

Early Regulatory Support as an Enabler of Medical Device Innovation

Medical device regulation is a key component of health innovation, particularly for digital health technologies, Software as a Medical Device (SaMD) and AI-enabled products. For early-stage innovators, regulatory requirements can be difficult to navigate because decisions about intended purpose, qualification, classification, evidence, quality management and market route often need to be made while technology and commercial models are in development.

HIRANI's key role is in regulatory navigation and readiness support, helping innovators recognise where regulation affects their development pathway, identify questions that require regulatory advice and connect regulatory requirements with evidence generation, funding, commercialisation and adoption.

A key challenge is ensuring that the availability of MHRA clinics in Northern Ireland translates into measurable early-stage engagement. HIRANI has clear evidence that demonstrates innovators frequently assume they need a well-developed regulatory strategy, detailed technical documentation or a mature product before approaching the regulator, which risks delaying advice until important development decisions have already been made. HIRANI



and Invest NI can help address this by positioning the clinics as an opportunity to test early assumptions, clarify regulatory questions and identify next steps, rather than as a formal review requiring a fully developed regulatory plan.

Common regulatory challenges that are seen from HIRANI SME support clinics for early-stage innovators.

Since the close of the £7.5 million Northern Ireland Innovate UK Life and Health Sciences Launchpad programme, HIRANI has continued to provide ecosystem support to SMEs through weekly Innovation Clinics. Since May 2026, approximately 45 hours of one-to-one support have been delivered, including around 20 hours with companies developing technologies that may require medical device regulatory approval. Common regulatory challenges identified through these clinics include uncertainty around whether a product qualifies as a medical device, classification and intended purpose, understanding the appropriate GB, Northern Ireland or EU regulatory pathway, planning clinical and technical evidence, and knowing when and how to engage with the MHRA or specialist regulatory advisers. For early-stage companies, these issues are often closely linked to funding, product development and commercial adoption, reinforcing the value of identifying regulatory requirements early rather than treating regulation as a later-stage activity.

Qualification and intended purpose

For digital health companies, an initial challenge is determining whether a product falls within medical device regulation. This is particularly important for software, where the regulatory position depends heavily on intended purpose and the function the software performs.

Classification and evidence requirements

Once a product qualifies as a medical device, its classification affects the regulatory pathway, including conformity assessment and evidence requirements. For software and AI-enabled technologies, classification may depend on how the product influences clinical decision-making and the potential consequences of incorrect output. This can require

regulatory interpretation and may be difficult for an early-stage company without dedicated regulatory expertise. Regulatory strategy also affects evidence generation. Clinical, technical and usability studies should therefore be planned with future regulatory requirements in mind. Otherwise, companies risk generating evidence that is useful commercially but insufficient for regulatory purposes.

Quality, risk and lifecycle obligations

Medical device regulation introduces requirements that may be unfamiliar to technology start-ups, including quality management, risk management, technical documentation, verification and validation and post-market surveillance. These activities require specialist knowledge and additional resources. For small companies, this creates both a capability and funding challenge, particularly where founders are simultaneously managing product development, clinical engagement and commercialisation.

Regulation as an adoption issue

Regulatory readiness also affects commercial adoption. Healthcare organisations, insurers and other potential partners may require reassurance regarding regulatory status, evidence, clinical safety, AI governance and accountability before progressing pilots or deployment. Regulation therefore becomes relevant well before formal market authorisation. It can directly influence whether an innovation is considered sufficiently mature to enter clinical or commercial discussions.

Northern Ireland specific context

EU MDR and IVDR apply to devices placed on the Northern Ireland market, while Great Britain continues to operate under the UK Medical Devices Regulations 2002, as amended. Different conformity assessment, marking and market-access arrangements may therefore apply depending on the intended market. This creates both opportunity and complexity for Northern Ireland companies. The region provides access to both UK and EU-facing markets, but innovators must understand the distinction between the regulatory routes and requirements that apply in Northern Ireland and Great Britain.

HIRANI's role within the regulatory support pathway

HIRANI support adds value before and during direct regulatory engagement. Through innovation clinics, mentoring and wider company engagement, HIRANI often encounters innovators whose initial concerns relate to funding, product development, clinical partnerships or commercialisation. Regulatory dependencies may emerge through these discussions even where regulation was not the company's original reason for seeking support.

HIRANI supports companies to:

- recognise when regulatory requirements may materially affect development;
- understand the importance of intended purpose, claims and market selection;
- identify questions requiring authoritative regulatory advice;
- connect with MHRA and specialist regulatory expertise;
- align regulatory requirements with evidence-generation plans;
- identify funding or resource requirements associated with regulatory work; and
- consider regulation alongside commercialisation and adoption.

AI-enabled digital triage

A recent HIRANI-supported case illustrates how this pathway can work in practice.

An early-stage company developing an AI-enabled digital triage technology was progressing discussions with prospective healthcare and insurance partners while also seeking to understand the appropriate medical device regulatory pathway. As commercial interest increased, questions arose around medical device status, classification, AI governance, evidence requirements and conformity assessment.

The case illustrates a common innovation challenge: commercial development can progress faster than regulatory readiness.

HIRANI's role was not to provide a definitive regulatory determination. Instead, the company was supported to recognise the importance of the regulatory questions, pursue authoritative advice and integrate regulatory planning into

its wider development pathway. The innovator subsequently engaged directly with the MHRA and sought specialist regulatory support to develop a more structured approach to intended purpose, risk management, clinical evaluation, quality management and market strategy. The significance of the case is not the individual regulatory outcome. It is the process by which an early regulatory dependency was identified and connected to appropriate support.

The pathway can be summarised as:

- Innovation or commercial opportunity
- Regulatory dependency identified
- HIRANI navigation and support
- MHRA engagement and specialist regulatory input
- Regulatory work integrated with evidence, funding and product development
- Improved readiness for adoption and market access

The case also demonstrates how regulatory questions can emerge directly from commercial engagement. Potential adopters may require clarity regarding regulatory status and AI governance before progressing a pilot or implementation. Being able to demonstrate that an appropriate regulatory pathway is being followed can therefore support confidence in further engagement.

The case supports a broader rationale for integrating regulatory readiness within regional innovation support. Regulatory support should not be viewed only as assistance with obtaining a CE or UKCA mark. It should begin earlier, when decisions about intended purpose, claims, evidence, risk, markets and product design are still being made.

HIRANI is well placed to identify these needs because it engages companies across multiple stages of innovation and commercialisation. Embedding regulatory readiness questions within innovation clinics and other support activities could help identify regulatory dependencies earlier and direct companies efficiently towards MHRA or specialist advice.

The strengthened MHRA presence in Northern Ireland provides an opportunity to formalise this pathway.

A place-based model could operate as follows:

- Innovator or researcher
- HIRANI / Invest NI innovation support

- Regulatory need identified
- MHRA clinic or appropriate specialist engagement
- Regulatory requirements integrated into development plans
- Evidence, funding and commercialisation activities aligned
- Greater readiness for clinical adoption and market entry

This model is particularly relevant in Northern Ireland because innovators must navigate the interaction between NI, GB and EU regulatory arrangements. The wider value of HIRANI is in supporting innovators to access it earlier and use it more effectively. By incorporating regulatory readiness into wider innovation support, HIRANI can help ensure that regulatory requirements are considered alongside product, evidence and commercial development, reducing the risk that they emerge as a late-stage barrier to adoption.