Software as a Medical Device

- Software as a medical device (SaMD): standalone software and software included in wider hardware and including artificial intelligence (AI) as a medical device (AIaMD).
- Majority of changes required in this area are likely to be in the form of guidance rather than legislation.

Scope and Definitions	• New definition of 'software' to be added to the UK medical device regulations: "A set of instructions that processes input data and creates output data."
Distance Sales	• The UK Government will further explore the scope of distance sales, aligning requirements for manufacturers that provide this from abroad with Medical Device and IVD (In vitro diagnostics) requirements for distance selling.
Airlock Classification Rule for SaMD	• Government remains interested in the potential to introduce an airlock conditional authorisation. • MHRA plans to scope further for this possible change, and potentially include in a future public consultation.
Classification: Risk Categorisation	• Government intends to amend UK Medical Device Regulations (MDR) classification rules to include the International Medical Device Regulators Forum (IMDRF) SaMD classification rule for general medical devices, with supporting definitions and implementing rules. • In Vitro Diagnostics (IVDs) will not be included at this stage as this significantly diverges from the European Union In Vitro Diagnostics Regulation (EU IVDR) classification system. • Government proposing to adopt the risk categorisation in the IMDRF Software as a Medical Device: Possible Framework for Risk Categorization and Corresponding Considerations for classifying SaMD that are general medical devices (not IVDs) with consequential implementing rules, definitions and clear guidance.
SaMD Cyber Security	• The Government wants to ensure that sufficient cyber security and information security measures are in place for SaMD – for the purpose of direct safety of the device (e.g., whether its functioning could be tampered with) and consequent impacts on patients and the public, plus the security of personal data held on or in relation to the device. • The position on cyber security is linked to that set out in the Pre-market Requirements. There is an intention to introduce a requirement akin to EU MDR General Safety and Performance Requirement (GSPR) 17.4 (for medical devices) and EU IVDR GSPR 16.4 (for IVDs) covering cyber security and associated requirements.
AI as a Medical Device	• Artificial Intelligence as a medical device (AIaMD) is a subset of software as a medical device (SaMD). MHRA considers that the changes outlined in SaMD Chapter 10 would be beneficial for the regulation of AIaMD. • The government does not propose to define AIaMD or set specific legal requirements beyond those being considered for SaMD, as this would risk being overly prescriptive. • The MHRA will issue guidance including on clinical performance evaluation methods • In relation to mandating logging of outputs to enable auditability for SaMD and AIaMD, the Government does not intend to introduce this requirement at this time.

Pre-Market Requirements

- The government intends to proceed with proposal to introduce further Essential Requirements to assure the safety & performance of SaMD specifically and additional items include:

    - **Cyber security** - policy position include cyber security as an essential requirement.
    - **Data protection, privacy, or confidentiality** – the Government will work closely with the following to ensure that patient data is protected: Department for Digital, Culture, Media & Sport (DCMS), Information Commissioner's Office, National Data Guardian, and the Health Research.
    - Improved alignment to Data Coordination Board (DCB) standards. Government working with NHS Digital and NHSX to map and align where possible, using guidance to better harmonise with these standards. Shifting essential requirements to match DCB standards would risk international divergence for the benefit of national convergence.
    - Specific requirements for AI as a medical device to be clarified via guidance on how to meet a GSPR akin to EU MDR's GSPR 17.2 (which includes verification & validation) rather than setting up a separate essential requirement / GSPR specific to AI as a medical device.

Post-Market Requirements

- Government not intending to mandate a 'report adverse incident' link at this time and will consult further. However, they are intending to proceed with proposal to enable pre-determined change control plans (PCCPs), enabled but on a voluntary basis. Government considers that proceeding with the consultation proposals on PCCPs will:

    - Implement a robust post market surveillance and MHRA market surveillance system that produces a strong and clear safety signal, allowing for quicker and thorough capture of adverse incidents for SaMD.
    - Utilise real world evidence to provide further assurance that SaMD functions as intended, maintains performance, and continues to provide assurance with respect to safety.
    - Articulate clear change management requirements for SaMD.
    - Encourage assured changes to SaMD and AIaMD that improve the performance of the devices.