Case study

Navigating the complex world of regulation: AI innovators need a starting point

Artificial intelligence (AI) has the potential to revolutionise health and social care and the UK is at the centre of it, with organisations focussed on everything from streamlining diagnostics to personalising treatment. Yet, for developers building these tools, and for clinicians and health organisations seeking to adopt them, navigating regulation remains one of the biggest barriers to progress.

Rather than a single, clear route to adoption, many innovators and adopters face a maze of fragmented guidance, overlapping processes, and uncertain expectations. Regulation is complex by nature, and for AI technologies in health and care, the lack of a clearly signposted starting point is slowing down innovation and making adoption harder than it needs to be.

We listened to users through workshops and data analysis

To better understand this challenge, NHS England and CERSI-AI in collaboration with BJSS ran **in-depth workshops in London** with two key user groups:

- Developers creating AI tools for health and care
- Clinical adopters working to integrate these technologies into NHS settings

These conversations were paired with behavioural insights, and service usage data. A clear picture emerged: the regulatory journey is hard to navigate, time-consuming, and often disconnected from real-world workflows.

Despite the growing appetite for digital innovation in the NHS, the current system makes it too easy to stall, and too difficult to progress.

Our approach: defining what users really need

Through the workshops, we set out to identify the real-world pain points across the AI regulation journey and to translate them into actionable opportunities for improvement.

Our goals were:

- To build on our understanding of the different routes developers and adopters take
- To uncover blockers that delay or derail progress
- To validate user needs that regulation support platforms must meet

What we heard was that innovators don’t need more guidance, they need better-structured, timesaving, and task-relevant support, specifically tailored to the unique regulatory considerations of AI in health and care.

What users told us they need

Users want more than abstract policy or dense documentation. They need:

- **A recognisable, authoritative entry point** that signals: "This is where to start."
- **A step-by-step journey** with clearly defined milestones and what "success" looks like at each stage.
- **Realistic insight into timeframes** - how long each stage typically takes, and who to speak to early to avoid delays.
- **Clarity on evidence** - what counts as sufficient, how to compare to standard of care, and how it aligns with NHS procurement.
- **Support embedding AI into workflows** - including change management, safety governance, and training.
- **Help navigating NHS vs. private sector pathways**, including divergent governance, data sharing and digital maturity.
- **Practical resources** - checklists, templates, and real-world case studies that reflect the full complexity of implementation.
- **Help progressing through stages**, including clearer definitions of when a stage is complete and what comes next.
- **Insight into upcoming changes** and access to **peer support networks** for real-time knowledge sharing.

Where AIDRS fits in

The **AI and Digital Regulations Service (AIDRS)** exist to make this journey easier. They provide structure, clarity, and visibility across the regulatory landscape, particularly for those developers who may be engaging with regulation for the first time.

But while AIDRS is already delivering critical value, users told us they want more:

- Deeper integration with **practical tools**
- Clearer signposting to **live support**
- Pathways that reflect the **non-linear complexity** of real-world projects

In other words: AIDRS shouldn't just explain the rules: it should actively help people move forward.

Looking ahead: AIDRS as the front door to AI Regulation

Looking to the future, AIDRS has the potential to become the "front door" for AI and digital regulation in the UK - combining the authority of MHRA, the evaluative rigour of NICE, and the usability, interactivity, and clarity that neither fully offer on their own today.

Imagine a single, trusted platform that offers:

- Guided, interactive pathways based on real user needs
- Integrated resources, from evidence standards to ethics processes
- Cross-agency navigation that eliminates duplication and dead ends
- A connected community of experts, adopters, and innovators sharing insight in real time

This is what the next decade of health and social technology regulation could look like - and AIDRS can lead the way.

Conclusion

AI in health and care is moving fast and regulation must evolve to keep pace. Innovators and adopters alike are calling for support they can actually use. With the right investment and collaboration, AIDRS can become more than a resource - it can be a catalyst for faster, safer, more confident innovation across the UK health system.

Disclaimer

This case study is a personal account of experiences shared with us by developers or adopters of AI for health and social care. It is intended to provide insights into individual experiences but does not reflect the views or recommendations of the AI and Digital Regulations Service partners (NICE, CQC, MHRA and HRA). AIDRS emphasises that users should continue to seek and adhere to formal statutory guidance and legal requirements applicable to their specific circumstances. It is the responsibility of the legal manufacturer to comply with all applicable statutory regulations.