Blog post

Navigating the Future: Building the AI and Digital Regulations Service

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Recognising the need for a comprehensive regulatory and evaluation pathway, we embarked on a collaborative journey to create the AI and Digital Regulations Service (AIDRS). This initiative is a joint effort by the National Institute for Health and Care Excellence, the Medicines and Healthcare products Regulatory Agency, the Health Research Authority and the Care Quality Commission. We aim to guide developers and adopters of AI and digital technologies through the complex regulatory and evaluation pathways.

Collaboration in action

The motivation behind AIDRS lies in the understanding that regulating emerging technologies, particularly AI, may be complex and benefit from a collaborative response. Building the AIDRS website was a huge collaborative effort involving a diverse range of stakeholders. Our collaboration was prompted by common challenges developers and adopters were telling us about, such as software products changing over time, the need for continuous monitoring to ensure safety and effectiveness and how to manage these challenges in the context of an AI product. There was also a need to signpost to existing guidance from regulators from one common accessible place. By working together, we harnessed our collective expertise to overcome hurdles and highlight guidance to our users.

The website represents over two years of hard work from our partners and stakeholders, from the discovery phase of researching what challenges developers and adopters face, right through to live website launch. A key part of the website was developing an underpinning ‘pathway map’ of key legal requirements and best-practice guidance for developers and adopters. We translated this into user-friendly website content. This was an iterative process with lots of quality assurance and input from a range of partners and stakeholders, including workshops to discuss and outline the pathway, and in-depth meetings with regulators to understand the unique complexities of each of their remits.

We also had support from various partners, including an independent evaluation partner who helped us understand and stay aligned with the focus and goals of the service and the mechanisms through which it hopes to achieve impact. An independent digital agency also supported us in developing the platform and maintaining a user-centred approach throughout its design.

Looking ahead

The hard work doesn’t stop here. As we continue to refine the AIDRS, our commitment to collaboration and to our users remains unwavering. Our journey serves as both a

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testament to the challenges posed by AI in healthcare and a guide for those venturing into similar collaborations. In sharing our experiences, we hope to contribute to the growing dialogue on regulatory approaches to emerging technologies, championing a future where collaboration and innovation go hand in hand.

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