ChatGPT

Navigating UK Regulatory Approval and NHS Market Access for an AI Clinical Decision Support Tool

Introduction:
Developing *Clerky* – an AI-driven clinical decision support tool that aligns patient documentation with medical guidelines – requires a multi-pronged strategy to achieve regulatory approval and adoption in the UK healthcare system. The journey involves **medical device certification**, **regulatory clearance**, **validation programs**, **data governance compliance**, and **market adoption pathways**. Below is a step-by-step guide covering each aspect, including key requirements, documentation, useful portals, milestone planning, and approximate timelines.

Step 1: UKCA Class IIa Medical Device Certification

Classify and Plan: Determine that the software is a medical device and confirm its classification (Class IIa in this case). Class IIa devices are moderate-risk and *require involvement of a UK Approved Body (similar to an EU Notified Body) for conformity assessment* [1] [2]. Early on, define the device's *intended purpose* and ensure it meets the definition of a medical device (in Clerky's case, likely for assisting diagnosis/treatment decisions, thus meeting the definition of a SaMD) – use MHRA's guidance on software qualification if needed [3].

Quality Management System (QMS): Implement a QMS aligned with ISO 13485 to manage design, risk, and manufacturing processes. A QMS is essentially mandatory for Class IIa devices – in practice most companies get ISO 13485 certification as part of their conformity assessment [4] [5]. The QMS should cover software development life cycle controls (per IEC 62304), risk management (per ISO 14971), usability engineering (IEC 62366) and include plans for clinical evaluation and post-market surveillance [4] [6]. Preparing the QMS early (and possibly having a pre-assessment audit) is a key technical milestone before seeking certification.

Technical Documentation: Compile a comprehensive Technical File (or Design Dossier) addressing all *Essential Requirements* (safety and performance requirements) from UK Medical Devices Regulations 2002 (analogous to EU MDR Annex I) [7]. This documentation must include:

- **Device description and intended use** – clearly explain how Clerky works and its clinical context.
- **Risk analysis and risk management report** – identify potential hazards (e.g. incorrect recommendations) and mitigation measures, following ISO 14971.
- **Clinical evaluation report** – evidence that the device's output is clinically valid and beneficial. This may involve literature review and/or study data demonstrating that Clerky's recommendations align with accepted guidelines and improve decision-making (a key clinical milestone is to gather this evidence, possibly via pilot studies or retrospective validation against patient cases).
- **Software documentation** – per IEC 62304, include software architecture, development plan, verification/validation testing, and cybersecurity measures. For AI/ML components, document the algorithm's training data, performance metrics, and measures to control bias or drift.

- **Usability and human factors** – show that the UI was tested with clinicians to ensure it's safe and easy to use (important for clinical safety).
- **Labeling and Instructions for Use** – draft clear user instructions, including the device's intended purpose, proper use, and any warnings (e.g. "decision support only, not a standalone diagnostic").

Ensuring these documents are complete and well-evidenced is crucial before approaching a conformity assessment. It's wise to conduct an internal audit or hire regulatory experts to review the tech file for gaps.

Conformity Assessment with an Approved Body: Apply to a UK Approved Body (e.g. BSI UK, SGS, UL, Intertek – note there are only a few in the UK [8]) for a Class IIa conformity assessment. There are a few routes available, but commonly **Full Quality Assurance (Annex II)** is chosen, where the Approved Body audits your entire QMS and technical documentation [9]. This involves:

- Submitting your technical documentation for review.
- Undergoing a QMS audit (on-site or remote) by the Approved Body.
- Addressing any non-conformities identified.

For Class IIa, once the Approved Body is satisfied that your device meets all requirements, they will issue a *UKCA Certificate* (sometimes separate QMS and product certificates). **Timeline:** The certification process can take on the order of **6–12 months** from application to certificate, depending on the device complexity and the Approved Body's queue [10]. It's prudent to initiate this early; you can overlap this with ongoing validation studies to save time.

UKCA Marking and Declaration: After receiving the certificate, draw up a UK Declaration of Conformity and affix the **UKCA mark** on the product (e.g. in the software's "About" info or documentation) [11]. Ensure labeling includes the Approved Body's number alongside the UKCA symbol (for Class IIa) and, if applicable, the UK Responsible Person's details (required if the manufacturer company is not UK-based) [12] [13]. At this stage, your device is *legally certified* for the Great Britain market, subject to final MHRA registration.

Step 2: MHRA Software as a Medical Device (SaMD) Approval and Registration

MHRA Registration: Before marketing or deploying the device in the UK, you must register it with the Medicines and Healthcare products Regulatory Agency (MHRA). *All medical devices (including software) must be registered with MHRA prior to being placed on the market in Great Britain* [14]. If your company is UK-based, you will register it directly; if not, you need to appoint a UK Responsible Person to register on your behalf [12] [15]. Registration is done via the MHRA's Device Online Registration System (DORS) and requires submitting device details, classification, and your Approved Body certificate information, plus paying the applicable fee (currently **£120–£310** depending on the class/category). Only once MHRA confirmation is obtained can you fully market the product [16] [17].

Software-Specific Considerations: The MHRA recognizes the unique challenges of Software as a Medical Device. It has a dedicated **Software and AI medical devices team** ("Software Group") to assist

manufacturers with pre-market queries and to ensure the regulatory framework is fit-for-purpose for AI [18]. While there isn't a separate "SaMD license" beyond the UKCA process, it's wise to:

- **Follow MHRA Guidance for SaMD**: Review MHRA's guidance on "when software applications are considered a medical device" [3] to double-check your software's qualification and classification. Ensure Clerky's intended use is clearly defined, as this drives classification [19]. The MHRA is in the process of updating SaMD regulations (adopting IMDRF risk categorization, etc.), so stay updated on any new classification rules [20].
- **Engage Early if Needed**: You can contact MHRA's Software Group for informal advice or clarification on novel aspects (for example, if your AI has adaptive algorithms, you might discuss how to handle future model updates within regulation). This proactive engagement can de-risk the approval process.
- **Clinical Investigation Approvals**: If you need to conduct a clinical investigation in the UK (e.g. a trial in NHS hospitals to gather clinical performance data before full approval), you must obtain MHRA approval for the trial. This involves a separate application to MHRA for a "Letter of No Objection" for medical device trials, as well as ethics approval via the Health Research Authority. Plan this step if a prospective clinical study is a milestone for evidence development; it can run in parallel with product development but requires a fully developed prototype and safety precautions.

Post-Market Vigilance Setup: As part of MHRA requirements, establish a post-market surveillance and vigilance system. Class IIa SaMD devices require you to monitor performance and report any adverse incidents or safety issues to MHRA's Yellow Card scheme. Set up mechanisms to collect user feedback and real-world performance data. MHRA's guidance includes vigilance reporting specifics for software manufacturers [21], and new UK regulations by 2025 are strengthening post-market requirements (e.g. regular safety update reports for medium-risk devices) [22] [23]. Technical and clinical teams should be prepared to handle these obligations once Clerky is in use.

Timeline & Milestones: *Regulatory approval* (UKCA + MHRA registration) is often the critical path. Key milestones include: completing technical documentation, QMS certification, obtaining the UKCA certificate, and MHRA registration. In total, these steps typically take on the order of **12+ months** (assuming documentation is already in progress). Once UKCA and registration are achieved, you have the necessary regulatory clearance to deploy Clerky in real healthcare settings. This must be in place before any wide NHS roll-out or commercial sales, although research/pilot deployments can occur under controlled conditions prior to full approval (with proper approvals as noted). Keep in mind that as of mid-2025, the UK will continue to accept CE-marked devices until 2030 for market access [24], but pursuing UKCA certification early is prudent for futureproofing.

Step 3: Leveraging the NHS AI Lab Sandbox and Validation Programs

Achieving regulatory clearance is only the first step – you also need *robust clinical validation and NHS acceptance*. The UK offers specialized programs through the NHS AI Lab and partners to support **validation, safety evaluation, and adoption** of AI health technologies:

- **MHRA's AI Airlock (Regulatory Sandbox):** In 2024 the MHRA launched *"AI Airlock,"* its first regulatory sandbox for AI-as-a-Medical-Device, in collaboration with the NHS AI Lab and other regulators [25] [26]. This program allows a limited cohort of AI tools to be tested in a *controlled environment with close oversight*. If selected, you work with MHRA experts, NHS clinical partners, and even Approved Bodies to examine the tool's performance on real (or simulated) data,

identify regulatory challenges, and refine safety measures. For example, the pilot cohort included an AI clinical decision support for oncology and an LLM-based guideline search tool, similar in spirit to Clerky [27] [28]. **Outcome:** While participation *does not guarantee approval*, it provides valuable feedback and can influence future regulatory guidance [29]. The Airlock's *Phase 1 pilot ran through early 2025* and a Phase 2 (2025–26) has been announced [30]. **Action:** Monitor MHRA's AI Airlock page for new application calls. If Clerky involves novel AI elements or uncertainties in regulation, applying to the sandbox could greatly support its safety evaluation and speed to market.

- **NHS AI Lab's *AI in Health and Care Award*:** This is a flagship programme run by NHS England's Accelerated Access Collaborative (AAC) in partnership with NIHR [31]. It provides funding and structured support for AI innovators across **4 phases**: from feasibility (Phase 1) to product development/validation (Phase 2), *real-world clinical testing in NHS sites (Phase 3)*, and *initial NHS adoption at scale (Phase 4)* [32] [33]. Each phase has its own application criteria and funding levels (Phase 3/4 awards can be £1m+ and involve multi-site NHS evaluations over 1–3 years) [34]. For a Class IIa decision support like Clerky, you might target:

- **Phase 2 or 3** if you need to gather clinical evidence in NHS settings. Phase 3 in particular supports *real-world testing*, pairing you with NHS sites to pilot the tool and independently evaluate outcomes [35]. For example, winning companies have been matched with NHS hospitals to deploy their AI tool and collect impact data [36]. This can yield proof of effectiveness and health economic data – critical for later procurement.

- **Phase 4** once you have regulatory approval and some evidence, to drive *initial system adoption*. Phase 4 supports a larger rollout (typically 3+ NHS sites) and funds work needed for integration and economic evaluation, with the goal of informing national scale-up decisions [37] [38]. Independent evaluators (NICE, academic centres) will study the outcomes of Phase 4 projects to recommend whether the AI tool should be adopted widely across the NHS [39].

Action: Watch for AI Award competition rounds (there have been 3 rounds so far). If eligible, prepare an application highlighting how Clerky meets NHS priorities (e.g. improving clinical efficiency, adherence to guidelines) and includes a robust evaluation plan. *Join the AI Virtual Hub* community [40] to get guidance on the application process and connect with past winners. Being an AI Award recipient not only provides funding but also validation – it signals to NHS stakeholders that your tool has been vetted for promise and is being evaluated formally.

- **NICE Evidence and Sandboxes:** The National Institute for Health and Care Excellence (NICE) is increasingly involved in digital health. They have an *Evidence Standards Framework for Digital Health Technologies* that outlines what level of evidence is expected for tools of varying risk [41]. Ensure you design your clinical studies to meet these standards (e.g. prospective outcome data for higher-risk interventions). Additionally, NICE is collaborating with NHS England to evolve evaluation processes for AI – for instance, NICE may produce **Early Value Guidance** or **Medtech Innovation Briefings** on promising AI tools. It's worth engaging with NICE (either through the AI Award Phase 4 evaluation or directly via their Office for Digital Health) to seek advice on evidence generation. A future milestone might be to obtain a NICE endorsement or inclusion in guidelines, which would greatly boost adoption.

Technical and Clinical Milestones in Validation: During this stage, plan key milestones such as:

- Completing a *retrospective validation study* (e.g. testing Clerky on past patient records to measure if it improves guideline adherence or catches missed recommendations).

- Iterating the AI model based on pilot feedback (improving accuracy or usability issues found in sandbox/pilot).
- Gaining letters of support from clinicians or NHS sites (this can strengthen AI Award or procurement efforts).
- Publishing results in a peer-reviewed journal or conference – while not mandatory, this builds credibility and can be used in your Clinical Evaluation Report and marketing materials.

Estimated Timeline: Participating in an AI Lab program can add **6–24 months** of structured testing, but it runs in parallel to other efforts. For example, you might secure a Phase 3 Award while finishing UKCA certification, allowing you to start NHS pilots soon after regulatory approval. These programs are designed to accelerate evidence gathering – a Phase 3 trial might be ~12 months of data collection, and Phase 4 another 12–18 months for early adoption and assessment. Thus, engaging in them early (even as you await regulatory sign-off) can shorten the time to broad adoption by providing the necessary proof for NHS decision-makers.

Step 4: Meeting NHS Data Governance and Compliance Requirements (DTAC and Beyond)

To deploy *Clerky* in the NHS, compliance with data governance, security, and interoperability standards is as crucial as clinical efficacy. The NHS has established a **Digital Technology Assessment Criteria (DTAC)** as a unified framework to ensure any digital health product meets minimum standards for use. **DTAC covers five key domains: clinical safety, data protection, technical security, interoperability, and usability (including accessibility)** [42] . Preparing for and meeting the DTAC is a must-do before NHS organizations will procure or even pilot your tool. Here's how to approach it:

- **Clinical Safety (DTAC Section 1):** Demonstrate that the product is clinically safe and that you manage any risks of harm. The NHS mandates compliance with *DCB0129: Clinical Risk Management for Manufacturers of Health IT* [43] . In practice, this means you need to appoint a **Clinical Safety Officer** (a suitably qualified clinician) and maintain a *Clinical Safety Case* with a Hazard Log. This documentation should enumerate all potential patient safety risks (e.g. "AI gives an incorrect recommendation that could lead to suboptimal treatment") and the mitigations in place (such as clinicians retaining final decision authority, or specific validation checks in the software). Have the Clinical Safety Officer sign off on the safety case. Many NHS buyers will ask to review your DCB0129 safety documentation or at least a statement of compliance. Ensuring *Clerky* already has a thorough clinical risk management file is a significant milestone prior to NHS deployment.

- **Data Protection & Privacy (DTAC Section 2):** Because Clerky will handle patient documentation, you must comply with UK data protection laws (UK GDPR and Data Protection Act 2018). Key requirements and suggested actions:

- Conduct a **Data Protection Impact Assessment (DPIA)** detailing what data you use (e.g. patient history, lab results), the purpose (decision support), lawful basis for processing (likely direct care, which is a legitimate basis via the healthcare provider using Clerky), data flows, and how you mitigate privacy risks. NHS organisations will expect a DPIA – they might do their own, but your input is needed.
- Implement strong data minimisation and retention policies (process only data necessary for the task and don't store patient data longer than needed).

- **Information Governance Security:** Ensure all personal data is stored and transmitted securely (encryption in transit and at rest, access controls, audit trails for data access). Prepare documentation on your security architecture.

- **Data Security and Protection Toolkit (DSPT):** The NHS requires any organization with access to patient data to complete the DSPT self-assessment annually [44]. As a vendor, completing the DSPT (and achieving "Standards Met") provides NHS customers assurance that you follow the National Data Guardian's 10 security standards. **Action:** Register for the DSPT (via NHS Digital's portal) and assemble the evidence needed (policies, technical controls, training records). This process covers many detailed items (from cybersecurity measures to staff training on data handling) but is invaluable for trust-building. In fact, *all NHS suppliers handling patient data must use the DSPT to show they are keeping data secure and using it properly* [45]. Achieving DSPT compliance should be a core project goal during development.

- **Technical Security (DTAC Section 3):** Beyond the DSPT, NHS IT departments will scrutinize the tool's cybersecurity and resilience. Be ready to provide:

- Penetration test or vulnerability assessment reports for your software (it's good practice to have external experts pen-test Clerky's application and fix any high-risk issues).
- Details on authentication and authorization: e.g. does Clerky integrate with NHS Single Sign-On or Active Directory? At minimum, use strong authentication methods and role-based access if applicable.
- Certification or standards: while not mandatory, having **Cyber Essentials Plus** (a UK government-backed cyber security certification) or even ISO 27001 for your information security management can significantly boost confidence. These can be pursued as business milestones in parallel.

- **Resilience and uptime** plans: NHS will want to know how reliable the service is and how you handle outages or incidents. Document your business continuity and incident response plans, as these may be queried in the DTAC assessment.

- **Interoperability (DTAC Section 4):** The NHS favors solutions that can integrate with existing systems (EHRs, etc.) and adhere to standards. To meet this criterion:

- Use **NHS Data Standards**: For example, ensure any clinical terminology follows SNOMED CT or ICD-10 as appropriate. If Clerky ingests or outputs coded data (like diagnoses or medications), using standard codes is important.
- **APIs and Integration**: Provide APIs or integration interfaces that conform to NHS standards (FHIR is the preferred standard for healthcare data exchange in NHS). If Clerky is to pull patient data from electronic health records, implementing a FHIR API client or using NHS Digital's integration mechanisms will be needed. Identify early which systems you need to integrate with (primary care systems like EMIS or hospital EHRs like Cerner/Epic) and plan for those integrations. Reaching a successful integration in a pilot site is a key technical milestone that proves interoperability.
- Offer data export and audit logs in usable formats, so the NHS can incorporate outputs into their records.

- Consult the **NHS England interoperability toolkit** or guidelines for any specific interoperability requirements relevant to decision support tools.

- **Usability & Accessibility (DTAC Section 5):** This ensures the product is usable by clinicians and, if relevant, by patients, and meets accessibility standards:

- Conduct **User Experience testing** with NHS staff. Document feedback and improvements made. A user-centric design reduces training burden and errors.
- **Accessibility:** If Clerky has a user interface (especially if any part is patient-facing), it should meet Web Content Accessibility Guidelines (WCAG 2.1 AA level). Even clinician-facing tools should consider color-blind friendly displays and compatibility with assistive technologies. The DTAC will ask if you have done an accessibility assessment – be prepared to attest that your UI is inclusively designed.
- Provide training materials or user guides as part of your documentation. NHS organisations often seek assurance that the supplier will support user training and that the tool is not too complex to deploy.

DTAC Submission: The DTAC is typically assessed by each NHS organisation during procurement, but you can **pre-fill the DTAC questionnaire** (available as a template) to have ready for any interested Trust [46]. This is essentially a dossier of evidence for all the points above. Many innovators choose to proactively complete a DTAC self-assessment and even get an informal review by an NHS partner (for example, an AHSN can sometimes review your DTAC responses and advise improvements). Reaching a *"DTAC-ready"* status is an important business milestone prior to large-scale marketing in NHS. It means you have all policies and proofs in place so that when a buyer asks, you can hand over the full package without delay.

Related Governance Requirements: Aside from DTAC, ensure compliance with other NHS governance processes:

- **Clinical Safety Standards (NHS DCB0129/0160):** We addressed DCB0129 for you as manufacturer. Note that any NHS site deploying Clerky must comply with DCB0160 (the counterpart standard for health organisations implementing health IT). They will need your safety documentation to do this. Make it easy for them: provide a *Clinical Safety Management Package* that they can use, including your hazard log and any mitigations the site needs to implement (like "train users on X", or "ensure double-check of AI recommendations for certain high-risk cases"). This collaboration on safety will smooth local approvals.
- **Regulatory Alignment:** Given that your tool aligns clinical decisions with guidelines, it may also fall under clinical governance at hospitals. Be prepared to engage with each hospital's Clinical Governance or AI ethics board. Having a **transparent algorithm description** and explanation capability (how Clerky arrives at its recommendations) will address concerns about AI "black boxes" and will align with emerging MHRA guidance on AI transparency [47].
- **Data Agreements:** If your solution will involve any cloud processing of patient data, NHS customers will need a Data Processing Agreement in place with you, per GDPR. Work with legal counsel to have a standard NHS Data Processing Contract ready, covering roles (the hospital is Controller, you are Processor), compliance, and UK-specific requirements (like NHS Cloud Security Principles if hosting data). The NHS may also require that data stays in UK or certain certified regions – ensure your cloud infrastructure complies with this.

Timeline: Data governance preparation should run *concurrently* with development and regulatory steps. It can take a few months of effort to put all policies and evidence in place, but it's largely within your control. A recommended approach is to start working on DTAC items early (even as early as prototype stage for things like DPIA and cybersecurity) so that by the time you have a viable product, you are already near compliance. Typically, companies spend **3-6 months** doing the heavy lifting of documentation and certification (e.g., achieving Cyber Essentials, writing safety cases, etc.). Make these part of your early project plan. By product launch, you should have completed the DSPT and have a filled DTAC form. This ensures that slow governance processes won't become a bottleneck when an eager clinician wants to try Clerky – you'll be ready to answer the Information Governance and IT security questions swiftly, which significantly speeds up pilot approvals and procurement.

Step 5: Engaging NHS Procurement and Innovation Pathways (DigitalHealth.London, AHSNs, etc.)

Finally, to achieve market access, you need to navigate **NHS procurement and stakeholder engagement**. The NHS is a large, complex system, and adoption often hinges on building the right relationships and being on the right purchasing channels. Here are strategies to facilitate uptake:

- **Connect with Academic Health Science Networks (AHSNs):** The AHSNs are regional innovation hubs across England (15 in total) whose mission is to accelerate the spread of proven innovations in the NHS [48] [49]. Engaging with your local AHSN (or an AHSN relevant to your target clinical area) can open doors to pilot opportunities and provide guidance on demonstrating impact. Many AHSNs run **Innovation Exchange** programs to match innovators with NHS needs [50]. Introduce Clerky to them early – if they see promise (e.g. improving guideline adherence, which could improve outcomes and efficiency), they might help broker introductions to NHS trusts, assist in designing evaluations, or even support funding bids. *Milestone:* Securing an AHSN-supported pilot site or getting onto an AHSN "adoption spotlight" can considerably boost credibility. For instance, some AHSNs have "Innovation showcases" or networks of NHS champions for AI – aim to get Clerky featured. Also, should Clerky prove its value in one region, AHSNs help spread the word to others, supporting scale-up.

- **DigitalHealth.London Accelerator:** If your company targets the NHS in London (or even if not, the learnings apply nationally), consider the **DigitalHealth.London Accelerator** program. This is a competitive, 12-month program that has a track record of helping digital health SMEs refine their approach and win NHS contracts [51]. Companies on the accelerator are assigned an NHS Navigator (an expert with insider NHS knowledge) and get coaching on product-market fit for NHS, meet NHS stakeholders, and attend workshops on NHS procurement, regulations, etc [52]. Crucially, the program brokers **connections between innovators and NHS organizations** facing relevant challenges [53]. Many alumni report that it sped up adoption by getting them in front of decision-makers and shaping their product to better meet NHS needs [54] [55]. **Action:** Watch for the annual call (typically, cohorts are announced each year). Companies usually need at least one NHS pilot or proof of concept completed and must be ready to scale – so a good time to apply is once you have regulatory approval and one or two pilot results in hand (perhaps late 2025 for the next cohort, given your current timeline).

- **NHS Innovation Accelerator (NIA):** Distinct from DigitalHealth.London, the NIA is an NHS England national initiative that selects a handful of high-impact innovations each year and supports their adoption at scale [56]. It's delivered in partnership with all AHSNs, and focuses on mature innovations that have proven benefits. NIA Fellows (the innovators) get a 12- to 24-month support package including mentorship from senior NHS leaders, exposure to AHSN networks, and guidance on scaling (policy, business models, etc) [57]. Notably, **over 2,100 NHS sites were using NIA innovations as of recent years** [58]. To be competitive for NIA, Clerky would need solid evidence (clinical and economic) and an implementation track record. This might be a target a couple of years down the line (e.g. after some Phase 4 AI Award data). Keep it on the radar as a mid-term goal – being an NIA alumnus can significantly ease conversations with hospital executives (it acts as a quality stamp).

- **NHS Procurement Frameworks:** NHS buyers often prefer purchasing via established *framework agreements* – these are pre-vetted lists of suppliers/products that meet certain standards, making procurement faster and compliant with public sector rules [59] [60]. To improve market access:

- Look into the **Health Systems Support Framework (HSSF)** [61] . This is an NHS England framework for digital and data tools (covering categories like population health, AI decision support, workflow tools, etc.). Being on HSSF allows any NHS organisation to procure your solution without a full tender, since you've effectively passed a vetting. Check the HSSF categories and see where Clerky might fit (possibly under "decision support/AI" services). The HSSF has periodic application windows – contact NHS England's procurement team or check the Innovation Service site for guidance on joining.
- Use the **G-Cloud Framework** on the UK Government Digital Marketplace [62] . G-Cloud is a popular route for NHS IT procurements, especially for software-as-a-service solutions. By listing Clerky on G-Cloud (an online catalogue for cloud software and services), you make it easy for NHS buyers to find and purchase it. G-Cloud applications are typically open annually; the process involves providing service details and set pricing. It's relatively straightforward and *highly recommended as an early step* once you're market-ready, because many NHS procurement teams will ask "are you on G-Cloud?" as a basic checkpoint.
- Explore **Dynamic Purchasing Systems (DPS)** for innovation. NHS Supply Chain has an Innovation DPS for new medtech products [63] . However, this often requires a NICE endorsement or an AHSN referral and is focused more on medical devices and hardware categories. It might not squarely fit software like Clerky, but keep an eye on any DPS that covers digital tools. DPS are open-entry, meaning you can apply anytime if you meet the criteria [64] [65] .

- Be aware of **regional procurement hubs** (like London Procurement Partnership, etc.) [66] . Sometimes getting on a regional contract or approved list can help (for example, an NHS Trust could buy via a contract that another trust or region already set up). Leverage your pilot sites – if one hospital is impressed and wants to procure, their procurement department might lead on creating a framework that others can join. This "reference site" approach is often how digital tools spread (one NHS trust leads, others piggyback on the contract).

- **Engage Clinicians and Decision-Makers:** Alongside formal channels, invest in building clinical champions. Identify influential clinicians (e.g. a Chief Medical Information Officer or a guideline committee lead) who see the value in Clerky. Their backing can drive adoption from the ground up – they will advocate internally for the tool. Present at NHS conferences (like NHS Expo, Digital Health Rewired, etc.) to raise awareness. Often, *business milestones* in healthcare involve gaining trust: letters of support, positive user testimonials, inclusion in an NHS England case study, etc., are intangible but powerful assets. The NHS AI Lab's **AI Knowledge Repository** and community events are good venues to share learnings and network [67] .

- **Plan for Commissioning and Funding Models:** Ultimately, NHS organisations will ask, "How do we pay for this and is it worth it?" Ensure you have a clear value proposition: does Clerky save clinician time, reduce errors, or improve outcomes in a way that can be quantified (e.g. reduced adverse events or admissions)? If so, build an economic model. Engage with the NHS England commissioning or reimbursement bodies if applicable – for example, if using Clerky could be tied to an incentive program (like improving compliance with NICE guidelines might align with CQUIN targets or similar quality programs). While the NHS doesn't yet have a universal reimbursement code for AI decisions, demonstrating cost-effectiveness could lead to inclusion in future funding mandates (NHS has a MedTech Funding Mandate for certain proven technologies [68]). Keep an eye on these policy levers; it might be more relevant after initial market entry, but laying groundwork now (collecting health economics data in your pilots) is wise.

Timeline: Gaining significant NHS market traction can take **1–3 years post regulatory approval**, as it requires building evidence and trust one step at a time. A realistic sequence might be: a) 0–12 months: one or two NHS pilot evaluations (possibly via AI Award Phase 3) – use these to refine the product and

prove benefits; b) 12–24 months: initial procurements at early-adopter sites (with help of AHSNs or Phase 4 award funding) – here you might get 5-10 hospitals using Clerky; c) 24+ months: broader adoption, potentially accelerated by national support (NIA fellowship, NICE recommendations, or an NHS England directive if your tool aligns with a policy goal). This trajectory can be shortened with the right support – for instance, AI Award Phase 4 projects that show strong results have seen rapid spread, and NIA reports millions in savings and thousands of sites using alumni innovations in a few years [58]. The key is to hit the **milestones** along the way: positive pilot results, satisfied reference customers, completion of DTAC and procurement onboarding, and continual improvement of the product based on user feedback.

Roadmap and Estimated Timeline

Bringing an AI clinical decision support tool like *Clerky* to UK market involves overlapping workstreams. Below is a high-level roadmap with indicative timelines and milestones (these can vary, but serve as a guide):

- **Months 0–6:** *Foundations.* Finalize device classification and intended use. Begin QMS implementation (draft SOPs, hire regulatory consultant if needed). Initiate risk management and gather existing clinical evidence (e.g. retrospective analysis of guideline adherence). Possibly apply for an AI Award (Phase 1/2) for feasibility funding. **Milestones:** Complete initial DPIA and cybersecurity plan; have an Intended Use statement and hazard analysis; engage clinicians in design feedback.

- **Months 6–12:** *Regulatory Submission Prep.* Finish technical documentation (iterative testing and document writing). Undergo a pre-assessment audit of QMS to ensure ISO 13485 readiness. Select and contract with a UK Approved Body (note: lead times to schedule audits can be a few months). Start MHRA conversations if any clarification needed. Meanwhile, if you received a Phase 2 AI Award, develop the product further and perhaps do a small-scale evaluation to include data in the clinical evaluation report. **Milestones:** Tech File completion; QMS documents in place; (Optional) Phase 2 AI Award secured; application to Approved Body submitted.

- **Months 12–18:** *Conformity Assessment and Pilot Planning.* Approved Body conducts audit and document review – address any findings. Attain UKCA certification around this time if all goes well [10]. Immediately after, register device with MHRA (registration itself can be done in days once you have the info [17]). In parallel, set up an NHS pilot (perhaps through an AHSN or an AI Award Phase 3 that kicks off around month 12). Ensure DTAC evidence is prepared for the pilot site's governance. **Milestones:** UKCA certificate received; MHRA device registration complete; first NHS pilot site on-board (with data sharing agreements and local approvals in place).

- **Months 18–30:** *Real-World Testing and Iteration.* Conduct the NHS pilot(s) – e.g. a 6-12 month evaluation at 1-3 sites. Monitor outcomes (safety, guideline adherence improvement, user feedback). Meanwhile, maintain compliance: perform post-market surveillance, collect any incidents, and feed this back into risk management. If in AI Airlock sandbox (if selected), work closely with MHRA/NHS experts to resolve any emerging regulatory questions. Start engaging more broadly: demonstrate pilot results at AHSN or NHS events to drum up interest. Also at this stage, **apply to procurement frameworks** like G-Cloud and HSSF so that procurement channels are ready by the time demand grows. **Milestones:** Pilot study results reported (e.g. "Clerky improved adherence to NICE guidelines by 20% with no safety issues"); DTAC assessment passed at pilot trust; product iteration (v2.0) released addressing any usability or safety findings; listed on G-Cloud marketplace.

- **Months 30–48:** *Initial Adoption and Scale-Up.* Leverage positive evidence to win early adopters. Possibly secure Phase 4 AI Award for scaling, or get selected for the NHS Innovation Accelerator – these provide resources and validation for wider rollout. New NHS sites procure the product via frameworks (this avoids lengthy tenders, speeding implementation to maybe a few months per site). Work with procurement hubs for multi-site contracts. If outcomes are strong, engage with NICE for a potential health technology assessment or endorsement. Continue to enhance data governance as user base grows (e.g. ensure all new updates go through clinical safety review, maintain ISO 13485 certification with surveillance audits). **Milestones:** 10+ NHS sites live; AHSN case study published; consideration for NICE evaluation or inclusion in NHS England innovation catalogues; NIA fellowship (if achieved, typically around this time).

- **Beyond 4 years:** *Widespread NHS Integration.* Aim for inclusion in national policy (for instance, if Clerky addresses a national priority like reducing unwarranted clinical variation, NHS England might recommend it). At this stage, you may pursue formal NICE Guidance or integration into electronic health record systems as a standard module. Also prepare for ongoing regulatory compliance – the UK is updating medical device regulations by 2026, so be ready to transition to new requirements (likely similar to EU MDR) and to re-certify by the 2030 UKCA deadline for CE-marked devices [2]. **Milestones:** Sustainable revenue via NHS contracts, evidence of improved patient outcomes across deployments, and institutionalization of the tool in routine care pathways.

Throughout this journey, remain agile and document everything. Regulatory and clinical compliance is not a one-time box-tick but a continuous process – maintain your technical documentation with any changes, continue engaging users for feedback, and keep an open line with regulators and NHS stakeholders. By meeting each requirement step-by-step – from UKCA marking [1] and MHRA registration [14], through rigorous validation in the NHS AI Lab programs [31] [25], to satisfying NHS data standards and procurement protocols [42] [69] – you will build the necessary confidence in *Clerky*. The end result is a clinically safe, trusted decision support tool that not only achieves regulatory approval but is positioned for successful adoption across the NHS.

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