



Software as a Medical Device

A Provider View

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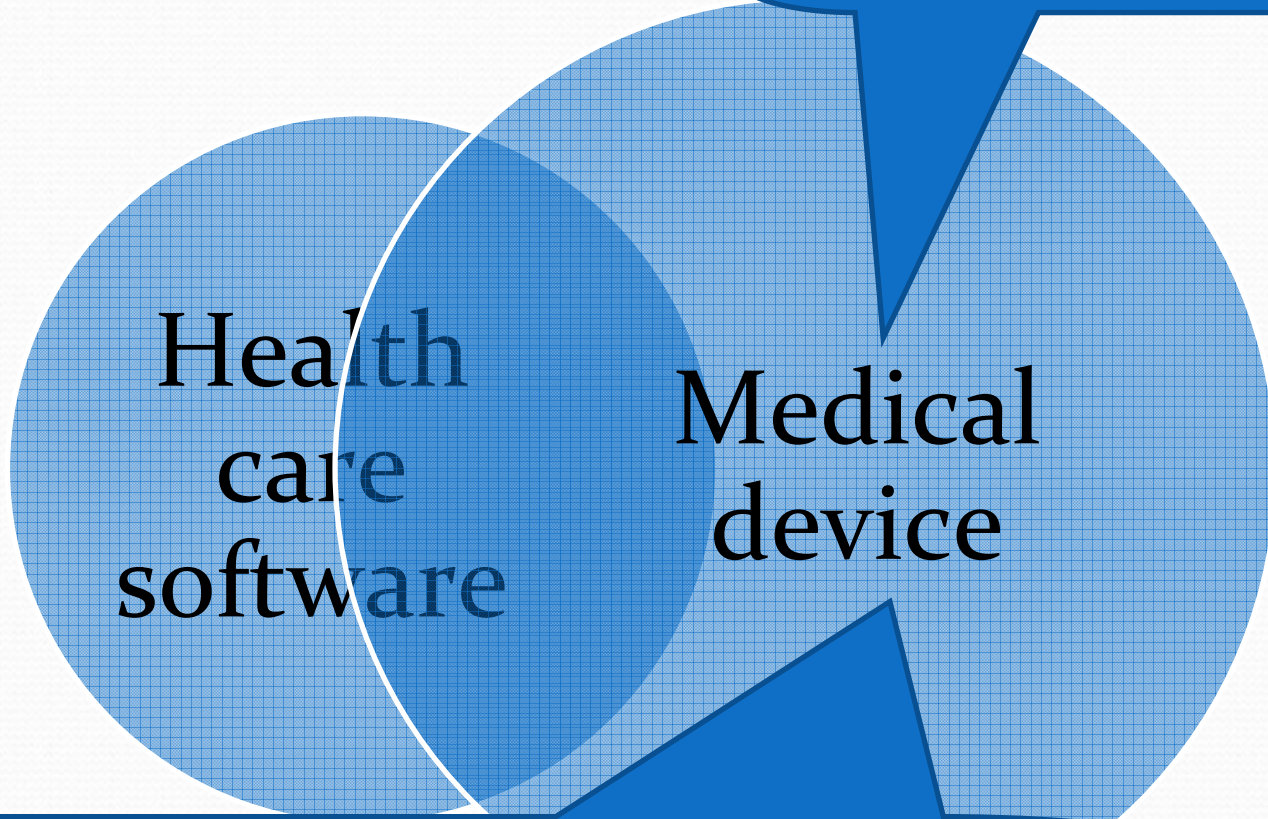


Current Approach in the UK

- Patient safety and high quality healthcare are top priorities in the UK
- Care Quality Commission is the regulator responsible for registering and monitoring quality performance of care providers
- National Patient Safety Agency monitors adverse incidents
- NHS Connecting for Health has implemented clinical safety risk management processes for software
- MHRA has on-going responsibility for regulation of medicines and devices

Why is there a problem

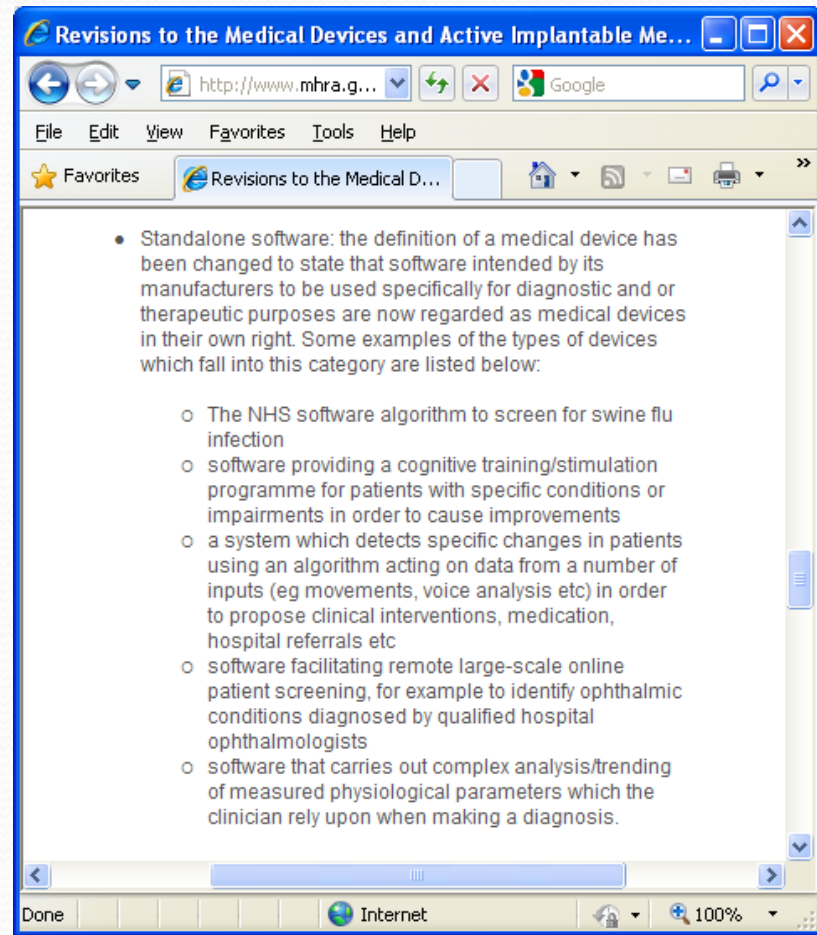
The MHRA has a tighter understanding



Some Competent Authorities in European Union countries perceive most software used by clinicians is a medical device

Medical devices

- Some, but not all software used in healthcare qualifies as a medical device in the European Union
- MHRA provide examples of software which qualifies as a medical device



- The NHS software algorithm to screen for swine flu infection
- software providing a cognitive training/stimulation programme for patients with specific conditions or impairments in order to cause improvements
- a system which detects specific changes in patients using an algorithm acting on data from a number of inputs (eg movements, voice analysis etc) in order to propose clinical interventions, medication, hospital referrals etc
- software facilitating remote large-scale online patient screening, for example to identify ophthalmic conditions diagnosed by qualified hospital ophthalmologists
- software that carries out complex analysis/trending of measured physiological parameters which the clinician rely upon when making a diagnosis.



BSI contribution

- Formed a portfolio with experts within IST35, the TC251 mirror committee to focus on Software as a medical device
- Actively supporting CEN in their contribution to the Working Group looking at the borderline and classification of software as a medical device
- Contributors include (but not limited to):
 - NHS Connecting for Health
 - Medicines and Healthcare Products Regulatory Agency



SAMD concerns

- How best to ensure patient safety and highest quality care
- IEC TC62 proposal to extend their scope to include standalone software
- Impact on ISO TC215 and CEN TC251 working arrangements
- Need effective representation from software industry, consumers and regulators
- Need for development of a new “harmonised” standard for a new essential requirement concerning software