New European Medical Device Regulation

Jesús Rueda Rodríguez

MTE Director International Affairs

MedTech Europe

from diagnosis to cure

EU Regulation… when is it happening?

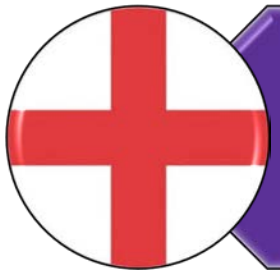
Database

- Based on Availability of Eudamed to ensure registration of devices
- Earliest – March 2020 – even a small delay would push it to the end of 2020 because specific transition rules

Label

- UDI on labels depends on risk class of devices
- Class III – May 2021
- Class IIa & IIb – May 2023
- Class I – May 2025

How relevant are the regulatory timeframes?



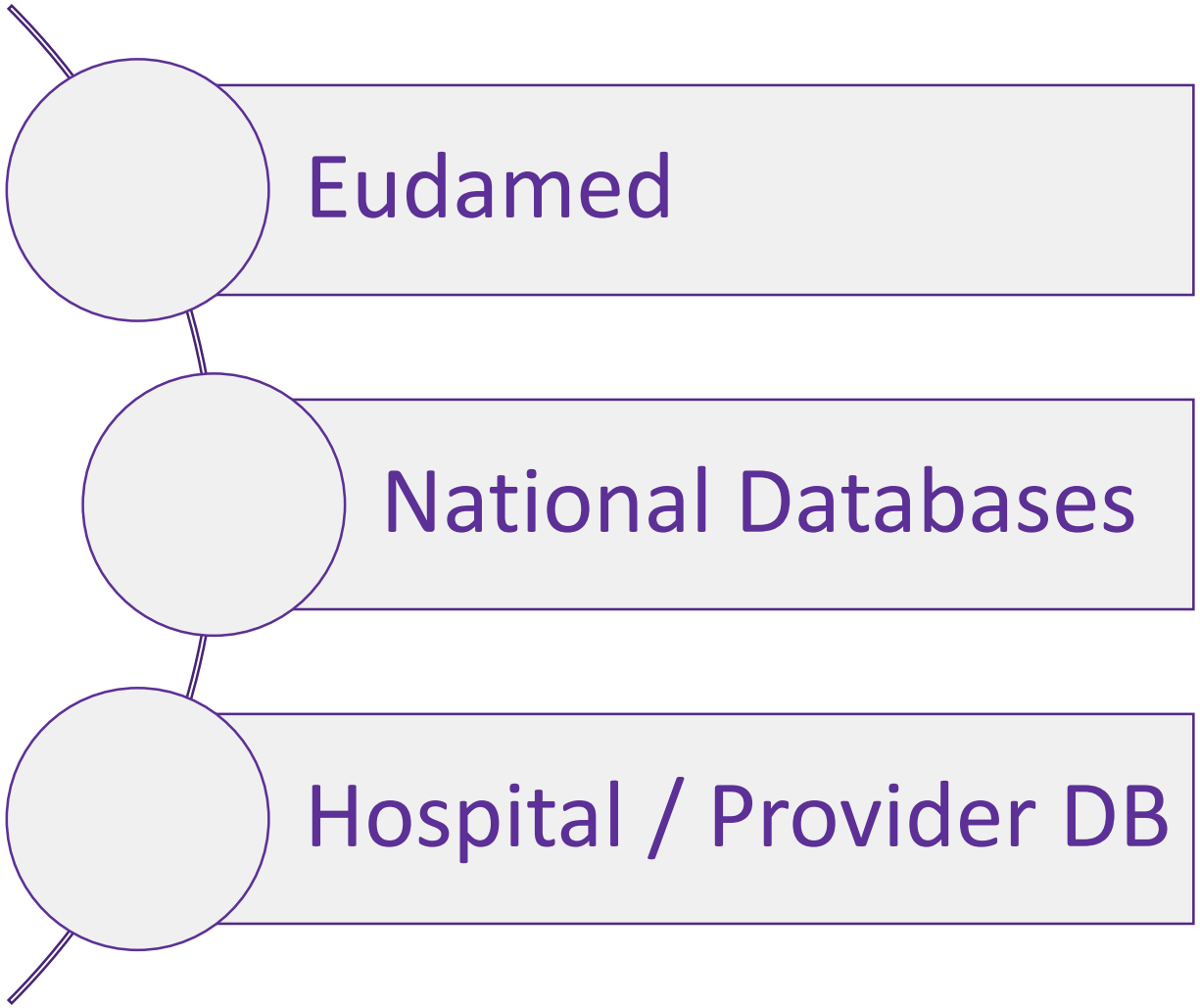
NHS – e-procurement scan for safety pilot

The Netherlands – agreement on UDI

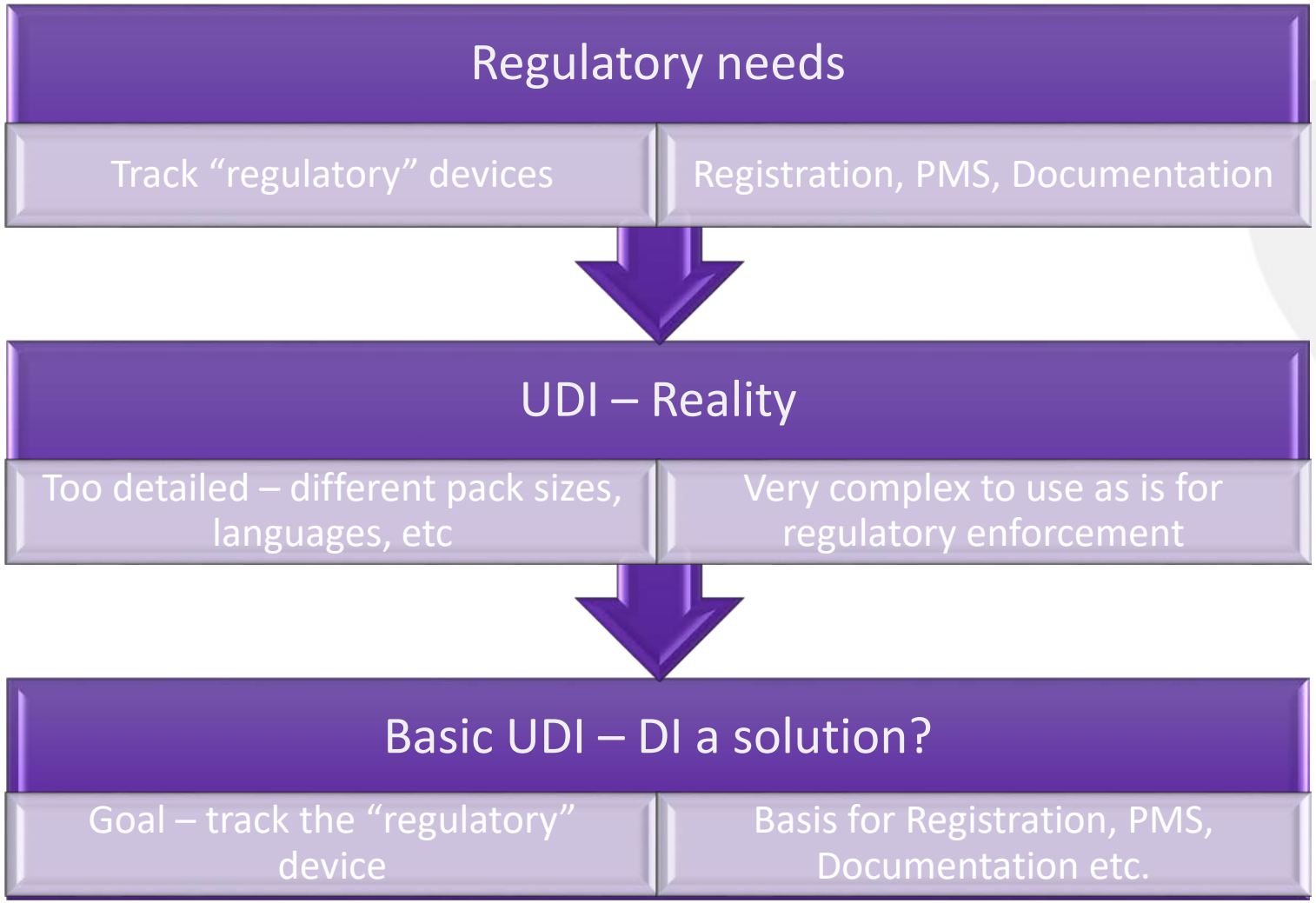
Turkey – Rollout of TITUBB – full traceability

Growing pressure from Hospitals for UDI carriers on medical devices in the EU

And talking of databases…



Basic UDI – DI, a regulatory concept



Challenges – Basic UDI - DI

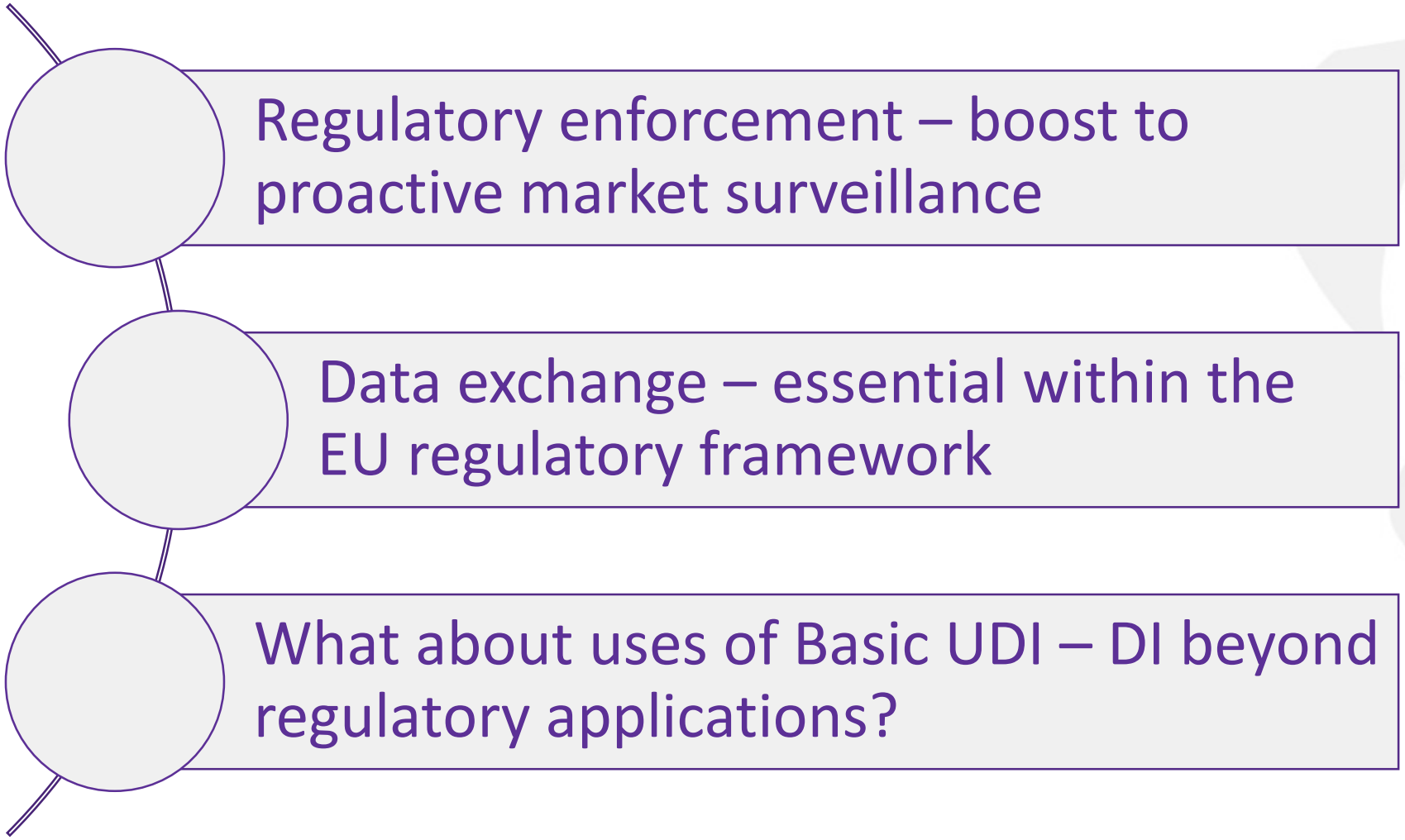
Defining Basic UDI - DI

- The Basic UDI-DI is the ***primary identifier of a device model***. It is the DI ***assigned at the level of the device unit of use***. It is the ***main key for records in the UDI database*** and is referenced in relevant certificates and EU declarations of conformity.

Maintenance & Changes to Basic UDI-DI

- When is a new Basic UDI – DI needed?
- Updating datasets – when will new Basic UDI-DIs be triggered

Opportunities – Basic UDI – DI



Will this stay in the EU?

UDI in a regulatory context

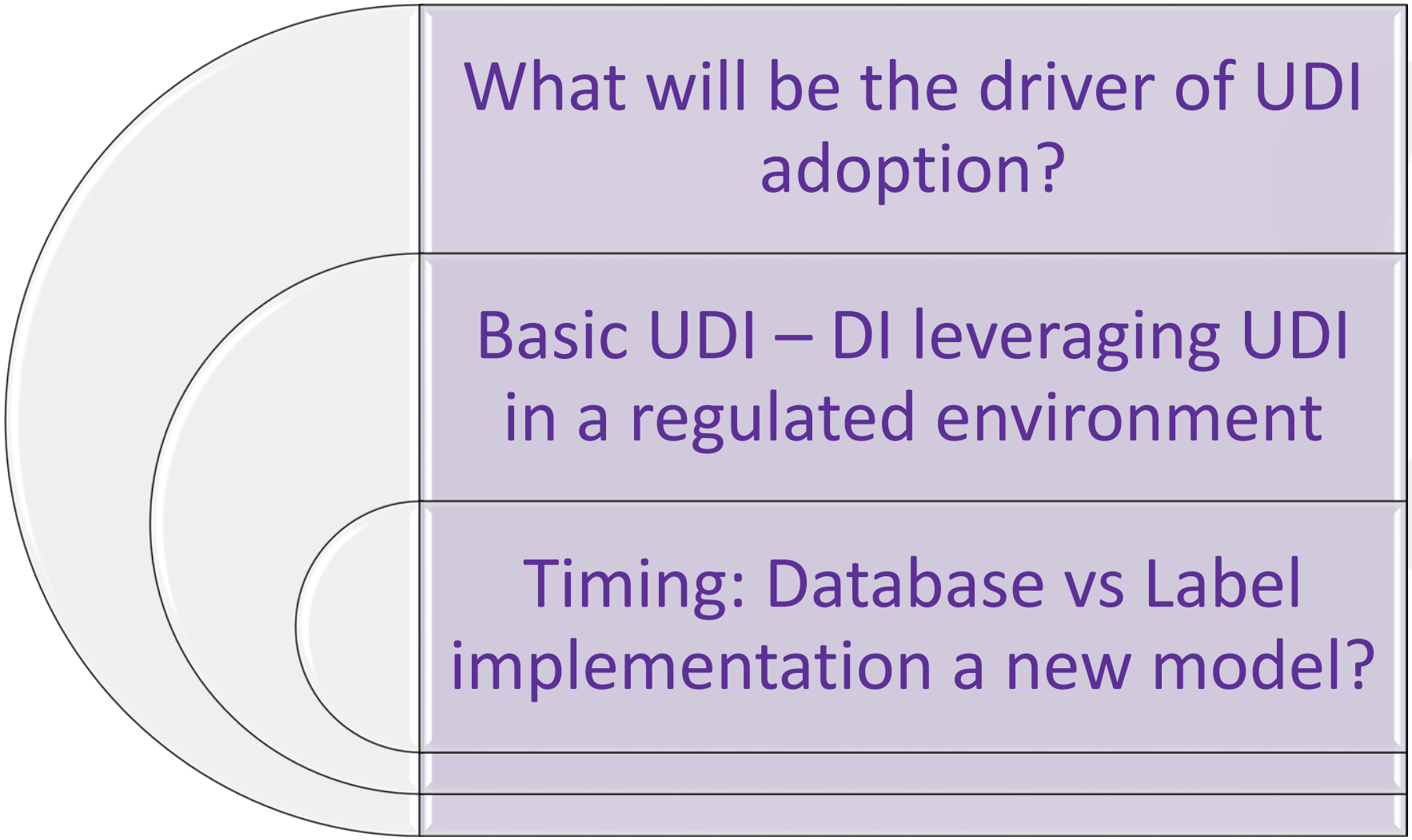
- Basic UDI – DI or something equivalent will be needed – how will it be adopted?

Access to Eudamed

- Commission can grant access to Eudamed to other authorities – Ease UDI adoption.

Overall – Accelerate UDI Adoption?

Reflections and lessons from EU – UDI implementation




Questions?