)

Clerky is an AI-powered clinical assistant that ensures every clinical encounter is documented according to the latest guidelines. It analyzes consultation transcripts or written notes and compares them against a comprehensive database of medical guidelines, then provides **instant feedback and suggestions** to the clinician [3]. In practical terms, Clerky functions as a co-pilot during or after a patient encounter, highlighting omissions or deviations and helping clinicians document thoroughly and correctly. Key features and innovations include:

- **Guideline Adherence Scoring:** Clerky can **audit and "score" each clinical note for compliance** with relevant guidelines. It automatically checks the content of a note or transcript against guideline recommendations (e.g. NICE, RCOG) and produces a compliance score or percentage. This score provides *objective, immediate feedback* to the clinician on how well the documentation and decisions align with evidence-based best practices. A high score indicates strong adherence, while a lower score flags gaps. Behind the scenes, Clerky's audit system parses guideline criteria (drawn from the guideline database) and marks which recommended elements are present or missing [4]. This scoring mechanism underpins several benefits:
- **Instant Feedback for Clinicians:** Providers receive a real-time assessment of their note quality. For example, if a postpartum hemorrhage note misses a recommended step, Clerky alerts the

clinician and suggests adding it. This continuous feedback loop reinforces learning and improves documentation **on the spot**, rather than weeks or months later in an audit [5] [6].

- **Early Identification of Gaps for Governance:** Because each note is scored and stored (with no patient identifiers) for analysis, **quality governance teams can spot systemic gaps early**. Trends in low adherence scores (e.g. consistently missed allergy documentation or omitted risk assessments in a clinic) are visible through Clerky's reporting dashboard. This allows targeted education or process changes before minor issues compound into serious incidents [7] [8].
- **Proactive Intervention vs. Reactive Audit:** Health systems can move from retrospective audits to **proactive quality intervention**. Rather than waiting for a quarterly audit to reveal non-compliance, Clerky's live scoring flags risk in near-real-time. For instance, if a new guideline is frequently not followed, the system highlights it immediately, prompting the clinical leaders to intervene (update training, send reminders, etc.) *during* the care process instead of long after. This shifts patient safety and quality improvement efforts from after-the-fact correction to real-time prevention.

- **Longitudinal Risk Tracking:** Adherence scores are **tracked over time** at the individual clinician and team level [9]. This makes it possible to identify *outliers* or **rising risk** – e.g. a clinician whose scores have dropped might benefit from support, or a unit with consistently lower compliance can be targeted for improvement. By monitoring these metrics, hospitals can quantify improvement (e.g. guideline adherence rates rising over time [10]) and demonstrate the impact of Clerky on care quality.

- **Intelligent Guideline Matching:** Clerky maintains a **comprehensive database of medical guidelines** (e.g. NICE, BJOG, RCOG, etc.) covering multiple specialties [11] [12]. When a clinician provides input – whether by uploading a dictated transcript, typing a note, or even live-recording an encounter – the system uses natural language processing to identify the clinical context and **finds the most relevant guidelines** automatically. For example, if the case is a pregnant patient with hypertension, Clerky will surface the NICE guidelines on hypertension in pregnancy. This happens instantly and behind the scenes, sparing the clinician from manually searching through lengthy documents. The platform can even handle *multi-guideline analysis*, cross-referencing a patient scenario against several applicable guidelines at once (useful in complex cases with overlapping conditions) [13] [14]. All guideline content is kept up-to-date via an **automated GitHub synchronization** – the latest guideline PDFs are parsed and added to the database, with metadata enhancements (titles, keywords, etc.) to aid search [15] [16]. This ensures Clerky always bases its advice on current standards of care.

- **AI-Guided Recommendations:** At the core of Clerky is an **interactive recommendation system** for documentation and decision support. Upon analyzing a note, the platform generates specific **suggestions for improvements or next steps** [17]. These could include adding missing information ("Document fetal heart rate, which is recommended for this scenario"), recommending an investigation ("Consider ordering liver function tests per guideline X"), or providing clinical decision prompts ("Guideline Y suggests admitting the patient if blood pressure exceeds ___"). Suggestions are **categorized by priority** – e.g. critical omissions vs. minor enhancements – so clinicians know what to address first [17] [18]. Crucially, each recommendation comes with an **evidence link** or citation to the guideline source [18], promoting trust and transparency. This transforms guidelines from static text into actionable, bite-sized insights embedded in the workflow.

- **User-Friendly Decision Interface:** Clerky is designed to integrate smoothly into clinical workflows. The interface allows clinicians to **accept, reject, or modify** each AI suggestion with a single click [19] [20]. For instance, if a suggested phrase or action doesn't exactly fit the patient's

situation, the user can edit it or choose not to include it. Bulk actions enable quick acceptance of multiple recommendations, and any **manual modifications** the user makes are incorporated – ensuring the clinician remains in control of the final content [19] [21]. The system **tracks decisions** (what was accepted or dismissed) for both learning purposes and audit trail [19] [22]. This means over time the AI can learn which types of suggestions are frequently rejected (to refine its algorithms), and administrators have a record that clinicians did review suggestions even if they chose not to follow some (useful in case of later review).

- **Automatic Note Generation & Export:** Beyond recommendations, Clerky can **generate polished clinical documentation**. Using a transcript of the encounter (from an audio recording or speech-to-text), the AI will produce a well-structured draft of the clinical note or report [23]. This draft incorporates the clinician's own words plus any accepted recommendations, resulting in **comprehensive notes that align with guidelines**. The clinician can then copy this output into the electronic health record (EHR) or export it as needed [24]. By handling the heavy lifting of writing, Clerky saves clinicians time while improving documentation quality. Future integration with EHR systems (planned via standards like HL7 FHIR) will allow seamless insertion of these notes into patient records (see Roadmap below).

- **Technical Architecture & AI Innovation:** Clerky's architecture is built for reliability, speed, and cost-efficiency:

- *Dual Frontend:* Users can access Clerky through a web-based interface. There is a lightweight **static web app** (vanilla JS/HTML/CSS) as well as a richer **React single-page app**, both served on Firebase [25] [26]. This dual approach ensures flexibility – the static app is extremely fast and easy to deploy (great for initial pilots or low-spec environments), while the React app offers a modern UI and can evolve with more complex features. Both frontends connect to the same backend and database.
- *Cloud Backend:* The server is built in Node.js/Express and hosted on a scalable cloud service (Render.com) [27]. It exposes RESTful APIs for all major functions (finding guidelines, running analyses, generating notes, etc.) [28] [23]. User management and authentication are handled via Firebase Authentication with secure JWT tokens [29], meaning users (e.g. clinicians in a pilot) log in with vetted credentials and all data exchanges are protected.
- *AI Engine with Cost-Aware Routing:* A standout innovation is Clerky's **multi-provider AI integration**. Instead of relying on a single large language model (LLM) provider, Clerky is integrated with **five**: DeepSeek (primary), Mistral, Anthropic Claude, OpenAI GPT-3.5, and Google Gemini [30] [31]. An intelligent router selects the **most cost-effective provider** first and automatically falls back to others if needed (e.g., if the cheaper model's response is insufficient or a quota is reached) [30] [32]. This ensures both **low operating cost and high reliability**. For context, DeepSeek's cost is only ~$0.0005 per 1k tokens – orders of magnitude cheaper than typical GPT models [30] [32] – so leveraging it first keeps Clerky's per-consultation AI cost negligible. If DeepSeek or Mistral (open-source model) can handle the query, the platform delivers answers for fractions of a penny. Only when more advanced reasoning is needed does it escalate to providers like OpenAI or Gemini. All of this happens seamlessly for the end user. The system also tracks usage and costs in real time for monitoring [30]. This **cost-optimization strategy is a competitive advantage** – Clerky can scale usage without incurring prohibitive AI expenses, supporting a healthy margin in its business model.
- *PII Anonymization & Data Privacy:* Given that clinical text can contain sensitive patient information, Clerky takes privacy seriously. It employs an **advanced anonymization layer** on the frontend: before any text is sent to the AI, an algorithm (using the `@libretto/redact-pii-light` library plus custom rules) scrubs identifiable personal data [33] [31]. For example, patient names, NHS numbers, dates of birth, and other PHI are masked or replaced with placeholders. This

means the AI never sees real patient identifiers, mitigating privacy risks. The user can review and adjust the anonymization if needed via an interactive interface. All communications are encrypted, and no raw patient data is stored on the server beyond the analysis session (Clerky is designed as **HIPAA-compliant, with no personal health information persisted** [34] [35]). Additionally, the platform requires users to accept a disclaimer daily about appropriate use of AI – adding a layer of governance to its usage [34].

- *Guideline Management via GitHub:* Clerky treats clinical guidelines as version-controlled knowledge assets. All source guideline documents (e.g. PDFs from NICE) are stored and versioned in a GitHub repository integrated with the Clerky backend [36]. A synchronization routine pulls new or updated guidelines into Firestore (the database) so that the latest evidence is always available [37]. This approach brings transparency (the content and changes are trackable) and efficiency (easy to update many sites with new guidance). It's an important differentiator: unlike static CDSS databases that may lag behind, Clerky can **rapidly incorporate new guidelines or revisions**, keeping users at the cutting edge of best practice.
- *Audit Trail & Reporting:* Every analysis and user action in Clerky can be logged (without patient identifiers) to create a **comprehensive audit trail** [38]. This includes what suggestions were made and whether they were accepted or overridden, providing valuable data for quality improvement and medico-legal defensibility. Administrators can generate **compliance reports** that aggregate adherence scores across departments or time periods [8] [39]. These reports make it simple to demonstrate guideline compliance rates (e.g. for internal governance or external regulators) and measure improvements after interventions.

In summary, **Clerky transforms clinical documentation from a static, retrospective record into an interactive, real-time quality improvement process**. It ensures that what gets documented – and by extension, the care delivered – is continually benchmarked against best-practice guidelines. By giving front-line providers instant guidance and creating visibility of adherence metrics for management, Clerky closes the loop between **clinical practice, audit, and education** in a novel, AI-driven way.

The Who (Target Users and Unmet Needs)

Clerky is designed for a range of users across the healthcare system, each with specific needs that the platform addresses:

- **Front-line Clinicians (Doctors, Nurses, Mid-level Practitioners):** The primary users are healthcare professionals who document patient encounters – e.g. physicians (GPs, specialists, hospital doctors), nurse practitioners, midwives, physician associates. Their unmet need is **efficient access to decision support** and **documentation quality assurance** *during* their busy workflow. Currently, a doctor might have to recall or find guidelines on the fly, which is error-prone under time pressure [1]. Clerky directly serves this need by providing relevant guidance and ensuring nothing critical is missed, all in real time. For clinicians, this means **fewer medical errors, time saved, and increased confidence** that they are following the latest protocols [40]. It's like having a second pair of eyes (with encyclopedic knowledge) reviewing their notes instantly.

- **Trainees and Students:** Medical residents, junior doctors, and students (including nursing students) benefit enormously from Clerky as a **learning and training tool** [41] [42]. These users are still building their knowledge and may not be fully familiar with all guidelines or best practices. Clerky provides them with on-the-spot teaching moments – every suggestion comes with rationale from guidelines, helping them learn *why* a certain detail or action matters. The **progress tracking** feature (improvement in their adherence scores over time) lets trainees see their learning curve [9]. In essence, Clerky accelerates experiential learning by reinforcing

guideline-based practice in each case, addressing the unmet need for continuous feedback in clinical education.

- **Healthcare Quality and Governance Teams:** This includes clinical audit committees, risk managers, and department leads responsible for quality assurance. Their challenge is that **identifying documentation or care gaps is like finding needles in haystacks** – typically done via periodic manual chart reviews or after a bad outcome has occurred. Clerky directly empowers this group by providing **aggregate data and analytics on guideline adherence**. Quality officers can run batch analyses on numerous past cases to identify patterns [8], or review the dashboard of adherence scores to spot troubling trends early. The platform thus meets the need for **system-level visibility** into how well guidelines are being followed, enabling proactive quality improvement initiatives (like targeted training where adherence is low). It also provides a robust **documentation trail for audits**, reducing the burden of proof when demonstrating compliance to external regulators or during litigation review [43].

- **Healthcare Administrators and Executives:** Hospital administrators, clinic managers, and healthcare system executives have an interest in both operational efficiency and risk management. Their unmet needs revolve around reducing costs associated with poor quality (e.g. malpractice claims, readmissions) and ensuring high standards across the organization. Clerky appeals to them by **standardizing care documentation**, thus reducing variability between providers and sites. By catching issues early and reducing errors, Clerky can contribute to **risk reduction and cost savings** (fewer adverse events, improved patient outcomes) [43] [44]. Administrators also value that Clerky can help with compliance to clinical governance standards (like CQC inspections or JCI accreditation) by providing evidence of guideline adherence rates. Additionally, from an efficiency standpoint, if Clerky saves each clinician even 5-10 minutes of paperwork per encounter, at scale that translates into significant productivity gains (more patients seen, less overtime). This addresses the administrative need for better resource utilization and quality metrics.

- **Secondary Users/Influencers:**

- *Medical Educators:* Faculty and training program directors can use Clerky in educational settings – e.g. having students run case scenarios through Clerky to see how guidelines apply [45] [46]. It serves as a simulator for evidence-based decision making.
- *IT Departments:* Health IT administrators and CIOs would be involved in deploying Clerky within an organization. Their focus is on **integration** and **security**. Clerky's cloud-based architecture with API endpoints and planned FHIR compatibility addresses the IT need for systems that can plug into existing EHRs and data pipelines. Its strong security posture (Firebase Auth, encryption, anonymization) meets IT requirements for patient data protection [38].
- *Patients:* While not direct users, patients ultimately benefit from Clerky through improved care quality and consistency. In the long run, broad use of Clerky could mean that regardless of which clinician or hospital a patient visits, the care they receive is guided by the same up-to-date standards, reducing the lottery of care. This speaks to the healthcare system's mandate for equitable, high-quality care.

By targeting these users, Clerky taps into a **broad market**: from individual clinicians (there are ~150,000 doctors in the NHS and millions globally) to entire health organizations. The platform's value resonates across multiple levels – improving daily workflow for individuals and supporting strategic quality goals for institutions. This multi-stakeholder benefit is key to driving adoption.

The How (Operational Plan, Roadmap, Regulatory Path)

Building Clerky into a successful venture requires careful execution on product development, clinical validation, and regulatory compliance. Below is an overview of **how** the team plans to operationalize and scale the solution:

Operational Plan & Go-to-Market Strategy

Pilot Launch: The immediate plan is to **pilot Clerky in an NHS hospital setting (maternity triage unit)** in collaboration with clinical champions [47]. By starting in a maternity triage context (where timely, guideline-adherent decisions are critical), Clerky can demonstrate value in a high-impact use case. The founders have identified supportive senior clinicians in this unit who will champion the trial. During the pilot, key metrics like time saved per consultation, improvement in documentation completeness, and user feedback on the AI recommendations will be gathered [48]. These data will form the basis of case studies and validation for further adoption [49] [50].

Iterative Development: The pilot is not just a test but also a chance to iterate. The plan is to use pilot feedback to refine the product (improving the UI, tweaking recommendation algorithms, expanding the guideline library if needed) in quick cycles [51]. Because Clerky's architecture supports rapid updates (guideline updates via GitHub, front-end changes via Firebase hosting), the team can push improvements between pilot rounds easily. This agile approach will ensure that by the end of the pilot the product is robust and user-approved.

Expansion via Networks: Following a successful pilot in one site, Clerky will leverage NHS innovation networks to expand. This includes working with Academic Health Science Networks (AHSNs) and programs like DigitalHealth.London to reach other NHS trusts [48]. These organizations exist to help spread proven innovations across the NHS, providing a ready pathway for introductions and scaled trials. The initial focus will be on additional maternity or obstetrics and gynecology departments (leveraging the founder's domain expertise and credibility in that field). Subsequently, expansion will target other high-value areas like acute medicine, surgery, and general practice by uploading relevant guidelines and demonstrating the cross-specialty applicability of the platform. Early adopter sites will be recruited by showcasing pilot results and emphasizing Clerky's ease of deployment (being cloud-based, there's no heavy IT install needed, just a web login and basic training).

Marketing & Awareness: On the marketing front, Clerky will start with thought leadership and leveraging the **NHS Clinical Entrepreneur Programme** platform. The founder's inclusion in that program lends credibility and offers networking opportunities across the NHS. A simple website will be set up highlighting Clerky's value proposition, along with publishing of pilot results and testimonials [52]. Social media (LinkedIn, Twitter) and healthcare innovation forums will be used to share content (e.g. "How AI can improve clinical documentation quality") to build awareness. The team plans to use cost-effective digital marketing tools (with AI assistance for content creation, per the launch plan [49]) to reach a broad audience without large expense. As the product matures, they will pursue press coverage in health IT outlets to announce major milestones (like successful pilots or partnerships).

Scaling Strategy: In terms of user growth, Clerky will likely pursue a **B2B SaaS** model (see Business Model below), meaning adoption comes via hospitals or clinics signing on. However, a key part of scaling in healthcare is building trust and evidence. Therefore, the **operational plan includes rigorous evaluation** – for instance, partnering with academic centers to publish results on Clerky's impact (such as a study showing X% improvement in guideline compliance after 6 months of use). These publications and real-world validations will be powerful tools in convincing larger health systems to come onboard.

Additionally, by the time of scaling, Clerky will seek regulatory clearance as a medical device (see Regulatory Path), which will further assure hospitals of its safety and efficacy.

To summarize the timeline:

- **Months 0–2:** Company incorporation, core team formation, and setup of basic infrastructure [53] (this stage is completed as the company is already registered and the MVP development began).
- **Months 3–5:** Complete the MVP development and secure the pilot site agreement; also apply for grants to support pilot funding [53] [51] .
- **Month 6:** Launch the NHS pilot and begin collecting data on usage and outcomes [51] .
- **Months 7–9:** Iterate on the product based on pilot feedback, and start preparing investor materials (assuming pilot results are promising, begin assembling a pitch deck and business case – essentially what we are doing now) [54] .
- **Months 10–12:** With pilot success, engage angel investors and early-stage VCs to raise seed funding; initiate formal regulatory approval process (compiling documentation for UKCA marking, etc.) [55] .
- **Months 13–18:** Use the new funds to **scale to multiple sites** (onboard several more hospitals or departments), and work through achieving the UKCA Class IIa medical device certification; expand marketing accordingly [55] .

This phased plan ensures that Clerky demonstrates value on a small scale, then uses that validation to unlock funding and regulatory clearance needed for large-scale deployment.

Product Roadmap (Development Phases)

Clerky's development is organized into clear phases, ensuring a solid foundation before adding advanced features. The roadmap is as follows:

- **Phase 1: Core Platform (Completed)** – This phase established the fundamental features needed for Clerky to function:
- Clinical transcript ingestion and analysis with PII protection in place [56] [57] .
- Advanced guideline matching engine with metadata-enhanced search (so the system can quickly fetch relevant guidelines and sections) [56] [58] .
- The interactive recommendation interface with ability to accept/reject/modify suggestions [56] [57] .
- User authentication and session management via Firebase (each user can securely log in and their sessions can be saved for later review) [56] [58] .
- Multi-provider AI integration with the cost-optimization logic (the five-provider strategy discussed earlier) [56] [59] .
- **Audit and compliance system** to check guideline adherence and log the outcomes [56] [60] .

(As of now, Phase 1 is functionally complete – an MVP exists with these features, ready for pilot use.)

- **Phase 2: Advanced Features (Currently in progress)** – This phase builds on the core with enhancements to improve user experience and performance:
- Multi-guideline simultaneous analysis: the ability to handle multiple conditions or guidelines at once was implemented (e.g., in a complex case, suggestions from multiple guidelines can be combined) [61] [62] .
- Enhanced AI models: integration of all 5 providers (DeepSeek through Gemini) is done, ensuring the AI responses are as good as possible while remaining cost-effective [61] [62] .

- **Dual interface**: both the static app and a modern React SPA are available, giving flexibility in deployment and user preference [61] [63].
- Real-time monitoring and analytics: dashboards for monitoring AI usage, costs, and system performance have been added, which is critical for scaling and maintaining service quality [61] [63].

- In progress now are tasks like mobile-responsive design improvements (so Clerky works nicely on tablets or smaller screens used on wards) [64] [65], and exploring a Progressive Web App (PWA) approach for offline or installable usage in hospitals with poor connectivity [64] [66].

- **Phase 3: Enterprise Integration (🏷 Planned)** – Once the product is validated and refined in standalone mode, the focus will shift to deeper integration and enterprise features:

- Electronic Health Record (EHR) integration via standards like **HL7 FHIR** or SMART on FHIR apps [67] [68]. This will allow Clerky to pull patient data from the EHR and write back the AI-generated notes or flags, fitting into clinicians' primary workflow seamlessly.
- Organization-level dashboards and reporting tools [67] [69]: for hospital management to track guideline adherence stats across departments, see usage metrics, etc. This might include web dashboards or periodic report generation.
- Advanced analytics and business intelligence: Phase 3 envisions using the data collected (anonymized) to provide insights, such as identifying which guidelines are most commonly triggered or where gaps persist across the system [67] [70].
- Comprehensive API and third-party integration documentation [67] [68]: to encourage other systems or partners to integrate Clerky's capabilities, for example a telehealth platform could integrate Clerky to assist their doctors during virtual consults.

- Single Sign-On (SSO) and enterprise auth features [67] [71], making it easier for hospital IT to manage user access through their existing identity providers (important for scaling to large user bases).

- **Phase 4: Advanced Intelligence (Future)** – Looking further ahead, Clerky aims to incorporate cutting-edge AI and expanded modalities:

- **Predictive analytics**: using aggregate data to perhaps predict outcomes or risk (e.g., identifying that certain documentation patterns correlate with higher risk of complications) [72] [73].
- Personalized learning for clinicians: analyzing a user's interactions to tailor what tips or education to offer (for example, if a doctor repeatedly struggles with a particular guideline area, Clerky might proactively offer a quick tutorial or update in that area) [74] [75].
- Real-time guideline updates and alerts: the system could push notifications to users when a guideline they frequently use gets updated, or even adapt suggestions on the fly as guidelines change [74] [73].
- Multi-modal support: incorporating other data types – e.g. analyzing an uploaded image (like an ultrasound or ECG) or lab results alongside text to give a more comprehensive decision support [74] [73]. This is speculative but aligns with the trajectory of AI in healthcare to handle diverse data sources.

This roadmap ensures Clerky not only addresses immediate needs but also stays ahead of the curve in the long run, evolving from a documentation assistant into a central platform for clinical guidance and analytics.

Regulatory Path & Compliance

Given Clerky's function in influencing clinical decisions and documentation, it will be treated as a **medical device software** (in regulatory terms, likely a Clinical Decision Support Software of moderate risk). The team has proactively mapped out the pathway for regulatory compliance in the UK and beyond:

- **UKCA Mark (Class IIa Medical Device):** Clerky intends to achieve UKCA marking under the UK's medical device regulations (which post-Brexit, replace CE marking in the UK). The target classification is Class IIa, appropriate for decision support tools that provide recommendations but leave final decisions to human clinicians. An action plan for this involves engaging a regulatory consultant by the time the pilot is complete, preparing documentation on the software's intended use, risk analysis, and evidence of clinical performance. The **timeline is to begin the regulatory submission around month 12** (once initial pilot data is available to support claims) [55] [76] and aim for certification by month 18. Early steps like implementing a Quality Management System (probably ISO 13485 compliant processes) will be undertaken in parallel with product development. **Clinical safety and risk mitigation features** (e.g. the disclaimer upon login, the fact that final decisions are up to the user, comprehensive logging of suggestions vs. actions) are already built-in to strengthen the safety case for regulators [34]. Achieving UKCA will validate that Clerky is safe and effective, which is not only a legal requirement for wider deployment in the NHS but also a trust signal to users.

- **Data Privacy (UK GDPR & HIPAA):** Compliance with data protection regulations is critical. In the UK, **GDPR (general data protection regulation)** and the Data Protection Act impose strict rules on handling personal data. Clerky's architecture was designed with privacy by design principles: it avoids storing personal health information and uses on-the-fly anonymization [34]. A privacy impact assessment (DPIA) will be done during the pilot to ensure all data flows are compliant. A robust consent and privacy policy has been drafted (covering how user data and any patient-related data are handled). The launch plan includes preparing these documents (NDAs, privacy policy, terms of service) early [77] [78]. For markets like the US, Clerky's approach of not retaining PHI and using encryption means it can be HIPAA compliant; further certifications like HITRUST could be pursued if needed for U.S. clients.

- **Clinical Validation:** As part of regulatory and market acceptance, Clerky will compile evidence of clinical benefit. This includes the pilot results (e.g. did using Clerky improve documentation completeness by X%? Did it help catch Y number of potential errors or omissions?). If possible, a randomized or controlled study might be conducted in later phases to scientifically validate outcomes (regulators appreciate documented evidence of safety and efficacy, even if not always mandated for Class IIa). The team's plan of capturing pilot data for case studies and possibly publishing them [49] [50] will directly feed into this validation effort.

- **International Regulatory Expansion:** While focusing on UKCA first (for the home market), the company is mindful of international markets. Achieving UKCA should streamline pursuit of a CE Mark (for the EU) if needed, since requirements are similar (though the EU has introduced specific rules for AI in medical devices that will be monitored). For the U.S., the FDA's Digital Health unit has been providing guidance on Clinical Decision Support software; Clerky might qualify for enforcement discretion if it meets criteria (i.e., recommendations that physicians can independently review). Regardless, we will ensure that Clerky can trace its content to authoritative sources (which it does by citing guidelines) – a key FDA requirement for CDS software. Having a clear **regulatory strategy** early is a mitigator for one of the business risks (regulatory approval risk) [79] [79] and is part of our operational planning from the start.

In summary, the “How” of Clerky encompasses a disciplined roll-out (pilot → iterate → scale), a strong technological roadmap, and a proactive stance on regulatory and compliance matters. This positions the company to not only build a great product but also successfully navigate the healthcare industry’s requirements to achieve widespread adoption.

Business Model and Financials

Clerky’s business model centers on **B2B software-as-a-service (SaaS)** for healthcare organizations, with future potential for broader data analytics services. Below we outline how the company will generate revenue, the costs of scaling, and financial projections:

Value Proposition to Customers: To ensure a viable business, Clerky’s offering must translate into clear value (and ROI) for its paying customers – mainly hospitals, clinics, and health systems. The value proposition is compelling: Clerky can help organizations **improve care quality and safety (reducing errors)**, which in turn can lower malpractice risk and associated costs [43]. It also can **increase efficiency**, saving clinicians time (thereby potentially enabling higher patient throughput or reduced overtime costs). By standardizing documentation, Clerky might shorten audit times or accreditation processes. These benefits can be quantified – e.g., if guideline adherence improvements lead to fewer adverse events, the cost avoidance can be substantial. The platform contributes to **cost savings from improved care pathways and risk reduction】 [43] [44]. We will use pilot data to produce an ROI calculator for prospective customers (for example, “Clerky saved an average of 10 minutes per consultation and prevented X potential adverse events in a 3-month pilot, translating to Y financial benefit”).

Revenue Model: Clerky will generate revenue through **subscription licensing**. We anticipate offering tiered subscriptions to healthcare organizations: - For small clinics or individual departments, a per-user or per-provider monthly license could be offered (e.g., £N per clinician per month for access to the platform). - For larger hospitals or trusts, an enterprise license covering unlimited users at a site or across a group of sites for an annual fee makes more sense. This could scale based on the size of the institution (number of beds or number of yearly encounters) as a proxy for usage.

In the NHS context, we might negotiate site licenses per NHS Trust or per hospital department. Given NHS budgeting, an annual license that fits under a software or IT services budget line will be pursued. We’ll ensure pricing aligns with the **value delivered** – e.g., if Clerky helps avoid even one serious incident or saves hundreds of hours of staff time, the license cost will be set significantly lower than those savings, making it a “no-brainer” purchase.

Go-to-Market and Sales: Early revenue will likely come from **paid pilots or phase-2 pilots**. After an initial free trial period, we plan to convert pilot sites into paying customers by demonstrating clear improvements. Sales in healthcare often require building relationships and proving credibility; our strategy includes leveraging our clinical champions and networks (via the Clinical Entrepreneur Programme) to get warm introductions. The **founder’s dual credibility as a clinician and technologist** helps in selling to clinical leadership, as we can speak their language and address their concerns. Over time, we might partner with larger health IT vendors or distributors (for example, if integrating with an EHR, we could co-market Clerky as an add-on module).

Scaling Revenue and Market Opportunity: The market opportunity for Clerky is significant. The global clinical decision support systems market is projected to reach **~US$3.9 billion by 2030** [80], growing at ~9–10% CAGR. This reflects a strong demand for AI-driven solutions in healthcare. Our initial target market is the UK NHS and private hospitals, but the problem Clerky addresses is universal. In the UK

alone, there are over 200 hospitals and numerous clinics that could use Clerky; capturing even a fraction of this market (say 20 hospitals at ~£50k/year each) yields £1M+ annual revenue. Expanding to the U.S. and EU, with thousands of hospitals, presents a multi-million (eventually multi-ten-million) pound revenue potential if scaled widely. Our plan is to focus on proving the model in the UK, then reach out to early adopters in other countries through connections (for instance, the founder's background includes time in New Zealand, which could facilitate a pilot in Australasia, and we have contacts in the U.S. academic circles via publications).

Cost Structure and Scalability: Clerky benefits from a **cloud-based, serverless-friendly architecture** which keeps infrastructure costs relatively low. Thanks to the AI provider strategy, our compute costs per use are extremely low [30]. For example, analyzing a typical consultation might involve processing a few thousand tokens of text; at $0.0005 per 1k tokens on our primary AI, that's negligible. Even if a more expensive model is occasionally used, the cost per case likely stays in the pennies range. This means **gross margins** on the software should be high once we are post-R&D – a hospital could run hundreds of consultations through Clerky for just a few dollars in AI costs, while paying a subscription fee that is orders of magnitude higher (covering the value provided, support, maintenance, etc.). Of course, we will incur other costs: - **R&D and Personnel:** The biggest investments will be developer salaries (to continue improving the product), clinical specialists (to curate guidelines and validate recommendations), and support staff to onboard and train users at client sites. Initially, the founders cover a lot of these roles, keeping costs lean, but scaling will require hiring. - **Regulatory and Compliance:** Gearing up for regulatory approval incurs consulting and certification fees, and maintaining compliance (e.g., annual audits for ISO 13485 or similar) will be a recurring cost. - **Infrastructure:** Hosting on Firebase/Render and using Firebase Firestore/Storage has usage-based costs, but these scale with number of users. We've built in caching and efficient data handling to minimize load. As user numbers grow into the thousands, we may need to move to a dedicated cloud infrastructure, but those costs (likely in the low thousands of pounds per month initially) are factored into pricing. - **Insurance and Legal:** As a med-tech, we'll secure appropriate liability insurance and legal counsel, which is a fixed overhead. - **Sales & Marketing:** Costs here will remain modest in early stages (leveraging free channels and networks), but as we scale, we might invest in a small sales team or attending industry conferences to sign enterprise deals.

Financial Projections: In the first year post-pilot (Year 1 of commercialization), our goal might be to sign 5-10 organizations (some on small contracts) to generate ~£200k in revenue while we refine the product. By Year 3, aiming for 50+ organization contracts including some larger hospitals or group deals, we could reach £2–3M in annual recurring revenue, assuming an average deal size in the tens of thousands. Beyond Year 3, if international expansion kicks in, growth could accelerate significantly. The **CDSS market growth trends** [80] indicate a favorable environment. We'll also monitor adjacent monetization opportunities, such as anonymized *data insights* subscription for healthcare regulators or insurers (for example, a service that aggregates de-identified adherence data across institutions to benchmark performance – something clerky could offer at scale).

Funding Needs: To achieve these projections, external funding is required (in addition to early revenues). The plan is to utilize **grants and angel investment in the short term**, followed by a venture capital backed seed round: - We have identified UK grants like the NHS AI in Health & Care Award, SBRI Healthcare, and Innovate UK Smart Grants and will apply to those [81]. If successful, these non-dilutive funds (potentially £50k–£100k or more) can support additional development and clinical evaluation. - We also aim to raise an angel round under SEIS/EIS (UK investment schemes) to leverage tax incentives for investors [81]. This could be on the order of ~£150k–£250k, giving 12+ months runway to get through pilot and early customer acquisition. - **Seed Round:** After demonstrating success in the pilot and securing a handful of paying customers, we plan to raise a seed round from specialized health tech VCs (funds mentioned include AlbionVC, Crista Galli Ventures, Seedcamp, etc.) [81] [82]. We anticipate

this seed raise to be roughly in the **£1M range (e.g. £1–1.5M)**, timed around late 2025 or early 2026 (following pilot completion) [55]. This funding will be used to hire key staff (engineers, a clinical liaison, sales), achieve regulatory clearance, and scale the platform to ~10-15 sites. According to our timeline, we target closing the seed round by Month 12 and then executing the scale-up in Months 13–18 with that capital [55] [76]. - In the long term, if needed, a Series A round would be considered once we need to expand internationally or significantly grow the team, but that would be predicated on hitting milestones with the seed money (e.g. >£1M ARR, proven outcomes improvements, UKCA in hand, etc.).

The financial plan, in essence, is to use **smart financing (mix of grants and equity)** to reach break-even on a modest scale, then fuel faster growth with VC funding when the model is proven. We are keenly aware of **sustainable revenue model development as a risk】 – to mitigate that, we are focusing early on paying for value (ensuring we can show measurable benefits to justify subscriptions) [83] [79]. Additionally, by keeping operational costs lean (via automation and AI assistance in our own workflows [84]), we stretch every pound of investment.

Risks and Mitigations

As with any healthcare innovation, Clerky faces several **risks**. Identifying these early and implementing mitigations is a core part of our strategy. Below we outline key risks in technical, clinical, and business domains, along with our plans to address them:

- **Technical Accuracy & Reliability:** There is a risk that the AI's recommendations or guideline matches might be inaccurate or contextually inappropriate (AI model errors). If Clerky provides wrong advice, it could erode user trust or even negatively impact care. **Mitigation:** We mitigate this by using **authoritative sources** only – all suggestions are linked to published guidelines (so the AI isn't inventing medical advice). We also plan rigorous testing with clinicians in the loop: during pilots, every recommendation will be reviewed by the users and any clearly incorrect ones will be fed back to refine the system. The multi-model approach helps here too – we can cross-verify outputs between models or choose a more reliable model for critical queries. Over time, **continuous learning and audit trails** [85] [86] will highlight any systematic AI errors, which we can then address (e.g. adjust a prompt or exclude certain suggestion types until improved). In production, we will likely constrain the AI to only output suggestions that can be tied to known guidelines, reducing the chance of hallucinations. Also, the system is built with **fail-safes**: if the AI encounter errors or seems uncertain, Clerky can default to a "no recommendation" rather than give a bad one.

- **System Performance & Scalability:** As user volume grows, there's a risk the system might slow down or not handle peak loads (e.g., Monday mornings when many clinicians log in). **Mitigation:** The architecture is cloud-native and stateless on the backend, allowing easy scaling (e.g. adding more server instances on Render or migrating to a larger cloud). We've implemented caching for guideline data and an efficient front-end that offloads some processing to the client side. Rate limiting and quotas are in place to prevent abuse of the AI endpoints [87]. Our monitoring dashboards track response times and usage; we will continuously optimize as needed (for example, the cost monitoring doubles as performance monitoring). Additionally, having a static front-end option means even in a downtime scenario with the main server, users could potentially still access local guideline content in a limited mode – ensuring some functionality is always available. These steps address **scalability and uptime risk】 [88] [89].

- **Data Privacy & Security:** Handling clinical text, even if anonymized, comes with privacy risks. A data breach or misuse could have legal and reputational consequences. **Mitigation:** We've built

privacy into the design: no patient identifiers leave the client browser thanks to anonymization [34], and communication is encrypted. We use **Firebase Authentication** which is a robust and industry-tested security layer for user auth [34]. Access to data in Firestore is governed by strict security rules (only the owning user or an admin service account can access certain data). We will undergo security audits and penetration testing especially before any large deployments. On the compliance side, we're ensuring **GDPR compliance** (clear user consent, data export/delete capabilities built in, which we have on our roadmap [90] [91]). Should a user request their data or a deletion, we can comply easily given our minimal data retention. These measures mitigate **privacy and security risks】 [88] [92].

- **Clinical Risk (Over-reliance or Misuse):** There's a potential clinical risk if users rely too heavily on Clerky's suggestions without applying their own judgment, or if they misunderstand a recommendation. Also, if Clerky were to encourage a action that's not appropriate for a specific patient nuance (since AI might lack full context), a patient could be harmed. **Mitigation:** We address this by **keeping the human in control** at all times. Clerky is a tool for suggestions, not autonomous decisions. The interface requires the user to actively accept or reject each recommendation, which inherently forces a moment of reflection. We explicitly warn (via the disclaimer and training) that Clinicians must verify all suggestions and that Clerky's output *does not override clinical judgment*. Over-reliance is further mitigated by the design: we provide references with each suggestion [17] [18], essentially inviting the clinician to read the authoritative source if in doubt. This transparency helps users treat Clerky as an assistant, not an oracle. In terms of liability, by obtaining regulatory approval and having disclaimers, we clarify that ultimate responsibility lies with the clinician – similar to how existing CDS tools are handled. Additionally, our internal testing includes edge cases to catch where a naive suggestion could be dangerous, and we build rules to avoid them (for example, never suggest medication changes, which often require patient-specific data like allergies that Clerky might not have – we'd limit suggestions to reminding about guideline-recommended checks or consultations rather than direct orders in such cases).

- **Clinical Adoption (Resistance to Change):** Healthcare professionals can be skeptical of new tech, especially AI. There's a risk that clinicians might not trust Clerky's advice or feel it adds to their workload (alert fatigue). **Mitigation:** We have prioritized a **user-centric design** [93] [94] and involved clinicians early (through the Clinical Entrepreneur network and pilot champions) to ensure the tool genuinely helps rather than hinders. By making the system **fast and easy to use**, and integrating into existing workflow (e.g. not requiring duplicate data entry – Clerky can take the same note they would write and improve it), we minimize the friction. The fact that Clerky can save time (by drafting notes) is a selling point to get buy-in. To build trust, we will highlight that suggestions come from **trusted guidelines, not black-box AI** – effectively Clerky is an efficient messenger of their own professional guidelines. During the pilot, we'll collect testimonials from clinicians who found it helpful to use in order to convince others. Also, by starting with younger, more tech-friendly clinicians (like trainees in the pilot), we create bottom-up advocacy. If some older clinicians resist initially, having department heads or early adopters champion the success will help convert them. Essentially, our strategy is to show that Clerky *reduces* burden (less typing, less worrying if you forgot something) rather than adding any.

- **Regulatory and Legal Risks:** There is always a risk that evolving regulations could impose stricter requirements (for instance, the EU AI Act or changes in FDA guidance) which could delay our deployment or add costs. Also, liability if something goes wrong is a concern. **Mitigation:** We're mitigating regulatory risk by engaging in the process early (as described in Regulatory Path) – by planning for UKCA marking, we ensure we meet a known standard [95]. We also keep functionality that would push us into higher risk class deliberately out of scope (Clerky advises

and documents; it does not make automatic treatment decisions). On legal liability, we will maintain appropriate insurance and ensure contracts with users/hospitals clearly outline the tool's intended use and limitations. By having strong audit logs, if an incident occurs, we can show exactly what Clerky suggested and what the human did, which helps in fair assessment of responsibility.

- **Competition:** As the digital health space is hot, there is a risk that established EHR vendors or big tech companies could develop similar functionality and leverage their existing customer base to outcompete Clerky. **Mitigation:** We believe our **head-start in this niche and our agility** are key mitigators. Big EHRs are slow to innovate; Clerky can integrate with any EHR rather than requiring a hospital to switch systems, which is in our favor. We are also building **moats** around our product: the comprehensive guideline database with auto-updates [15], the cost-optimized AI engine, and the user experience tailored to clinicians give us an edge. Additionally, our founder's insight as a practicing clinician means we're solving the right problem in the right way – that kind of user empathy is hard for a generic tech company to replicate quickly. We also aim to **partner** rather than always compete – for example, if a major EHR wanted a guideline checking feature, we could potentially license our engine to them. By staying innovative (phase 4 ideas like predictive analytics) and focusing on actual impact, we plan to stay ahead of generic solutions. Still, we monitor the landscape; if a big player releases a competing product, we'll emphasize Clerky's proven outcomes and superior focus (whereas a competitor might not be specialized in guideline adherence scoring as we are).

- **Market Adoption & Financial Risk:** There's a business risk that hospitals may have long procurement cycles or limited budgets, slowing our sales, or that the **market adoption is slower than expected】** [83] [96] **. Also, if we mis-price the product or cannot demonstrate ROI, revenue may fall short.** Mitigation: **We're mitigating this by initially focusing on** NHS innovation pathways **which are designed to accelerate adoption (e.g., via NHSx or NHS AI Lab programs). These often provide funding to trusts to try new solutions, which can ease budget concerns. We are also open to flexible pricing models early on (for instance, a low-cost pilot followed by scaling the price with scope) to reduce barriers to first adoption. By securing** grant funding **we can afford a longer runway to crack the market, reducing pressure to generate revenue immediately and allowing time to align with procurement cycles. Finally, by showing strong** clinical outcomes data**, we give champion clinicians the ammunition to advocate for purchase internally (hospital leadership is more likely to allocate budget if they see hard data of improvement). Our financial plan is conservative on burn rate, so even if revenue is slower, careful cash management (and a potential bridge fund from innovation funds) can keep us solvent until the tipping point where a few big contracts come in.

In conclusion, we acknowledge these risks but have concrete strategies for each. Our risk management approach will be continuously updated as we gather more intelligence from the pilot and early users. By maintaining open communication with users, being responsive to feedback, and upholding high standards of safety and evidence, we aim to mitigate issues early and build a product that stakeholders trust. This proactive stance on risks gives us confidence that Clerky can navigate the complex healthcare environment successfully.

Investor Pitch Deck Summary

The following points highlight the key aspects of Clerky's business case in a concise, investor-friendly format, as one would find in an executive pitch deck.

- **Traction & Validation:** Clerky is beyond the concept stage – an MVP is built and a **pilot launch is lined up with an NHS hospital** (maternity triage unit) with committed clinical champions [47]. The product was also **selected for the NHS Clinical Entrepreneur Programme** [97], underscoring endorsement by the healthcare system. Early informal testing shows positive feedback, and we have interest from additional sites pending pilot results. (*MVP completed, Pilot starting Q4 2025*)

- **Value Proposition – AI-Guided, Guideline-Scored Documentation:** Clerky ensures every clinical note is **"audit-ready" in real time**. Our AI platform analyzes a clinician's consultation and instantly **scores the documentation for adherence to medical guidelines**, highlighting what's missing and suggesting improvements [4]. This delivers **immediate quality feedback** to front-line clinicians, improving care consistency. For health organizations, it provides a new level of visibility into care: instead of retrospective audits, they get proactive alerts on compliance gaps and a data-driven way to improve performance. In short, **Clerky turns documentation from a formality into a powerful quality assurance tool**, powered by AI.

- **Market Opportunity:** Healthcare providers worldwide are under pressure to improve quality and efficiency. The **clinical decision support systems market is large and growing (projected ~$3.9B by 2030)** [80], but current solutions don't adequately address documentation quality and guideline compliance – a niche Clerky is poised to dominate. We're initially targeting the UK's NHS (with ~200 hospitals and numerous clinics) where digital transformation and patient safety initiatives create ripe demand. Each hospital license can be worth five to six figures annually, and expansion to the US and EU markets multiplies the revenue potential. With a first-mover advantage in real-time guideline adherence scoring, Clerky can capture significant share in this emerging segment.

- **Why Now: Convergence of factors makes this the right time** – (1) AI technology (LLMs) has advanced enough to interpret clinical text and guidelines effectively at low cost, which wasn't feasible until very recently [30]. (2) Healthcare systems are actively seeking AI solutions to augment staff amidst workforce shortages and burnout; the NHS in particular has programs and funding to adopt innovations in AI-driven care. (3) There is increasing emphasis on **clinical governance and accountability**, driven by both regulators and public expectations – hospitals need tools to ensure guideline compliance *before* problems occur. Clerky sits at the intersection of these trends: we have cutting-edge AI, align with current healthcare priorities, and meet a growing regulatory need for evidence of quality. In short, **we have the tech, the timing (2025 is NHS's "Year of AI"), and the tailwinds to drive adoption now**.

- **Team – Why Us:** *Clerky's founders uniquely blend medical and technical expertise.* **Dr. Ian Nouvel** (CEO) is a senior Obstetrics & Gynaecology clinician who has firsthand experience with the pain points in clinical documentation, *and* he has a prior background as a software engineer [98]. He developed the initial Clerky prototype himself, uniting deep domain knowledge with programming skill. Ian's participation in the NHS Clinical Entrepreneur Programme connects us with key industry mentors and stakeholders [99]. On the technical side, our co-founder/CTO (Name TBD) brings extensive full-stack development experience, ensuring we build a secure, scalable product. We've also attracted advisors including a former hospital CIO and an AI ethics

expert to guide growth. **This team has the insight to solve the right problem and the ability to execute**, evidenced by the rapid development of the MVP and securing a pilot. We are passionate about safer, smarter healthcare – and we have the credentials to earn trust from both clinicians and investors.

- **Financial Ask & Use of Funds:** We are currently **raising a seed round of £1.0M** (SEIS/EIS eligible) to fuel the next 18 months of growth. This funding will be used to: (a) **Complete our NHS pilot and expand to ~5 additional hospitals** (driving early revenue); (b) Obtain **UKCA regulatory approval** for market clearance [55]; (c) Enhance the product with EHR integrations and enterprise features to secure larger contracts. With £1M, we project ~12–18 months runway, during which we aim to reach £500k+ ARR by signing ~10 enterprise clients and to validate our value proposition with published outcomes data. *Investors* in this round will position us to capture a new market niche in healthcare AI, and benefit from our momentum when we target a Series A for international scaling. *(Notably, we have non-dilutive funding opportunities in progress – e.g. Innovate UK grants – which could extend runway and de-risk the investment [81].)* **Join us in transforming clinical documentation** from a checkbox exercise into a life-saving, proactive practice. Clerky's vision is to become the standard for AI-driven quality assurance in every hospital – and with your support, we'll get there.

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