# Medical Device Regulation

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# Medical Devices and Legislation Unit

- Medical device legislation and regulations
  - *Regulation is reserved and under the UK MHRA*
- Medical devices policy.
  - *Health is devolved*
- Medical devices supply.
  - *Usually UK wide but may have different impacts in each of the 4 nations*
- Medical device strategy

# *Medical Devices*

- 2 million medical devices
- Widely used in care pathways
- 1 in 10 have an  implantable device
- Highly innovative
- Relatively low barrier to  market entry
- Performance vs outcomes

**Cumberledge Report: First Do No Harm**

Rec 7: Central database linking patients to devices and linking to registers

**NHS Scotland Scan For Safety**

2022
NSS led delivery
Medical devices and Equipment

**UK MDIS**

Outcome Registries

2016 | 2020 | 2021 | 2022 | 2023 | 2024 | 2025

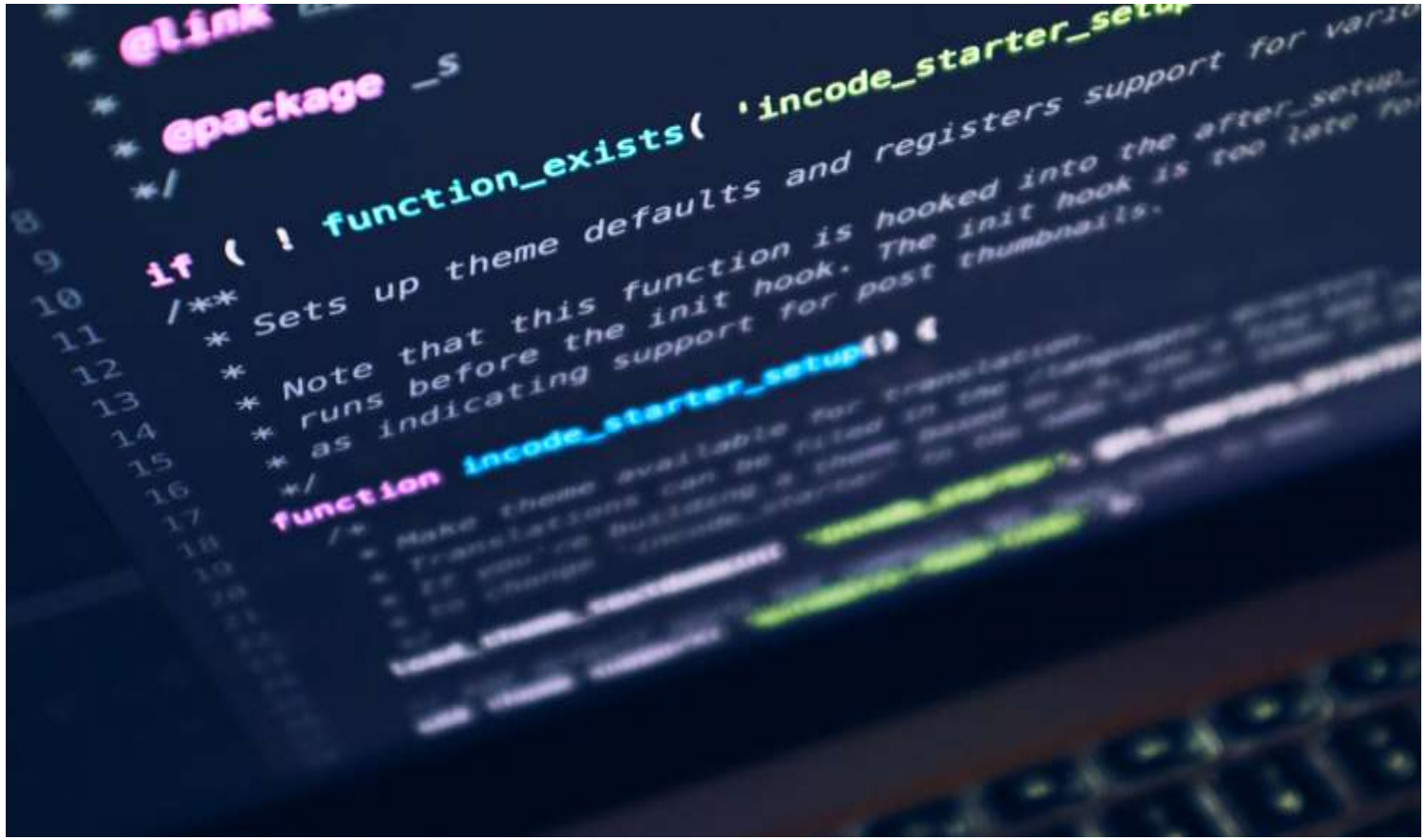
EU Exit

**Medicines & Medical Devices Act**

Framework Legislation
Clause 19 formation of UK MDIS

**UK Medical Device Regulations**

July 2024
Manufacturers must provide UDI
Health providers must store UDI for Class III and IIb devices




# New Medical Device Regulation

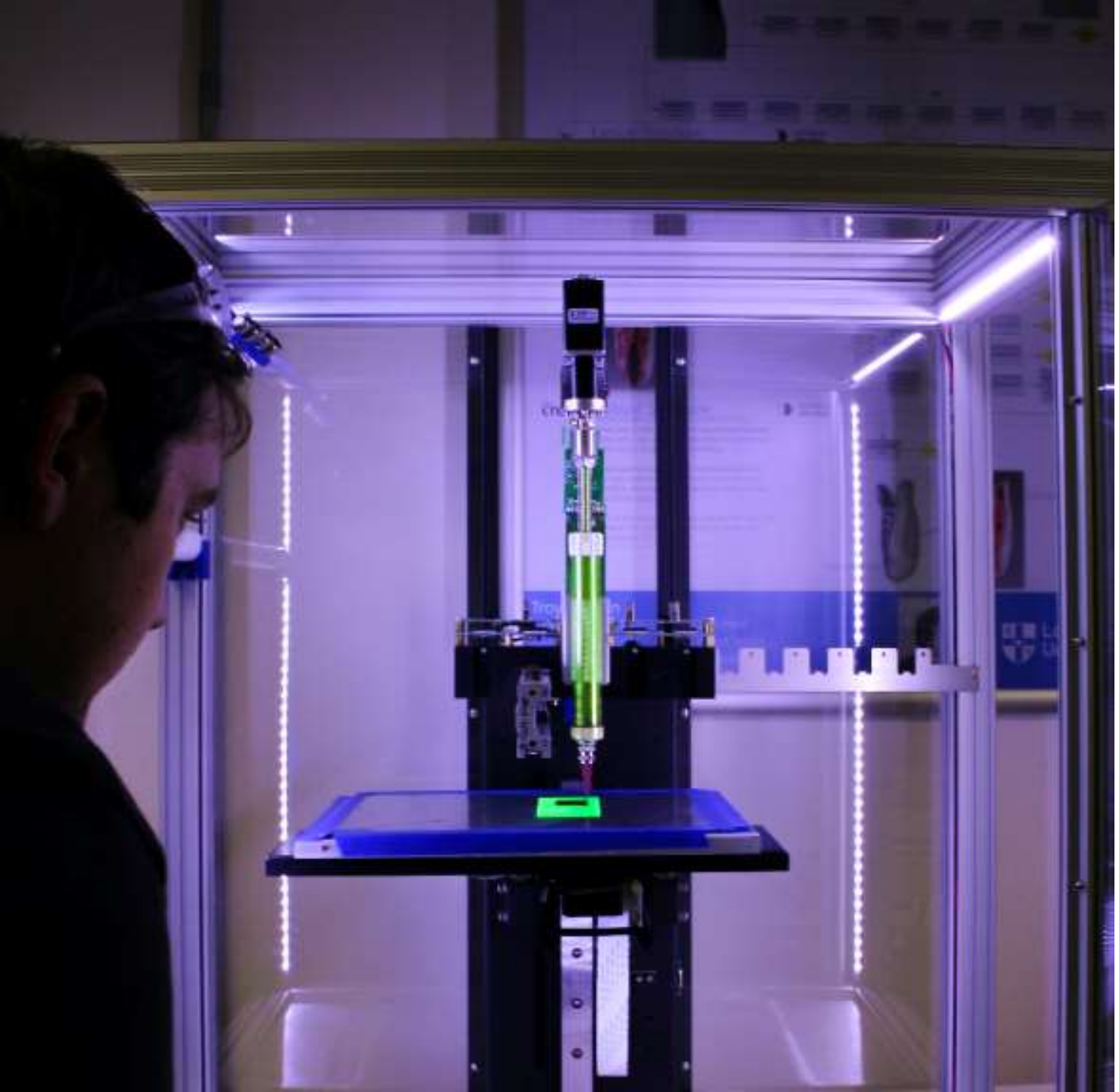
- Improving medical device data
- Software as a medical device
- In house device manufacture
- Post market surveillance

# Improving medical device data

- Unique device identifiers
  - Enables traceability and data linkage
  - Requires manufacturers to apply UDI
  - Requires healthcare providers to store UDI for implantable devices
  - >>>> NHS Scotland Scan For Safety Programme
- Post-market surveillance
  - Strengthen safety and performance data
  - Significantly increased requirements ; serious incidents, data from registries, scientific literature
  - Some improvement in transparency for highest risk devices


# SAMD & AI : a medical device

- 80% currently Class I
- Move to up – classification
- Multiple work programmes
- Digital Clinical Safety
- Significant skill gap



# In house manufacturing

- Many healthcare providers are effectively manufacturers
- At present Health Institute Exemption
- New UK MDR requirements
  - to register the device with MHRA
  - to have a quality management system (though not certified)
  - to retain a technical document file
  - to make provisions for adverse incident reporting
  - do not require CE

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