Medicines & Healthcare products Regulatory Agency

Guidance

Software and artificial intelligence (AI) as a medical device

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Contents

This publication is available at https://www.gov.uk/government/publications/software-and-artificial-intelligence-ai-as-a-medical-device/software-and-artificial-intelligence-ai-as-a-medical-device

Overview

Software (including AI) plays an essential part in health and social care. In the UK, many of these products are regulated as medical devices (or as in vitro diagnostic medical devices (IVDs). This guidance provides access to important Software Group outputs that might be of assistance.

Innovative devices: Software Group

Software Group is responsible for taking all reasonable steps to assure the safety of SaMD and ensure the UK public have access to technology that meets a clinical need. The group works across the MHRA to achieve this aim for SaMD and AIaMD through:

- assisting with pre-market and post-market enquiries from manufacturers
- conducting technical file reviews and post-market surveillance activities
- reviewing of technical and clinical aspects of clinical investigations and exceptional use authorisations
- ensuring medical device regulation is fit for purpose, meets the needs of software as well as AI, and is supported by robust guidance
- engaging with stakeholders including industry, healthcare organisations and professionals, as well as patients and public to support the functions noted above

Classify your software as a general medical device or an IVD

See our guidance on when software applications are considered to be a medical device and how they are regulated (https://www.gov.uk/government/publications/medical-devices-software-applications-apps). As Software Group works through its programme of work described in the Software and AI as a medical device change programme roadmap ('change programme') this guidance, along with other existing documents, will be updated as required.

If your product is a digital mental health technology (DMHT), we recommend you review the MHRA guidance on DMHT: device characterisation, regulatory

qualification and classification (https://www.gov.uk/government/publications/digital-mental-health-technology-qualification-and-classification).

Manufacturers as well as researchers may also wish to consult In-house manufacture of medical devices in Great Britain (https://www.gov.uk/government/publications/in-house-manufacture-of-medical-devices/in-house-manufacture-of-medical-devices) or our guidance on the Health Institution Exemption (HIE) – IVDR and MDR (Northern Ireland) (https://www.gov.uk/government/publications/mhra-guidance-on-the-health-institution-exemption-hie-ivdr-and-mdr-northern-ireland) as this may also have implications for the regulatory status of software.

Software Group also produced specific advice regarding software used during the COVID-19 pandemic (https://www.gov.uk/government/publications/regulatory-status-of-software-including-apps-used-in-the-diagnosis-treatment-and-management-of-patients-with-coronavirus-covid-19).

UK regulatory framework for software as a medical device

MHRA announced plans for an extensive change programme (https://www.gov.uk/government/publications/software-and-ai-as-a-medical-device-change-programme) and supporting roadmap to drive regulatory changes including key reforms across the software as a medical device lifecycle, from qualification and classification, to requirements that apply both pre and post-market. This programme also considers the challenges and opportunities posed by AIaMD, ensuring that these devices are appropriately evidenced, as well as addressing wider issues of transparency of AI (both explainability and interpretability), and adaptivity (retraining of AI models).

Software and AI as a medical device change programme roadmap

On 17 October 2022, the MHRA published the Software and AI as a Medical Device Change Programme Roadmap (https://www.gov.uk/government/publications/software-and-ai-as-a-medical-device-change-programme/software-and-ai-as-a-medical-device-change-programme-roadmap#introduction) that sets out further information on each work package of

the change programme, including deliverables to meet each set of broad objectives, and further information on how the broad change programme will be implemented. This page will be updated as new documents are published.

Qualification and classification

Creating an intended use statement (https://www.gov.uk/government/publications/crafting-an-intended-purpose-in-the-context-of-software-as-a-medical-device-samd) provides guidance to help manufacturers on defining intended purpose for software as a medical device (SaMD)

Post-market and vigilance

There is information for manufacturers of medical devices about reporting adverse incidents (https://www.gov.uk/government/collections/medical-devices-guidance-for-manufacturers-on-vigilance) and field safety corrective actions to MHRA. This includes specific guidance on the vigilance reporting requirements for manufacturers of software as a medical device (https://www.gov.uk/government/publications/reporting-adverse-incidents-involving-software-as-a-medical-device-under-the-vigilance-system) as part of a suite of device-specific guidance. The SaMD vigilance guidance outlines the types of events that may cause direct and indirect harm and which are considered to be reportable under the device vigilance system

If you have a problem with software as a medical or indeed any medical device, report it to MHRA using the Yellow Card scheme (https://yellowcard.mhra.gov.uk/) or via the Yellow Card app.

There are specific arrangements for healthcare professionals to follow in each of the devolved administrations.

Healthcare professionals should report incidents:

- in England and Wales to the Yellow Card scheme (https://yellowcard.mhra.gov.uk/) or via the Yellow Card app
- in Scotland to NHS National Services Scotland online incident reporting system and their local incident recording system (https://www.nss.nhs.scot/health-facilities/incidents-and-alerts/report-an-incident/)

- in Northern Ireland to the Northern Ireland Adverse Incident Centre and their local incident recording system (https://www.health-ni.gov.uk/topics/safety-and-quality-standards/northern-ireland-adverse-incident-centre-niaic)

Artificial intelligence

A Regulatory Pioneers Fund award enabled MHRA to undertake research on methodologies for determining significant change in the way adaptive AI algorithm medical device are working and how such change should be regulated. This work was done with Brunel University as an academic partner. The work included a series of workshops (https://mhra-gov.filecamp.com/s/d/nkx83MbfOhC44bEg) between October 2021 and March 2022 which have been written up as part of the final report. This is research work and is **not** a statement of MHRA policy.

MHRA and the U.S. Food and Drug Administration (FDA) and Health Canada have jointly identified 10 guiding principles (https://www.gov.uk/government/publications/good-machine-learning-practice-for-medical-device-development-guiding-principles/good-machine-learning-practice-for-medical-device-development-guiding-principles) that can inform the development of good machine learning practice (GMLP).

MHRA, FDA and Health Canada have also jointly identified 5 guiding principles (https://www.gov.uk/government/publications/predetermined-change-control-plans-for-machine-learning-enabled-medical-devices-guiding-principles) for the use of predetermined change control plans (PCCPs). These principles will help to ensure that our future guidance on PCCPs aligns internationally with these jurisdictions.

MHRA, FDA, and Health Canada have jointly established guiding principles on the transparency of machine learning medical devices (https://www.gov.uk/government/publications/machine-learning-medical-devices-transparency-principles). These transparency principles align with previously published guiding principles and offer good practice guidelines on transparency for all medical devices.

Digital mental health technology

A three-year project is now underway, focusing on effective regulation and evaluation of digital mental health technology. It is funded by the Wellcome Trust and led by MHRA. For more information see Digital mental health technology (https://www.gov.uk/government/collections/digital-mental-health-technology).

Collaborations

Software Group collaborates with several international regulators, academic groups, and UK health organisations to advance the work that is being undertaken on software and AI medical device regulation. We will highlight major programmes of partnership working with:

- the International Medical Device Regulators Forum, Software as a Medical Device Working Group (https://www.imdrf.org/working-groups/software-medical-device)
- the International Medical Device Regulators Forum, Artificial Intelligence/Machine Learning-enabled Working Group (https://www.imdrf.org/working-groups/artificial-intelligencemachine-learning-enabled)
- the AI and Digital Regulations Service for Health and Social Care (https://www.digitalregulations.innovation.nhs.uk/)
- Wellcome Trust funded project (https://www.gov.uk/government/collections/digital-mental-health-technology) on the regulation and evaluation of digital mental health technologies, led by the MHRA in partnership with NICE
- University of Birmingham, STANDING Together (https://www.datadiversity.org/)
- NHS England, AI Award
- NHS England, DART-Ed
- NHS England, Connected Medical Devices Security Steering Group