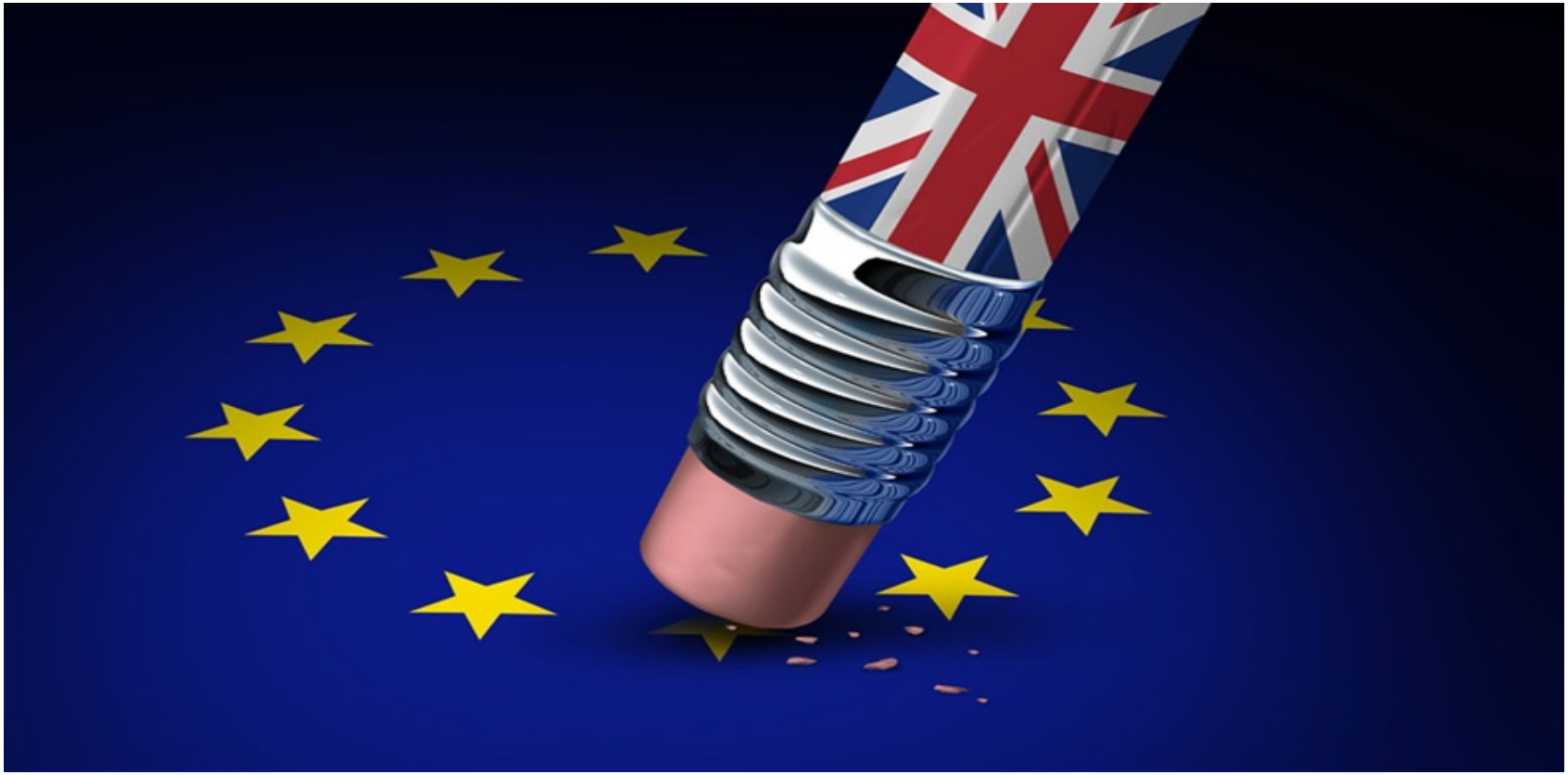
Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

New Regulations: The way ahead

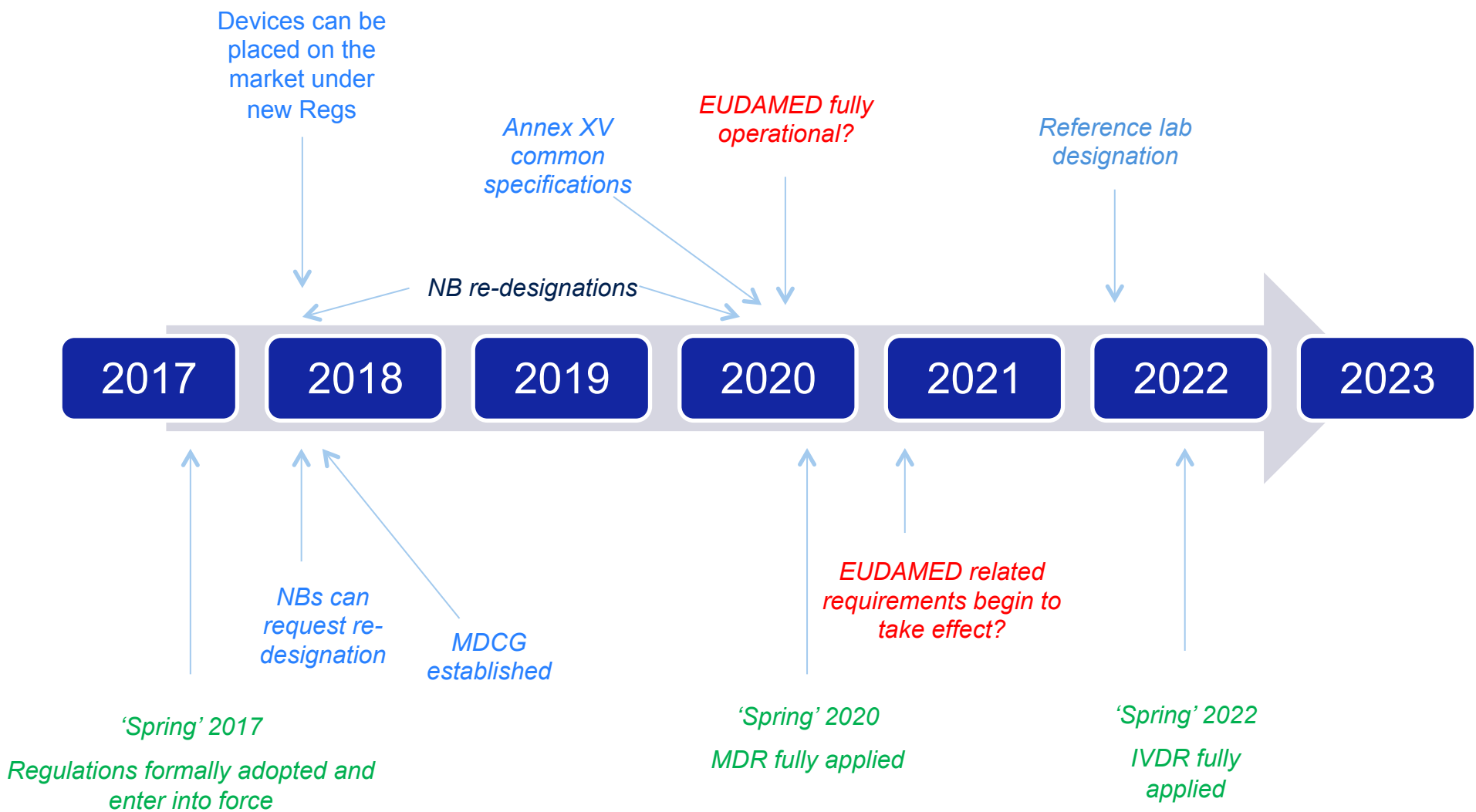
John Wilkinson, Director of Devices

Brexit

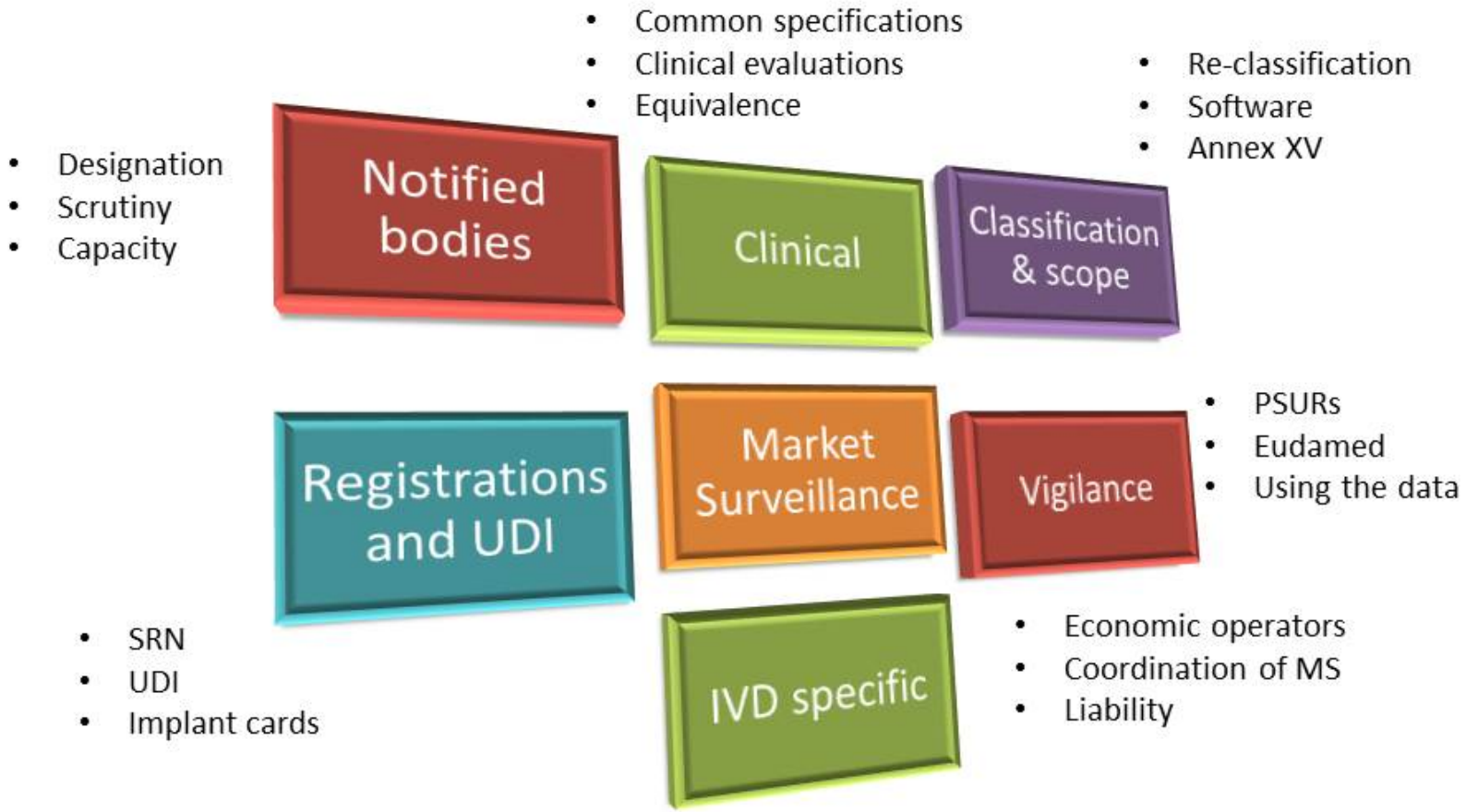


Implementation

Transition periods



EU activity; cluster approach



Implementation- European Commission

- Impact assessment
- Common specifications (e.g. Annex XV, re-processing)
- Mandatory Implementing Acts
- Eudamed

Implementation – System-wide

CAMD
Competent Authorities for Medical Devices

- Notified Body designations
- Pre-market scrutiny- expert panel/ ref lab composition
- Guidance requirements (e.g. software)
- Economic operator responsibilities/ education
- System coordination of implementation work streams

Implementation - MHRA

- Impact assessment
- Public consultation (re-processing, in-house manufacture etc.) - Caveats
- Statutory instrument
- Sanctions


Questions