

Executives' overview of EUDAMED

Strategic implications, transparency exposure, and executive decision points
under EU MDR/IVDR

MedTech Europe training

Training for executives



High-level overview of what EUDAMED will deliver (and what it will not)

Key transparency aspects, main timelines and obligations influencing executive decisions for strategic planning.

Aimed at senior business leaders and commercial executives from the medical technology industry.

Compliance & Regulatory, R&D, Quality, Labelling, Sales, Product Data Management, teams supporting Notified Body audit

About MedTech Europe

The European trade association for the medical technology industry including diagnostics, medical devices and digital health.



OUR MEMBERS



170+ multinational corporations*



50 medical technology associations

*medical devices, diagnostics and digital health

Guidelines on participation in MedTech Europe meetings

DON'TS

- **Don't** reach understandings or agreements or even hold discussions (especially with a competitor) on anything relating to commercially sensitive topics such as prices, credit terms and billing practices, production, inventory, sales, costs, future business plans, bids or matters relating to individual suppliers or customers.
- **Don't** attend meetings without clear indication of the purpose and/or written agenda, circulated in advance.
- **Don't** attend unscheduled gatherings unless you know that they are for a bona fide purpose or purely social gatherings.
- **Don't** use our association as a venue to engage in conduct that could be construed as intended to exclude competitors from the market or create a barrier to market entry.
- **Don't** accept written non-public information or agree to the exchange of oral non-public information with members who market competing products.
- **Don't** participate in information exchanges, market surveys, or benchmarking exercises without the advice of your and MedTech Europe's legal counsel.
- **Don't** engage in negotiations, joint sales or joint buying without legal advice.
- **Don't** exclude competitors or engage in collective boycotts.

DO's

- **Do** identify clearly the specific legitimate purpose of each association's project, meeting and conference call.
- **Do** carefully read the MedTech Europe Competition Law Guidelines, available on our website and upon request.
- **Do** object to any discussion, activity or conduct that may infringe EU competition law rules and inform the Chief Executive Officer of MedTech Europe if you disagree with any of its decisions and keep a copy for your files of any such correspondence.
- **Do** stop any meeting when the participants insist on discussing matters that may lead to violations of EU competition law rules.
- **Do** return commercially sensitive information you receive, without keeping copies, and explain in writing that you do not wish to obtain such information.
- **Do** inform your company counsel and MedTech Europe's legal counsel of any approaches seeking to exchange non-public information or coordinate conduct on the market.
- **Do** ask MedTech Europe's legal counsel to have counsel attend meetings of the organisation if you or your company have any doubts.

All information, interpretations, views and opinions expressed in this presentation are a result of a careful review of the cited sources of information at the time the presentation was given.

The presentation and its contents shall **not be considered to be a legal advice or legal opinion** to anybody. Adoption of an interpretation or view or opinion as contained herein shall occur at adopters' own risk.



DISCLAIMER

Presenters



- **Tania Pearson** is a Regulatory Affairs Director responsible for Lifecycle Management, Distribution solutions and Global UDI Implementation for Medtronic, Inc. She has been working in the medical device sector for 15 years. Prior to joining Medtronic, she worked in R&D for Pfizer for 12 years. She has a BS in Chemistry from the University of Illinois at Urbana-Champaign and a MS in Regulatory Affairs from San Diego State University.
- Tania is currently the MedTech Europe UDI Working Group Chair and is a member of the MedTech Europe Eudamed WG and Core team. She also serves as the DITTA UDI WG Chair. She is engaged in many other external industry groups including the GS1 Healthcare Global Public Policy group, GS1 US Executive Leadership Committee, and the Global Harmonization Working Party (GHWP) WG9.



- **Amber Harrison-Crudge** is an Associate Director within Regulatory Affairs for Johnson & Johnson MedTech and the EUDAMED Lead for the Electrophysiology & Neurovascular business. Amber has previously held roles with responsibility for Global Strategy & Global Enterprise Digital UDI Submission Solutions to enable compliance with Global regulations and customer requirements impacting Unique Device Identification (UDI). She holds a Masters (MSc) Computers & Information Systems, a Postgraduate certification in Applied Analytics for Business and holds qualifications as a Scaled Agile Program Consultant (SPC), Enterprise Agile Coach, PRINCE2 Project & Programme Management.
- She is a member of the MedTech Europe UDI Working Group & EUDAMED Working Group Core team.

Why EUDAMED matters to Executives

- EUDAMED is a **mandatory regulatory infrastructure** under the EU MDR/IVDR that directly impacts:
 - market access & product traceability
 - regulatory compliance and transparency
 - corporate reputation and trust
- Not an IT or Regulatory Affairs-only project: **requires sustained** cross functional **executive oversight**
- EUDAMED compliance has a **long-term structural and financial impact**

What is EUDAMED and what it will deliver

Which purpose will EUDAMED serve?



EUDAMED is the EU's central regulatory database for medical devices and IVDs.

What EUDAMED **will** deliver?

- Core regulatory and device identification including safety & performance information
- Market compliance platform
- Data transparency and visibility platform
- Phasing out member states' registrations

What EUDAMED **will not** deliver?

- Approval platform
- Marketing claims
- Pricing information
- Sales volumes
- Replacement of national distributor databases

What the public (and competitors) can learn from EUDAMED

Transparency and public visibility of data

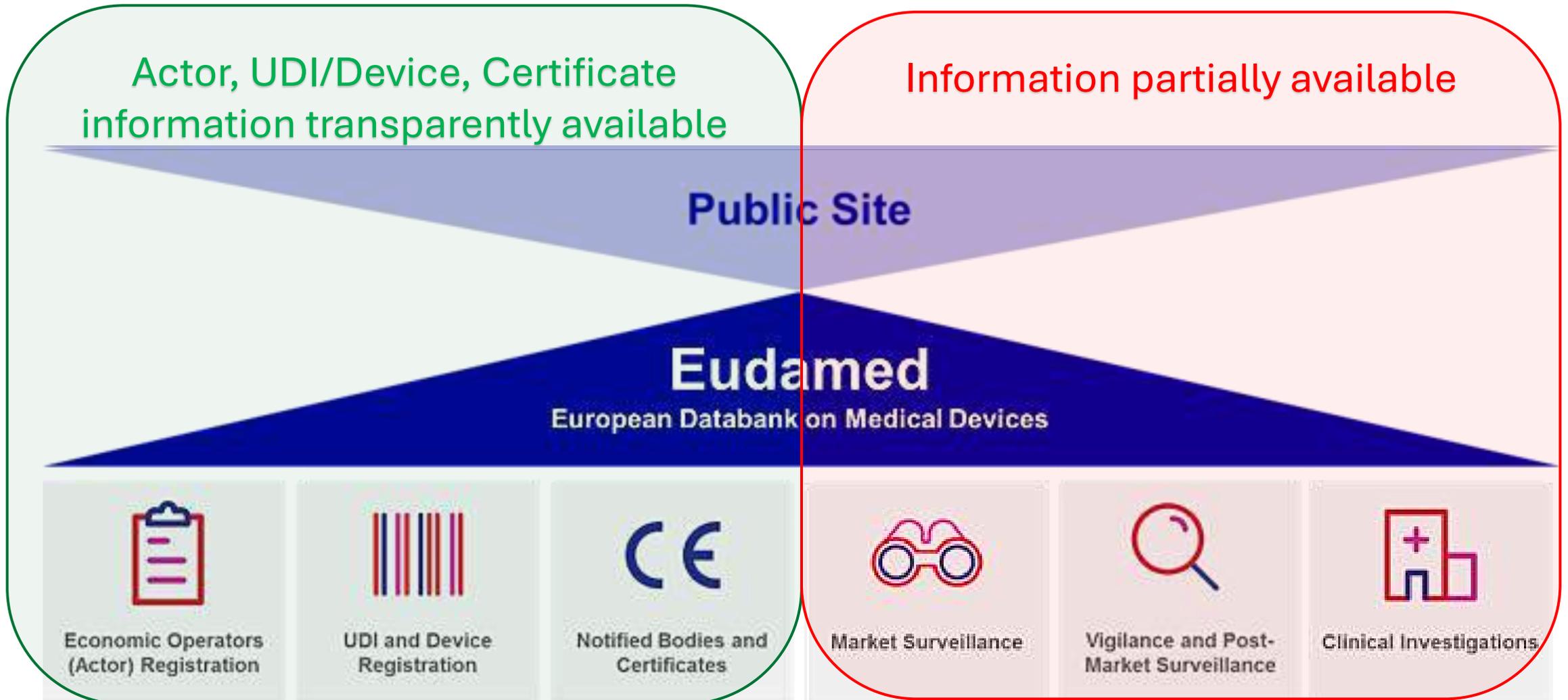
Who can access the information?



- **EUDAMED data is freely available and publicly visible worldwide**, including to:
 - Regulators and authorities
 - General public - healthcare professionals and patients/lay users
 - Competitors and market analysts

EUDAMED therefore creates regulatory, reputational, and commercial exposure beyond the EU.

Transparency through EUDAMED modules



What the public can learn from EUDAMED



EUDAMED - European Database on Medical Devices

Search for



Economic Operators

Search for economic operators (manufacturers, system/procedure pack producers, authorised representatives, importers)



Devices, Systems, Procedure packs

Search for UDI-DI and device data including SSCP



Certificates (Issued or Refused)

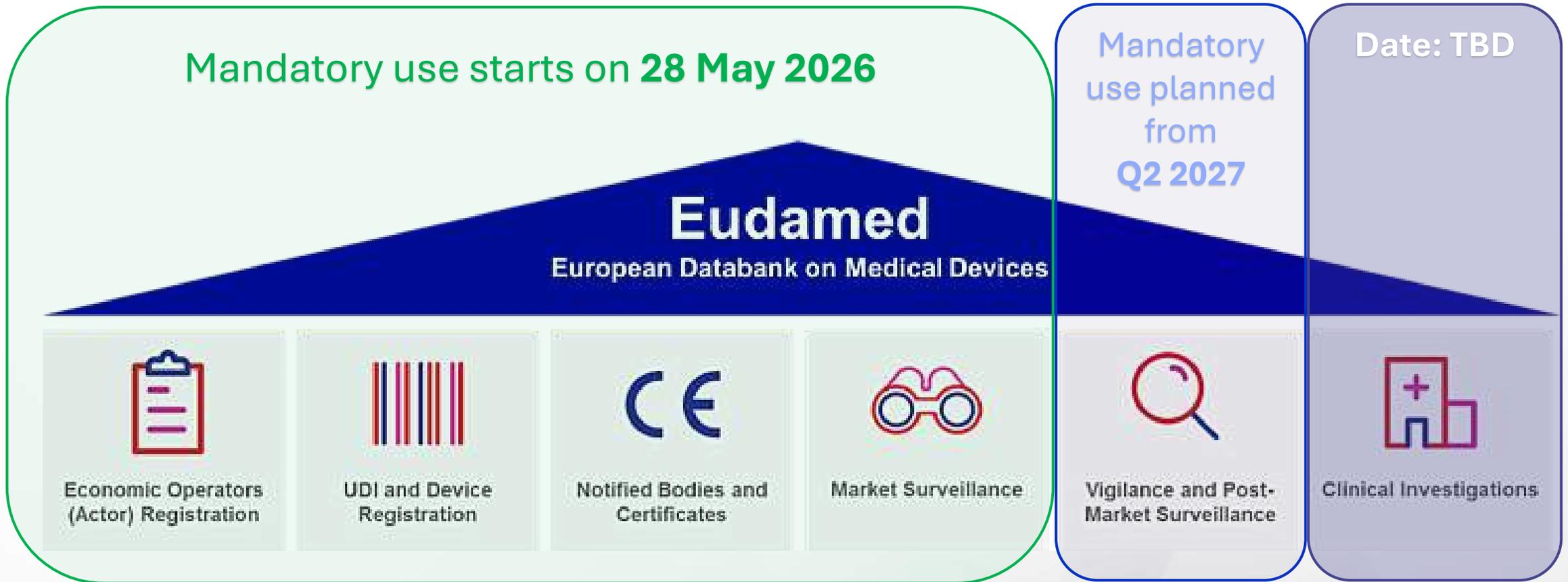
Search for certificates and refused certificates



When do you need you focus your resources?

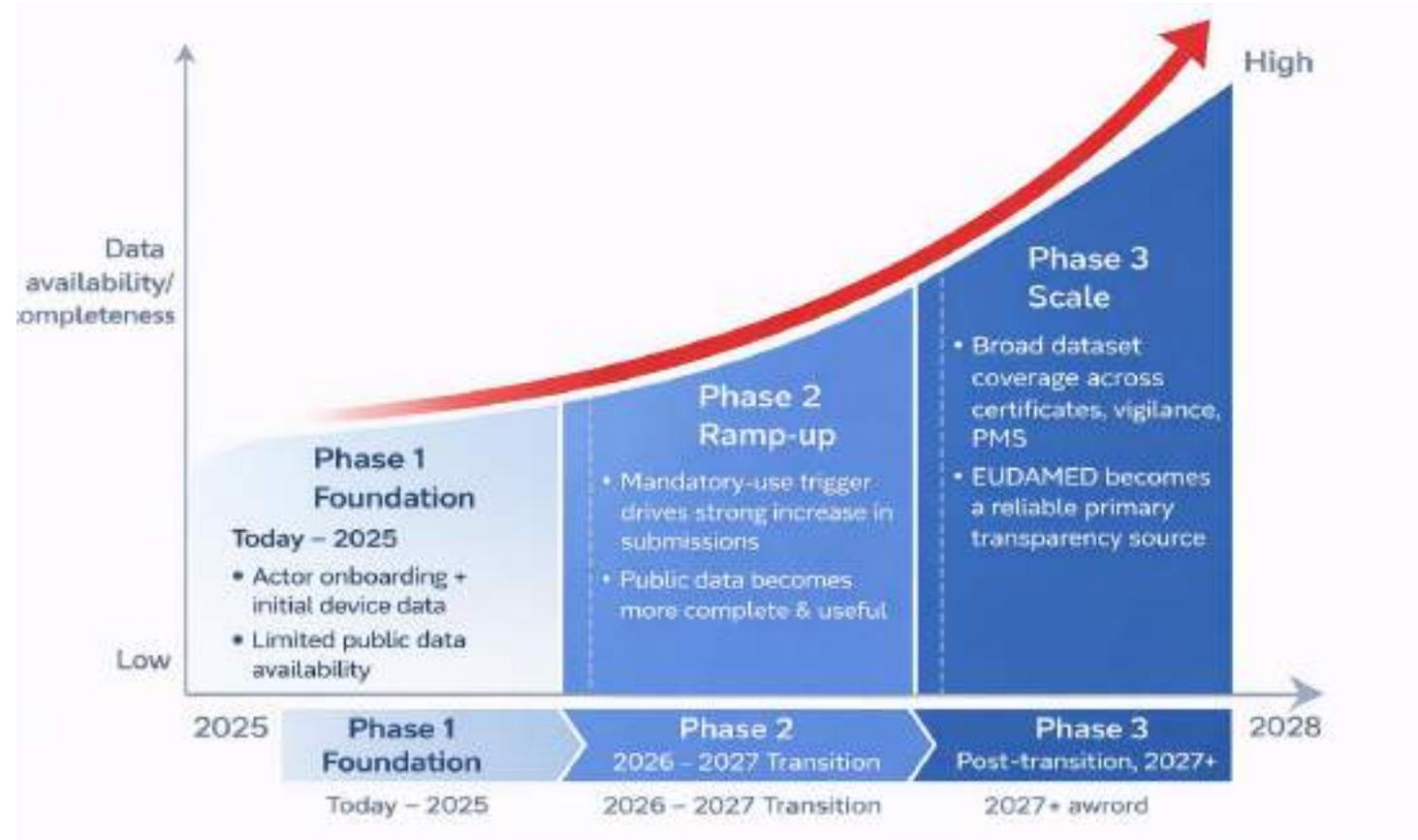
EUDAMED implementation timeline

Focus your resources: EUDAMED go-live dates!



EUDAMED data availability accelerates after mandatory use

GUDID Global Unique Device Identification Database	
~ 5 million devices registered in the US Food and Drug Administration GUDID database	Expected to grow 5 times in the next months 
	1.15 million devices registered to date in the European EUDAMED database



Take aways

EUDAMED is continuous evolving and has long-term obligation

Funding

1. Establish adoption & maintain budget for data governance and IT automation

Governance

2. Establish data ownership model for all data & documentation - cross-functional alignment: Regulatory / Quality / IT / Supply Chain / Vigilance / Clinical

Maintenance

3. Ongoing monitoring as EUDAMED will continue to evolve over the coming years

Thank you

MedTech Europe Regulatory
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