Clerky x EG Technology – Meeting Summary (9 Oct 2025)

Participants: Clerky – Founder (Chief Medical Officer/Product Lead); EG Technology – Danny Godfrey (Director) and John [Surname], Software Team Lead (Machine Learning Specialist)

Purpose: Explore EG Technology's ability to support Clerky in developing a compliant, scalable, and NHS-integrated version of its AI-driven clinical documentation platform.

1. Technical and Integration Pathway

• Clerky can be prototyped within the NHS Developer Sandbox using official FHIR-based APIs for secure data exchange.
• The NHS sandbox allows Clerky to demonstrate proof-of-concept interoperability with NHS systems before full deployment.
• All NHS APIs transmit JSON-formatted FHIR objects, providing a standardised structure for clinical data exchange.
• Hosting and data transfer issues can be mitigated by using cloud environments such as AWS, the Clinically Approved Cloud, or local trust servers.
• ISO 62304 may or may not apply depending on future classification as a medical device, but its software lifecycle principles should be adopted regardless.
• EG will share references to regulatory specialists to clarify SaMD applicability.

2. Regulatory and Deployment Considerations

• Clerky's prototype likely sits outside SaMD scope, as it focuses on documentation support rather than direct clinical decision-making.
• If future versions influence diagnostic or therapeutic decisions, SaMD Class I/IIa may apply.
• Phased plan: Phase 1 – compliant pilot version (4–6 months, £300–400k); Phase 2 – trust/NHS rollout; Phase 3 – SaMD-certified version (£500–600k, ~6 months).

3. Market and Adoption Strategy

• Clerky has multiple entry points: individual clinicians, hospital departments, regional NHS trusts, and compliance applications beyond healthcare.
• Investors will expect early market validation—multiple NHS trusts should be approached for expressions of interest and willingness to pilot.

4. Wider Commercial Opportunities

• If Clerky improves guideline adherence, insurers could offer lower professional indemnity premiums to verified users.
• This creates potential for secondary markets in risk mitigation and compliance analytics.

5. Team Formation and Leadership

A three-person founding team is planned to balance medical, technical, and operational leadership:

Role	Responsibility
Chief Medical Officer (Founder)	Clinical and product vision
Chief Technology Officer	Technical architecture and AI strategy
Chief Executive Officer	Operations, funding, and partnerships

6. Key Timelines and Cost Estimates

Phase	Objective	Timeline	Estimated Cost
Phase 1	Pilotable software for clinician use	4–6 months	£300k–£400k
Phase 2	Trust/NHS deployment	+2–3 months	—
Phase 3 (if SaMD)	MHRA-certified version	6–8 months	£500k–£600k

7. Agreed Next Steps

• EG to provide contact references for SaMD regulatory experts.
• Clerky to prepare technical documentation for review against ISO 62304 principles.
• Apply for NHS Developer Sandbox access to enable FHIR integration testing.
• Reconvene post-sandbox to define regulatory route and funding strategy.

Summary for Investors and Partners

• Clerky can progress to NHS pilot stage without immediate SaMD classification, reducing time and cost.
• The project has clear FHIR integration potential and scalable architecture.
• A structured 4–6 month path to pilot readiness positions Clerky well for early investment and NHS partnerships.