

SUMMARY MINUTES OF THE INTERIM DEVICES WORKING GROUP MEETING HELD ON 8TH SEPTEMBER 2026

Information is being withheld, under Section 43 of the Freedom of Information Act 2000, on the grounds that information regarding the issue under consideration and advice from the IDWG remains confidential at the date of this summary and will remain so until a final decision has been taken. Any request for future information should be made direct to the MHRA (via info@mhra.gov.uk) and will be considered in accordance with the FOI Act.

The Group considered and discussed the following:

- The Group considered the evidence presented concerning a neonatal resuscitation unit where the manufacturer was undertaking a Field Safety Corrective Action.
- The Group discussed the role of research studies in generating evidence where direct participant benefit may not be expected, including situations where important scientific or translational questions cannot be adequately addressed through pre-clinical, animal, simulation, or modelling studies alone. Discussion focused on the importance of clear justification, appropriate governance and oversight, the definition of participant benefit, and ensuring that studies contribute meaningful evidence generation rather than speculative or poorly defined research.
- The Group were presented with an update on the review of reports of suture breakage with an introducer kit used for gastrostomy feeding tube insertion. The Group supported the proposed actions.
- The Group received an update on the forthcoming publication of the National Commission into the Regulation of AI in Healthcare recommendations report, due to be published on 10th September 2026. The Group heard that the recommendations are grounded in an extensive programme of research and engagement, bringing together evidence from patients and the public, healthcare professionals, industry, academics and wider health system stakeholders through a Call for Evidence, public engagement, specialist working groups and wider research and engagement. The Group noted the report's key principles, including proportionate, lifecycle-based regulation; a system-wide approach to responsibility and safe management; and enhancing trust, transparency and predictability in the regulation of AI technologies.
- The Group was presented with a high-level summary of signals concerning medical devices assessed by the MHRA in June and July 2026.
- The Group was provided with a presentation on MHRA's Early Access Service which aims to enable safe, earlier access to innovative medical devices addressing unmet clinical needs. It will provide conditional market access and bridge access between clinical investigations and regulatory approval. The presentation covered a timeline for delivery of the service.
- The Group was provided with a presentation on how the MHRA MRI safety guidance has been updated. The presentation covered a rationale for the continued need to issue guidance and provided an overview of the changes.

Procedural Items

In addition, the Group completed its usual procedural business including the need to observe the confidentiality of the meeting, to declare interests, apologies, announcements, approval of minutes, and updates on items previously considered. No conflicts of interest were declared.

A list of members who participated in the meeting is at **Annex A**. Medicines Healthcare products Regulatory Agency staff may be present for all or part of the meetings or for specific items.

The meeting started at 10:03 and finished at 12:35. The next meeting is scheduled to take place on 6th October 2026 at 10:00.

Useful website links

MHRA Website:

[Medicines and Healthcare products Regulatory Agency - GOV.UK \(www.gov.uk\)](https://www.gov.uk/medicines)

MHRA Alerts, recalls and safety information:

[Alerts, recalls and safety information: drugs and medical devices - GOV.UK \(www.gov.uk\)](https://www.gov.uk/alerts-recalls-safety)

Yellow Card Website:

[Yellow Card Scheme - MHRA](https://www.mhra.gov.uk/yellowcard)

Drug Safety Update:

[Drug Safety Update - GOV.UK](https://www.gov.uk/drug-safety-update)

MEMBERSHIP OF THE INTERIM DEVICES WORKING GROUP

Post	Name and title	Affiliations
Chair	Professor Tom Clutton-Brock MBE MB ChB FRCP FRCA FFICM	Director, Medical Devices Testing and Evaluation Centre, Clinical Director, NIHR HealthTech Research Centre in Devices, Digital and Robotics (HRC-DDR), Chair, NICE Diagnostics Advisory Committee (DAC), Associate Medical Director, University Hospitals Birmingham NHS Foundation Trust, Professor of Anaesthesia & Intensive Care Medicine, University of Birmingham
Member	Mr Jonathan Boyle MB ChB MD MA (Cantab) FRCSEd FRCSEng FRCS (Gen.Surg)	Consultant Vascular Surgeon and affiliate Assistant Professor, Cambridge University Hospitals NHS Trust
Member	Professor Richard Bulbulia MA MD FRCS FRCS(Gen)	Associate Professor, Clinical Trial Service Unit and Epidemiological Studies Unit, Nuffield Department of Population Health, University of Oxford; Medical Research Council Population Health Research Unit at the University of Oxford; Honorary Consultant Vascular Surgeon, Gloucestershire Hospitals NHS Foundation Trust
Member	Professor Alastair Denniston MA MRCP FRCOphth PhD	Chair of Regulatory Science and Innovation, University of Birmingham Hon Consultant Ophthalmologist, University Hospitals Birmingham NHSFT
Lay Member	Dr Rebecca Harmston	
Member	Mr Michael Hart BSc (Hons) MBChB AHEA PhD FRCSEd (Neuro.surg) FEBNS (<i>apologies</i>)	Senior Lecturer & Honorary Consultant Neurosurgeon, St George's, University of London & St George's University Hospitals NHS Foundation Trust
Member	Professor Chris Hopkins BSc (Hons) FAHCS FIPEM CEng MIET (<i>apologies</i>)	Consultant Clinical Scientist, Honorary Professor and Clinical Director, Assistive Technologies Innovation Centre, University of Wales Trinity Saint David, Head of the Tritech Institute, Hywel Dda University Health Board, Assistant Director of Health Science and AHP's, Betsi Cadwaladr University Health Board, President-Elect of Academy for Healthcare Science
Observer	Farhan Ismail	Associate Director, Office for Digital Health and Medtech Topic Intelligence, National Institute for Health and Care Excellence
Member	Mr Sebastian Janner MSci MSc	Clinical Scientist, Royal Brompton and Harefield Hospitals
Observer	Sarah Jennings	Patient Safety Clinical Lead - Medical Devices, NHS England

Invited Expert	Dr Kathryn Johnson MBChB FRCPCH	Consultant Neonatologist & Research Lead. Leeds Teaching Hospitals NHST, Clinical Lead, National Disease Registration Service (NDRS), NHS England; Vice Chair of Commission on Human Medicines' Paediatric Medicines Expert Advisory Group
Member	Professor Tom Joyce PhD MSc Beng	Professor of Orthopaedic Engineering, Newcastle University
Member	Professor Daniel Martin OBE BSc MB ChB PhD FRCA FFICM	Professor of Perioperative and Intensive Care Medicine, Peninsula Medical School, University of Plymouth
Member	Dr Rubeta Matin PhD BSc (Hons) MBBS FRCP(Derm) <i>(apologies)</i>	Consultant Dermatologist, Oxford University Hospitals NHS Foundation Trust; Honorary Senior Clinical Lecturer, University of Oxford
Member	Dr Tom Pelly MBBS BSc (Hons) DCH PGCE FRCP FRCGP	GP Partner, Horfield Health Centre, Bristol; Clinical Director, Phoenix Primary Care Network, Bristol; RCGP Representative
Member	Professor Muireann Quigley BSc (Med) BSc (Hons) MBChB MA PhD	Chair in Law, Medicine, and Technology, Birmingham Law School, University of Birmingham
Observer	Iain Robertson	Medical Advisor Medical Devices and Legislation Unit, Scottish Government
Member	Dr Neil Smart BSc (Hons) MBChB FCAI MBA	Chair of the Scottish Health Technologies Group, Consultant Anaesthetist NHS Greater Glasgow and Clyde and Honorary Clinical Senior Lecturer, University of Glasgow
Lay Member	Ms Josephine Tapper <i>(apologies)</i>	