Software as Medical Devices (SaMD):
Relevance for patient safety

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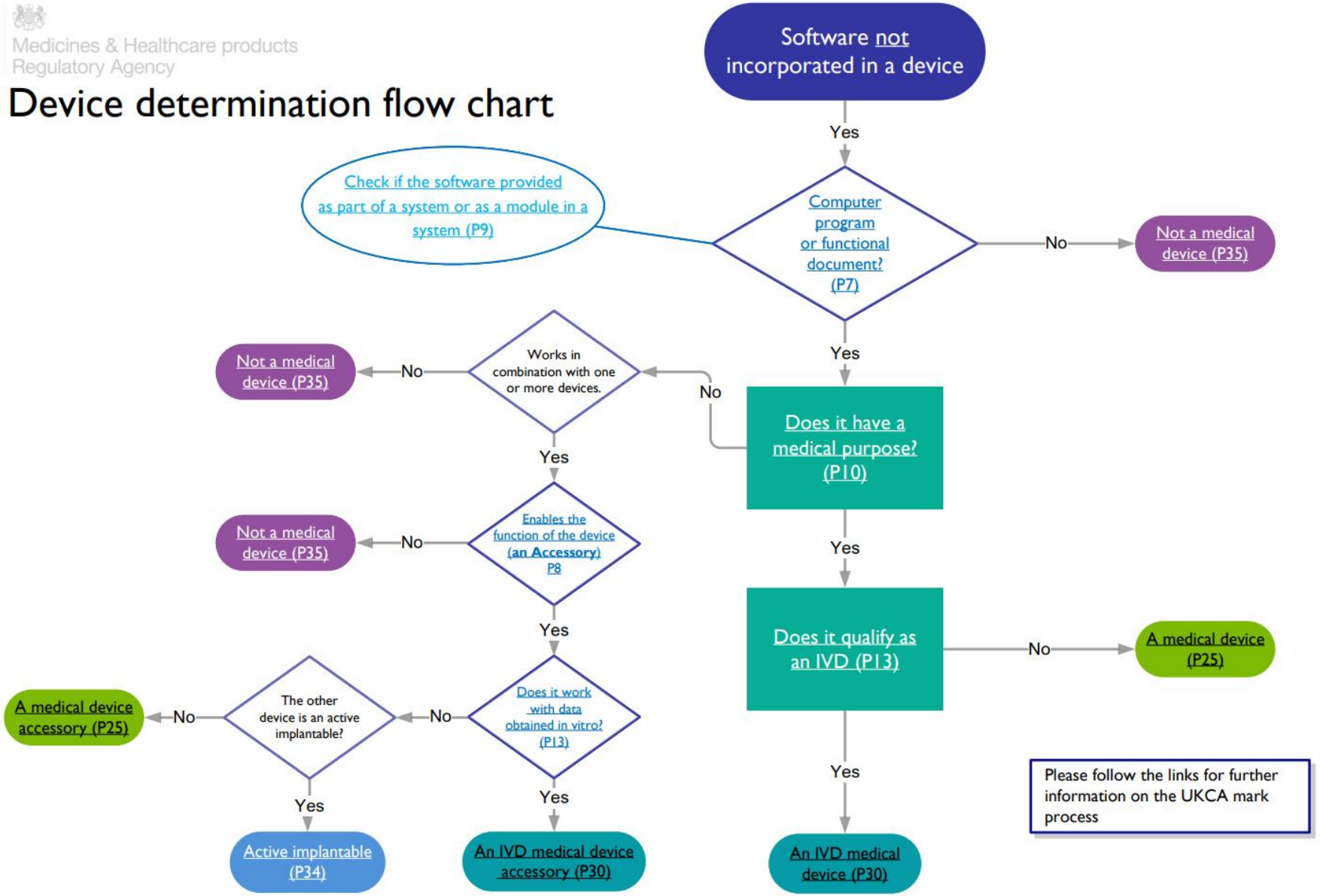
When is a software considered a SaMD?

SaMD is defined as **software** intended to be used for one or **more medical purposes that perform these purposes without being part of a hardware medical device.**

When is a software **Not** a medical device, a few examples-

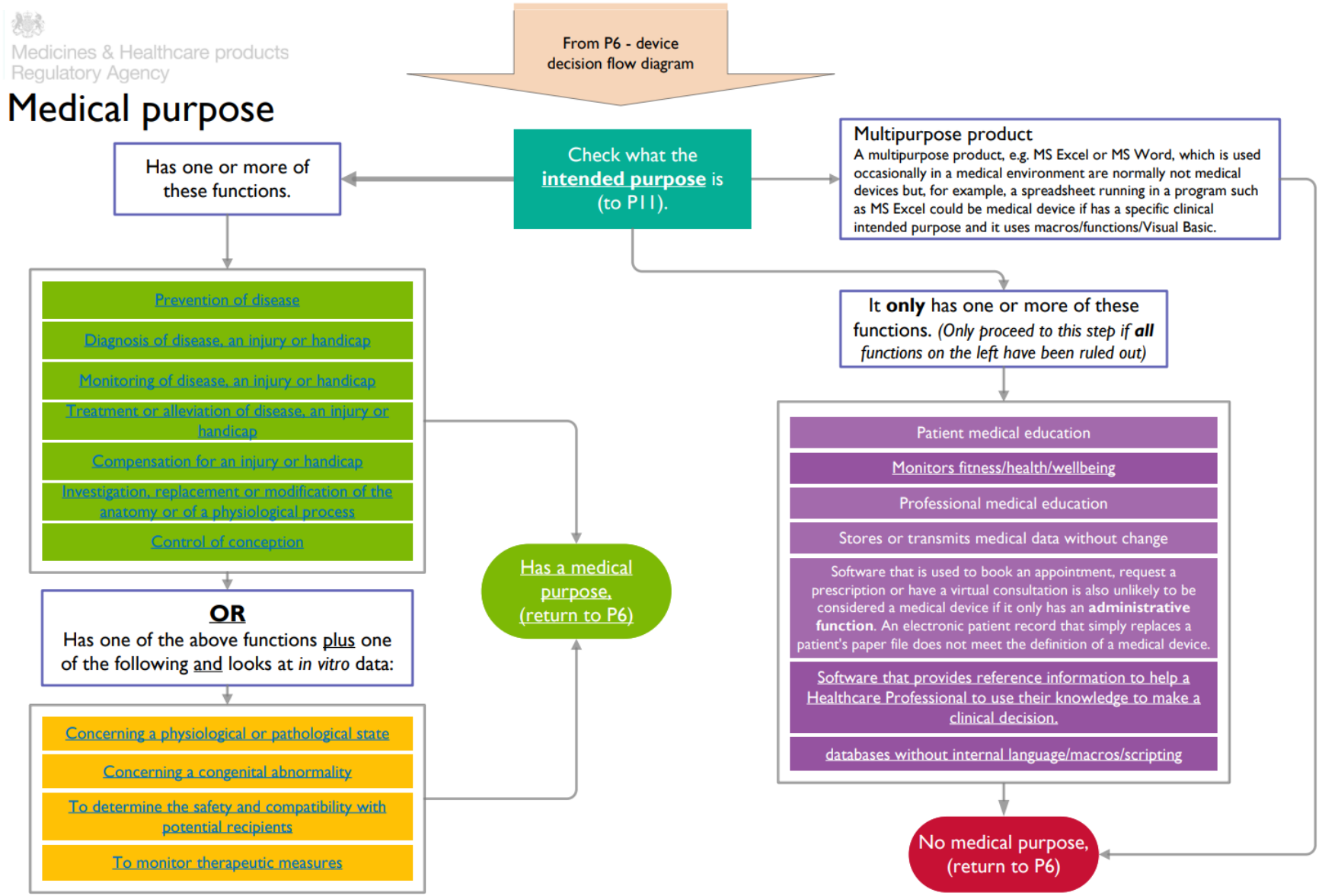
- Software that enables **clinical communication** and **workflow** including patient registration, scheduling visits, voice calling, video calling is not SaMD.
- Software to only **record data and retrieve data** like the EHRs- not a SaMD
- **Health apps** with no diagnosis, treatment or aiding in clinical decision-making such as to record steps-not a SaMD

MHRA has published some really good guidance on this topic here



Medicines & Healthcare products Regulatory Agency

Medical purpose



If the software is a SaMD…

The legal manufacturer needs to follow relevant regulatory requirements for **development**, **deployment** and **post market maintenance** to ensure product is safe and continues to be safe for clinical use.

NHS-E is the legal manufacturer of SaMDs like-

- NHS 111 Online
- Heart Age tool (on NHS.uk)
- Child BMI tool (on NHS.uk)

Registered with the MHRA as SaMDs

Compliant with regulations to ensure patient safety

Changing regulatory landscape

- **UK MDR (Medical Device Regulation) 2002** is the law governing medical devices in the UK. Based on old EU legislation MDD (Medical Device Directive)

- Many digital products are classified as **Class 1** based on this reg (lowest risk class) which means manufacturers can self-certify and register a DoC (Declaration of Conformity) with the MHRA (The regulator).

- EU has now moved to **EU MDR-** new stricter regulation

- Most software will be classed as a minimum of **Class IIa** under EU MDR rules, which means a **notified body/UK approved body** would have to review technical files and give a CE/UKCA certificate

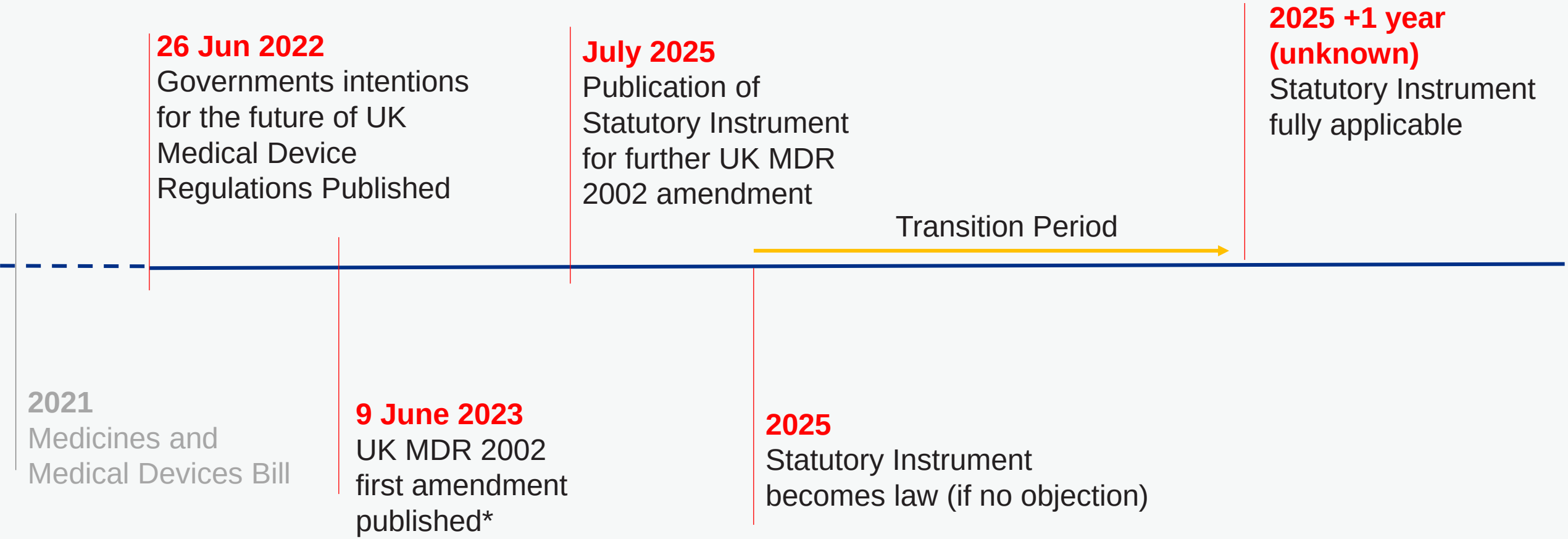
- MHRA is minded to align UK law with new EU MDR. UK MDR 2002 is currently being revised and will be published in **July 2025**

- **MHRA has indicated that the new law will follow IMDRF (International Medical device Regulatory Forum) guidance on software classification (to align with EU MDR)**

IMDFR guidance

State of Healthcare situation or patient condition	Significance of Information provided by the MDSW to a healthcare situation related to diagnosis/therapy		
	High Treat or diagnose *~ IMDRF 5.1.1*	**Medium** Drives clinical management *~ IMDRF 5.1.2*	**Low** Informs clinical management *(everything else)*
Critical situation or patient condition *~ IMDRF 5.2.1*	**Class III** *Category IV.i*	**Class IIb** *Category III.i*	**Class IIa** *Category II.i*
Serious situation or patient condition *~ IMDRF 5.2.2*	**Class IIb** *Category III.ii*	**Class IIa** *Category II.ii*	**Class IIa** *Category I.ii*
Non-serious situation or patient condition *(everything else)*	**Class IIa** *Category II.iii*	**Class IIa** *Category I.iii*	**Class IIa** *Category I.i*

Important dates for regulatory changes



**Some devices with a valid CE mark can be continued to be placed on GB market until 2028, provided certain conditions are met*

UKCA Mark

- Class 1 devices could be self-certified but Class IIa/b devices will require UK approved body review to remain on the market.

- The UK approved body will undertake a series of audit activities on the manufacturer and issue certificates accordingly. These audits need to be repeated on a rolling schedule.

- The UK AB will audit:
  - The ISO 13485 compliant Quality Management System
  - The Technical Files of each product

Key Takeaways

Software including AI software is already regulated under Medical Device Regulation

Fundamentally, the medical device regulation is asking Does the digital product work? Is it safe? Will it stay safe?

Crucial to have a clear Intended Use statement for the digital product

Prepare for the upcoming changes in the regulation in a timely manner

When deploying a new digital product

Ask yourself:

Could this be a medical device software?

Does the classification assigned by the manufacturer seem right based on the risk profile?

Can the device/manufacturer be found on the MHRA database as a registered medical device?

Thank you