IMDRF International Medical Device Regulators Forum

UK Regulatory Update

Dr Laura Squire

26th September 2023

Overview

- Progress on UK regulatory framework
- How we are supporting innovators
- International recognition

Progress on UK regulatory changes.

Progress	Purpose	Date (actual/estimated)
Transitional arrangements	Amended The Medical Device Regulations 2002 (SI 2002 No 618, as amended) (UK MDR) to extend the acceptance of CE marked medical devices on the Great Britain market, to support the ongoing safe supply of medical devices to GB and ease the transition to the future regulatory framework .	In force from 1 July 2023
Doubling UK CAB Capacity	The Medicines and Healthcare products Regulatory Agency (MHRA) has designated three new UK Approved Bodies, almost doubling the UK's capacity to certify medical devices, supporting faster certification of safe and effective medical devices for healthcare professionals and the public.	Announced August 2023
Post Market Surveillance	Bring into force the new post-market surveillance requirements for CE marked and UCKA devices as laid out in the government response to the public consultation	WTO consultation period for statutory instrument ends this week
Part 1 – to put in place essential elements of the UK regime.	Lay a statutory instrument to bring into force the essential elements of the strengthened UK regime as laid out in the government response to the public consultation.	2024, to be in force by 2025.

How we are supporting Innovators - Innovative Devices Access Pathway (IDAP).

Aims to develop a new **pre-market** pathway for medical devices that:

- Supports innovative medical devices (including diagnostics and digital health technologies) that meet unmet needs in the health and care system and that do not currently have regulatory authorisation in the UK
- Provides access support on post-marketing surveillance requirements, further evidence generation for HTA and docking with reimbursement pathways

Healthcare Improvement Scotland | SHTG Advice on health technologies

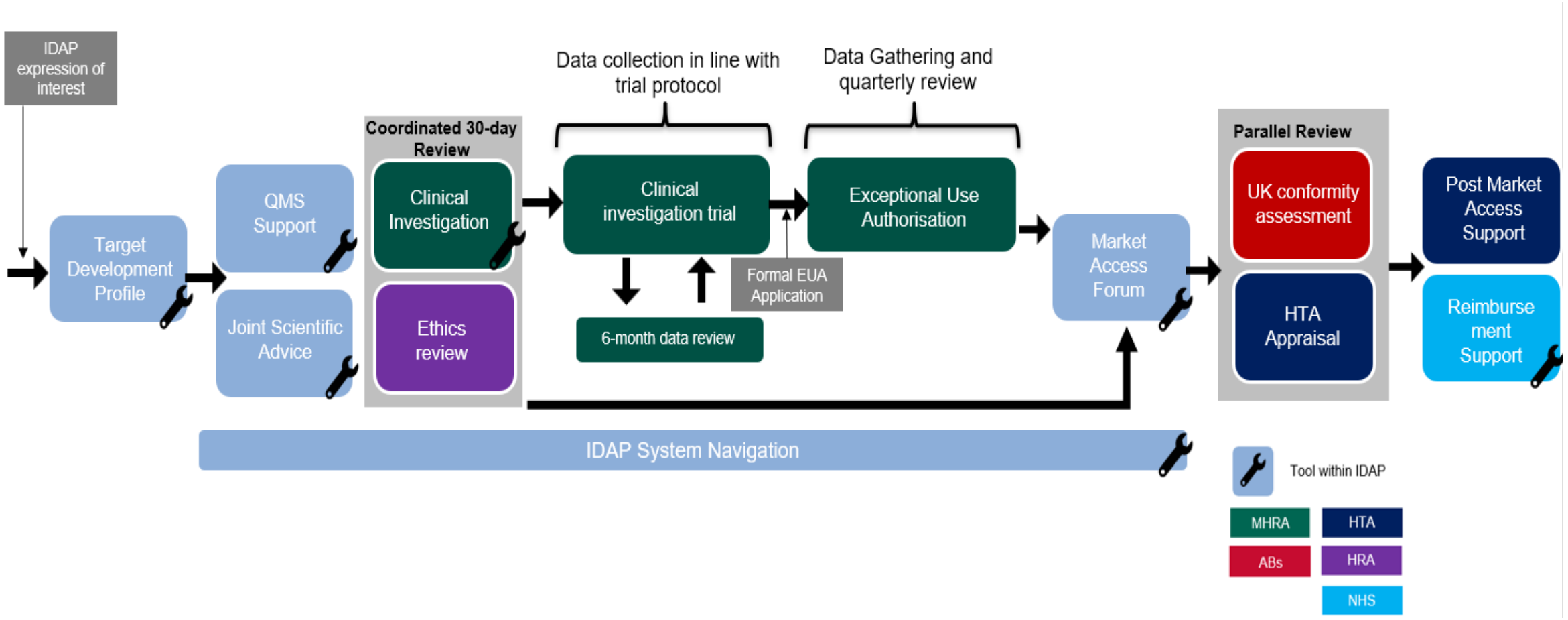
NICE National Institute for Health and Care Excellence

Medicines & Healthcare products Regulatory Agency

NHS England

Technoleg Iechyd Cymru Health Technology Wales

The IDAP Pilot Model



International Recognition

"From 2024, [MHRA] will move to a different model which will allow rapid, often near automatic sign-off for medicines and technologies already approved by trusted regulators in other parts of the world such as the United States, Europe or Japan.

At the same time from next year they will set up a swift new approval process for the most cutting-edge medicines and devices to ensure the UK becomes a global centre for their development"

Artificial Intelligence/Machine Learning-Enabled (AI/ML) Working Group

Dr Laura Squire – Chief Officer – UK MHRA

Background

- Established in summer 2023. The AI/ML Working Group (WG) seeks to prioritise consensus in the AI/ML sector, where rapid technological advancements and an influx of manufacturers from sectors beyond medical devices is seen.
- Regulatory consensus for AI/ML has a close interplay with Software as a Medical Device (SaMD) for many jurisdictions, it's therefore also a priority to maintain alignment with broader software guidance.
- The working group convenes monthly and held its first meeting on September 13th 2023.
- Currently the working group is reviewing a published document on Good Machine Learning Practice (GMLP) as a starting point for an IMDRF documents.

Guiding Principles for Good Machine Learning Practice (GMLP)*

- GMLP are accepted practices in AI/ML product development, evaluation, and monitoring that can help facilitate the safety and effectiveness of machine learning-enabled medical devices.
- Guiding principles for GMLP are intended to promote and align efforts for the development and identification of GMLP.

Good Machine Learning Practice for Medical Device Development: Guiding Principles	
1. Multi-Disciplinary Expertise are Leveraged Throughout the Total Product Life Cycle	2. Good Software Engineering and Security Practices are Implemented
3. Clinical Study Participants and Data Sets are Representative of the Intended Population	4. Training Data Sets are Independent of Test Sets
5. Selected Reference Datasets are Based Upon Best Available Methods	6. Model Design is Tailored to the Available Data and Reflects the Intended Use of the Device
7. Focus is Placed on the Performance of the Human-AI Team	8. Testing Demonstrates Device Performance during Clinically Relevant Conditions
9. Users are Provided Clear, Essential Information	10. Deployed Models are Monitored for Performance and Re-training Risks are Managed

*Published October 2021 by UK MHRA, US FDA and Health Canada

Adverse Event Terminology – Maintenance Working Group

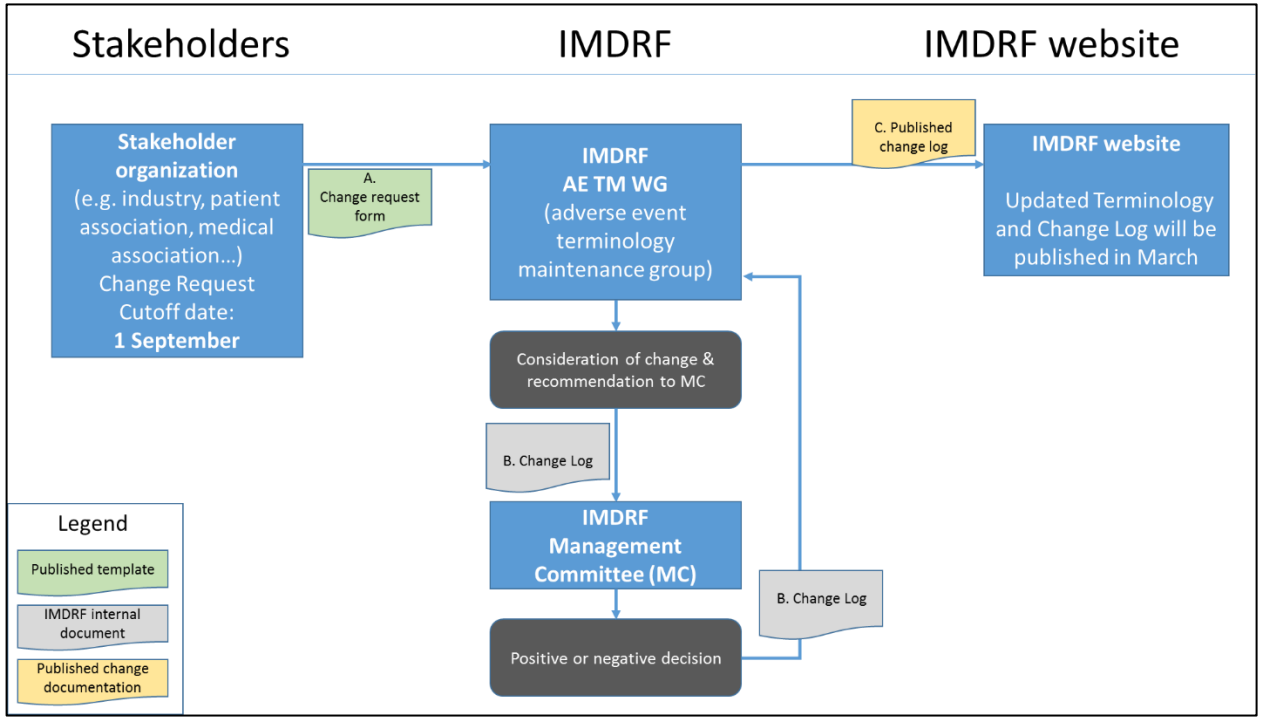
Dr Laura Squire – Chief Officer – UK MHRA

Adverse Event Terminology – Maintenance

UK now chair of Maintenance Working Group

Subgroup of main AE Terminology Working Group co-chaired by USA and EU

- 114 new or revised terms received (156 in 2022, 258 in 2021)
- Review at F2F meeting (Canada, October 2023)
- Collaborate with MedDRA on Health effect terms
- Revised version of Annexes to MC for March 2024



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Thank you/Questions