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ABHI REGULATORY ROUND UP - MHRA

Dec 2025/Jan 2026

A concise overview of UK MHRA developments in medical devices, IVDs, and digital health, with practical insights for ABHI members navigating evolving frameworks, standards, and stakeholder engagement.

UPDATES FROM MHRA

SUBJECT	UPDATE	RELEVANCE
Clinical investigations for medical devices (Guidance)	Guidance on 60-day assessment timelines, submission via IRAS and reporting via MORE.	Operational points for planning UK device investigations, budgeting and timelines.
	SME payment easements retained; Pilot fee waiver for micro/small UK enterprises (5 Jan–31 Mar 2026, up to 10 waivers).	Fee waiver pilot may benefit SMEs;
	IMP+Device process effective 5 Jan 2026 to align device and CTIMP assessments.	Study sponsors should adjust submissions to the new IMP+Device sequencing.
	Plus various other minor formatting changes. This webpage is frequently updated.	
In Vitro Diagnostics Medical Device Roadmap (v1.0)	Sets 2026–2027 deliverables on SaIVD guidance, CDx evidence routes and integrated pathways. Signals adoption of IMDRF clinical evidence framework for pandemic pathogens and expansion of reference materials.	Forward look for IVD manufacturers planning evidence strategies, CDx collaborations and standards usage.
Designated standards – IVD devices: proposal to amend (Notice 0128/26)	Update to GB designated IVD standards.	Check QMS and technical documentation mappings; plan transitions.
Designated standards – Medical devices: proposal to amend (Notice 0129/25)	Update GB designated medical device standards.	Check QMS and technical documentation mappings; plan transitions.

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A LinkedIn post from Mark Grumbridge at MHRA that I thought was worth (re)sharing	*"Dear Network* *One ambition of the clinical investigations team in 2025 was to try and reduce the number of invalid submissions. Whilst we have made some progress, we are still receiving a significant number.* *I have listed below the most common reasons for an invalid submission* *Labelling not correct* *Incomplete software plans* *Risk documentation missing* *GSPR missing* *List of applicable standards missing* *CV's missing* *Cover letter missing* *Sterilisation report missing* *Biocompatibility report missing* *Missing electrical safety information* *I'm sure you will agree an invalid submission is time consuming and costly, so I want to flag again the following,* *Clinical investigations guidance – this contains a wealth of information and guidance including flow charts and guidance from our internal assessors* *Validation checklist – this is the same list the team use to validate the submission so please ensure you refer to it to avoid delays* *We hope this is helpful and please do not hesitate to reach out before submitting an application if you need any clarification on the process"*	Highlights common validation failures and reinforces the need for complete technical, risk and labelling documentation. Useful for sponsors to reduce avoidable delays.
Clinical trials that include an in vitro diagnostic device (Guidance)	Guidance for CTIMPs using IVDs, including companion diagnostics, with GB sites.	Supports alignment between medicine trials and diagnostics.
	Clarifies documentation where the device is not UKCA/CE and HIE does not apply; adds a one-page process flow.	Sponsors using IVDs in CTIMPs should check the clarified evidence expectations.

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Patients to benefit sooner as UK boosts clinical trials attractiveness (Press release)	MHRA outlines 2026 reforms including fast-track notification for lower-risk trials and a 14-day Phase 1 route Reports 2025 increase in trial activity and 75% rise in scientific advice meetings.	Policy change that may influence study set-up timelines and interfaces with IMP+Device processes.
Regulation of AI in Healthcare (Open call for evidence)	MHRA invites evidence to inform the National Commission into the Regulation of AI in Healthcare. Call closes 2 Feb 2026; background materials outline current frameworks and AI use cases.	Opportunity for ABHI members to shape AIaMD policy including transparency, PCCPs and post-market expectations.
Guest blog: Chris Kessler: How access to innovative rare therapies can transform the lives of children like Charlie	A story of hope, medical innovation, and the impact of effective regulation on access to treatment.	Although the story is mainly about treatment options, it also shows why the healthtech industry is essential for children like Charlie – we develop the early diagnostics, monitoring tools and innovative technologies that give families real choices and the possibility of better outcomes.
Guidance Centres of Excellence for Regulatory Science and Innovation (CERSIs)	CERSIs aim to drive the development of safer and more effective medicines and medical products and ensure timely access for patients. By establishing a network of centres, launched in early 2025, CERSIs represent a landmark initiative in regulatory science. CERSIs foster collaboration between academia, industry and regulators to accelerate the delivery of safe innovation in human health.	We anticipate some helpful outputs from the UK CERSIs across a range of health technologies
Collection Digital mental health technology	Added link to news story: MHRA and NICE receive £2 million from Wellcome to improve safety and effectiveness of digital mental health technologies	Additional funding will allow the MHRA and NICE to continue developing clear, proportionate guidance for digital mental health technologies, supporting safer, more effective tools for people across the UK.

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News story Strengthening collaboration between the MHRA and the Department of Health Northern Ireland	The MHRA and Northern Ireland partners are working together to support innovation, enhance patient safety and ensure people in Northern Ireland benefit from world-class regulation.	Signals continuing alignment of regulatory oversight across the UK and NI, relevant for manufacturers supplying NI under the current dual system.
Press release UK and Singapore launch a regulatory innovation corridor to speed up access to breakthrough health technologies	Patients in the UK and Singapore could gain faster access to cutting-edge healthcare innovations under a new partnership bringing two globally respected regulators together with one of the world's leading biotech creators.	Developers will be able to seek early, informal joint advice, helping them plan ahead and design better clinical studies, avoid duplication and cut delays.
News story MHRA updates guidance on the Health Institution Exemption to support safe use of medical devices	Updated MHRA guidance will help health institutions, such as NHS Trusts and Boards, safely design and make general medical devices for patients. IVD guidance remains unchanged	Important for organisations designing or modifying devices inhouse or who supply research use (RUO) devices to health institutions.
Guidance Legal requirements for specific medical devices	Prosthetic, orthotic and ophthalmic devices including custom-made devices	How to comply with the legal requirements,
Guidance Medical devices: conformity assessment and the UKCA mark	How to conform with the legal requirements for placing medical devices on the market. Updated 'Conformity assessment routes flowchart'.	Practical reference for manufacturers planning GB regulatory routes during the transition period and when assessing NI/UK divergence.
News story Professor Bola Owolabi CBE: Creating the Climate for Health Equity	Exploring the MHRA's transformational impact on access, experience, and outcomes.	Provides context on MHRA's broader health equity priorities which may influence future regulatory expectations, including evidence requirements.

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Transparency data MHRA Performance Data	All clinical Investigation application assessments completed within target	Useful for monitoring assessment timelines, resourcing trends and operational predictability across MHRA functions.
Press release MHRA welcomes Professor Jacob George as he starts Chief Medical and Scientific Officer role	In this new role, Professor George will lead the Agency's science strategy and will oversee the MHRA's scientific, research and innovation activities.	Leadership change that may shape MHRA's scientific strategy, innovation priorities and engagement with industry.
Guidance Medical devices: get regulatory advice from the MHRA	How to apply for a regulatory advice meeting on medical devices and in vitro diagnostic devices.	This service provides regulatory advice meetings relating to medical devices, particularly where the application of existing regulatory guidance is not straightforward.

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