

SUMMARY MINUTES OF THE INTERIM DEVICES WORKING GROUP MEETING HELD ON 10TH DECEMBER 2024

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.

Papers for advice

- The IDWG discussed the safety, performance, and training requirements for an enteral access system. Discussion regarding the device's role for NG tube placement confirmation took place, and adherence to NHS England guidelines remains essential. The Group supported the addition of revised contraindications and highlighted the importance of comprehensive training, recognising the respective roles of manufacturers and Trusts in ensuring safe use.
- The IDWG continued to consider the evidence presented from the evaluation of risks associated with surgical mesh used for rectopexy. Proposed actions were presented, which were endorsed by the Committee.
- The IDWG was provided with a presentation on how newly proposed guidance has been developed as part of the MHRA and NICE 3-year Wellcome funded project to explore the regulation and evaluation of digital mental health technologies (DMHTs) that qualify as Software as a Medical Device (SaMD).

This was following an update item presented to the IDWG in September 2024, which outlined the full scope and proposed outputs of the project.

The presentation covered all aspects of the mechanisms of engagement undertaken to develop the guidance with stakeholders and the IDWG were asked whether they endorsed the guidance content and format that was presented.

The IDWG were overwhelmingly in favour of the guidance, welcoming its diligent approach to development in collaboration with relevant stakeholders and the content which was deemed to be highly valued to provide clarity for developers seeking to deploy products and understand their regulatory obligations for DMHT SaMD.

Other items

- The IDWG was provided with an update about an automated external defibrillator.
- The IDWG were presented with a high-level overview of the role of the MHRA's Innovation Office.

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. Stephen Taylor declared personal interests in one or more agenda items and the appropriate action was taken.

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 10:04 and finished at 12:42.

The next meeting is scheduled to take place on 14th January 2025 at 10:00.

Useful website links

MHRA Website:

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

MHRA Alerts, recalls and safety information:

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

Yellow Card Website:

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

Drug Safety Update:

<http://www.mhra.gov.uk/Publications/Safetyguidance/DrugSafetyUpdate/index.htm>

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 Interventional Procedures Advisory Committee, 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, University Hospital Southampton
Member	Professor Richard Bulbulia MA MD FRCS FRCS(Gen) (<i>apologies</i>)	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	Consultant Ophthalmologist (Uveitis and Medical Retina), University Hospitals Birmingham NHSFT, Honorary Professor and Deputy Director Centre for Regulatory Science and Innovation, University of Birmingham
Lay Member	Dr Rebecca Harmston	
Member	Mr Michael Hart BSc (Hons) MBChB AHEA PhD FRCSEd (Neuro.surg) FEBNS	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	Consultant Clinical Scientist, Honorary Professor and Clinical Director, Assistive Technologies Innovation Centre, University of Wales Trinity Saint David, Head of the Trittech Institute, Hywel Dda University Health Board, Assistant Director of Health Science and AHP's, Betsi Cadwaladr University Health Board
Member	Mr Sebastian Janner MSci MSc	Clinical Scientist, Royal Brompton and Harefield Hospitals
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
Invited Expert	Dr Gerri Mortimore PhD MSc Advanced Practice PgCert (IPPE) Ba(Hons) Health Studies iLM RGN NMP FHEA	Senior Lecturer Advanced Practice; NICE Nurse Expert Advisor & Member of Commission on Human Medicines (CHM)
Member	Professor Muireann Quigley BSc (Med) BSc (Hons) MBChB MA PhD	Chair in Law, Medicine, and Technology, Birmingham Law School, University of Birmingham
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	
Invited Expert	Stephen Taylor	Critical Care and Research Lead / Nutrition & Dietetics, North Bristol NHS Trust
Observer	Peter Barry	Consultant Clinical Advisor, Centre for Guidelines, National Institute for Health and Care Excellence
Observer	Sarah Jennings	Patient Safety Clinical Lead - Medical Devices, NHS England
Observer	Iain Robertson	Medical Advisor Medical Devices and Legislation Unit, Scottish Government