Haem.io: Regulatory Strategy & Pathway

Our Philosophy: Regulatory-First Design

From its inception, Haem.io has been engineered not as a general AI tool, but as a future medical device. Our entire technical architecture, data governance model, and product roadmap are built around a core principle of "regulatory-first." This proactive approach ensures that clinical safety, data integrity, and compliance are foundational pillars of our platform, not afterthoughts. Our strategy is to de-risk the regulatory pathway through meticulous planning, early expert engagement, and a phased, evidence-based approach to market entry.

Target Classification & Pathway

Target Jurisdiction: United Kingdom (initial)

Governing Regulation: UK Medical Device Regulations 2002 (UK MDR 2002)

Target Device Classification: Software as a Medical Device (SaMD), Class IIa

Conformity Route: UKCA Marking via a full Quality Management System audit by a UK Approved Body.

Core Compliance Pillars

Our pathway to certification is built on adherence to the key standards governing medical device software in the UK. We have active workstreams for each of the following:

- **Quality Management System (QMS):** We are implementing a QMS compliant with **ISO 13485**. This system will govern all aspects of our design, development, testing, and post-market activities.
- **Clinical Safety & Risk Management:** We are compliant with **DCB0129**. Our Co-CMO, Dr. John Burthem, who has held this role for several other organisations, acts as our designated Clinical Safety Officer (CSO). We maintain a comprehensive Clinical Safety Case and a risk management file compliant with **ISO 14971**.
- **Data Protection & Security:** We are registered with the ICO and adhere to UK GDPR. Our platform is being prepared for the mandatory **NHS Data Security & Protection Toolkit (DSPT)** assessment and is designed to meet all criteria of the **Digital Technology Assessment Criteria (DTAC)**.
- **Software Lifecycle Management:** Our development processes follow the framework of **IEC 62304**, ensuring a rigorous, documented, and auditable software lifecycle.

Phased Evidence Generation Strategy

Our commercial strategy is intrinsically linked to our regulatory strategy. We will use our pre-funding traction to generate the necessary clinical evidence for our UKCA technical file.

1. **Alpha Testing:** Our initial deployment with KOLs at MFT and other trusts will be conducted under a "Research Use Only" (RUO) framework. This allows us to gather crucial user feedback and performance data in a non-clinical setting, refining the product before formal investigation.
2. **Formal Pilot (Clinical Investigation):** The pilots, enabled by our seed funding, will be structured as formal clinical investigations. Conducted under HRA/REC ethics approval and MHRA notification, these pilots will generate the core clinical evidence and performance data required to prove the safety and efficacy of Haem.io.

Notified Body & Expert Engagement

We believe in proactive engagement with regulatory experts to de-risk our timeline and ensure our strategy is robust. We have already held preliminary consultations with **Scarlet, a leading UK Approved Body** for medical device registration.

This engagement has provided us with a clear and detailed understanding of the costs and processes involved, validating our strategic plan and funding requirements. The key takeaways from this consultation inform our financial planning:

- **Budgeted Costs:** Our financial model accounts for the significant costs associated with regulatory affairs professionals (£50k-£100k) and Notified Body fees for a Class IIa device (£60k-£70k initial fee + £30k-£40k in annual fees).
- **External Consultancy:** To augment our in-house expertise, we will engage a specialist external regulatory consultant (e.g., Formly.ai or other industry-recognised firms with a strong track record of successful submissions to UK Approved Bodies like Scarlet) to conduct a pre-submission review of our technical file and QMS.
- **Strategic Timeline:** As advised, our strategy is to establish our QMS and begin compiling our technical file *before* formally engaging Scarlet for the audit process, ensuring maximum efficiency.