CASE STUDY **Our Future Health**

Translating regulation, software engineering, and participant feedback needs into executive-ready decisions and operational systems at the UK's largest health research programme

---

Context

Our Future Health (OFH) is the UK's largest-ever health research programme, working to recruit and genetically characterise millions of UK adults to enable prevention, early detection, and treatment of common diseases. As the programme moved toward returning genomic insights to participants, it encountered unresolved questions at the intersection of regulation, software, and clinical responsibility - where the right path was not owned by any one team. Emergent Systems (James Siddle) supported OFH across three connected pieces of work, combining **regulated-software advisory**, structured **strategy work**, and **hands-on principal-engineer** delivery.

Phase 1 — Regulatory strategy enablement: T2D polygenic risk scores and regulatory deadlines

Led a cross-functional discovery into whether OFH should return Type-2 diabetes polygenic risk scores within a grace window ahead of EU Medical Device Regulations coming fully into effect. Working with Regulatory Affairs, Product, and engineering leads, the discovery mapped regulatory routes, SaMD boundaries, architecture options, and confirmatory testing pathways - structured around a conceptual framework that James developed to shape the options space. The resulting presentation informed the executive decision to focus on near-term delivery on non-clinical health feedback, avoiding premature regulatory and clinical exposure.

Phase 2 — Engineering leadership: the Health Insights platform

Acted as principal engineer and architect for *Health Insights*, a new OFH capability to deliver health reports to participants. Led end-to-end delivery across service architecture (Python / FastAPI, Next.js, PostgreSQL, Keycloak-based OIDC), a SaMD-aligned delivery pattern enabling third-party distribution without PII exfiltration, deployment on OFH's internal cloud platform, and the programme's first production multi-factor authentication flow. Oversaw the successful first-cohort launch of *Health Insights*, including operational runbooks and QC. Engaged closely with the security team to ensure ISO 27001 compliance, and delivered "epic" templates adopted by the team as a lightweight structure for cross-cutting oversight by security, clinical, and product.

Phase 3 — Regulatory discovery: deciding the minimum-viable path for returning genetic risk scores

Following launch of non-clinical Health Insights, led the discovery, analysis, and writing of a strategic report on the regulatory path for returning medically-actionable reports to participants. The approach defined candidate use cases (eg direct-to-participant, recontact, and others), then took a single use case through user-journey mapping, hypothetical architecture, applicable regulations, and responsibility mapping - surfacing regulatory impacts, laboratory compliance requirements (ISO 15189) and potential SaMD / IVD components. The report opened with structured context to bring executive and board readers up to speed, before presenting prioritised conclusions and recommendations across regulatory, implementation, organisational impact, costs and risks.

Outcomes

- Conceptual framework adopted to shape the executive decision on the T2D regulatory path.
- Health Insights launched to first participant cohort, including OFH's first production MFA flow.
- ISO 27001-aligned delivery evidence and process improvements.
- Regulatory discovery report reshaped strategy on medically-actionable participant feedback and informed subsequent executive and board discussion.

> *"The first meaningful progress on the regulatory topic and feedback of genetic risk scores in the history of the organisation."* — Senior stakeholder, OFH (attribution pending sign-off)