Transparency in the field of medical devices - implementation in the EU and Switzerland

EUDAMED	European Medical Device Database
EC	European Commission
MDR	Medical Device Regulation
IVDR	In Vitro Diagnostics Regulation
MDCG	Medical Device Regulation
DG GROW	DG for Internal Market, Industry, Entrepreneurship and SMEs
DG SANTE	DG SANTE is responsible for the EU Commission's policies on health and food safety.
SRN	Single Registration Number
UDI	Universal Device Identification
UDI DI	Universal Device Identification Device Identifier
MF	manufacturer
MDD	Medical Device Directive
GMDN	Global Medical Device Nomenclature
EMDN	European Medical Device Nomenclature
CND	Device Nomenclature (*Classificazione Nazionale Dispositivi medici*)
M2M	Machine-to-Machine
IT	Information Technology
CEF	Connecting Europe Facility
QMS	Quality management systems

Introduction

Richard Houlihan MBA, BSc.

25+ years IT.

8+ years EUDAMED (2011 - 2019)

European Commission (EC) Technical IT Manager for EUDAMED

- EUDAMED design, development, and implementation.

EC to provide very limited support to the MedTech industry

Our site: eudamed.com – for training, software, support, and consultancy

EUDAMED is needed because…

- MDR/IVDR has a far greater scope than MDD/IVDD
- EUDAMED requires a huge amount of data
- Publicly available data and increased transparency
- Far greater statistics/reporting will be possible

Transparency & EUDAMED

EC Categorises Transparency as Medical Device Data…

- made available to the public via EUDAMED
  - Purpose: to achieve public and patient confidence in the device safety
  - More and more could be added to EUDAMED if deemed necessary

- Pro-actively made available outside EUDAMED by EC, CA's, Industry, and NB's
  - Measures taken by CAs on reprocessed single use devices
  - NB Fees charged
  - National measure for assessment and designating NBs
  - and more

Public access to EUDAMED data

Devices

Device data via search forms

Summary of safety [and clinical] performance (SS(C)P)

Clinical Investigations and Performance Studies (CI/PS's)

Access to summaries of CI/PS – non-confidential data only

Summaries of Post-Market Clinical Follow-up (PMCF)

Summaries of Performance Follow-Up (PMPF)

Market Surveillance

Summary of the results of the reviews and assessments of the market surveillance activities of a member state

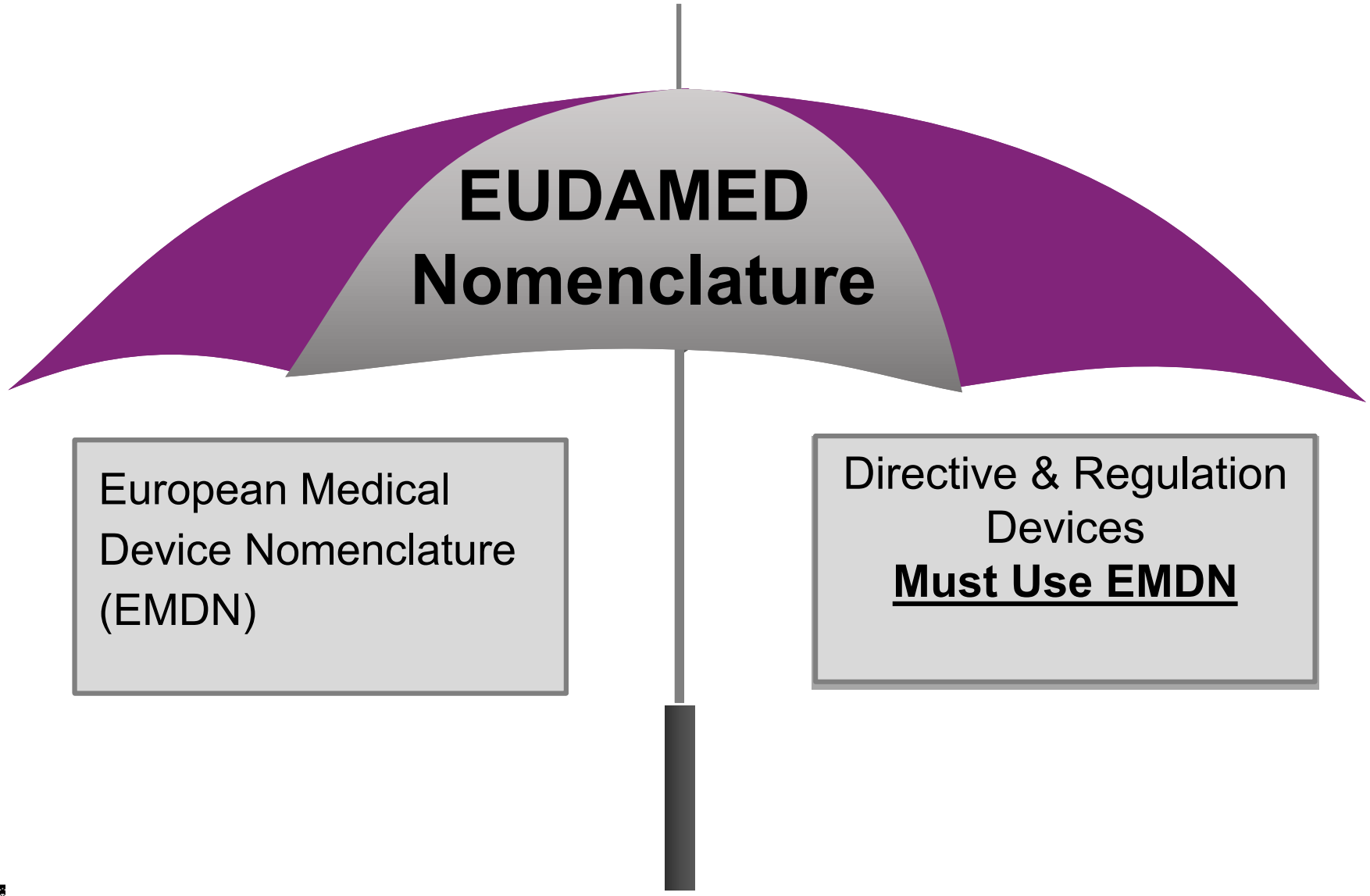
EUDAMED & Swiss Opportunities

Maintain a similar device database to EUDAMED, why?

- Eventually there will be a mutual recognition agreement
- **Closeness of databases will…**
  - reduce development and integration costs – future proofing
  - reduce burden on MedTech industry to comply
    - encourages more companies to supply Switzerland
  - public availability will ensure public transparency and faith in devices - future proofing

Opportunity: Cost savings and public transparency

EUDAMED Device Nomenclature



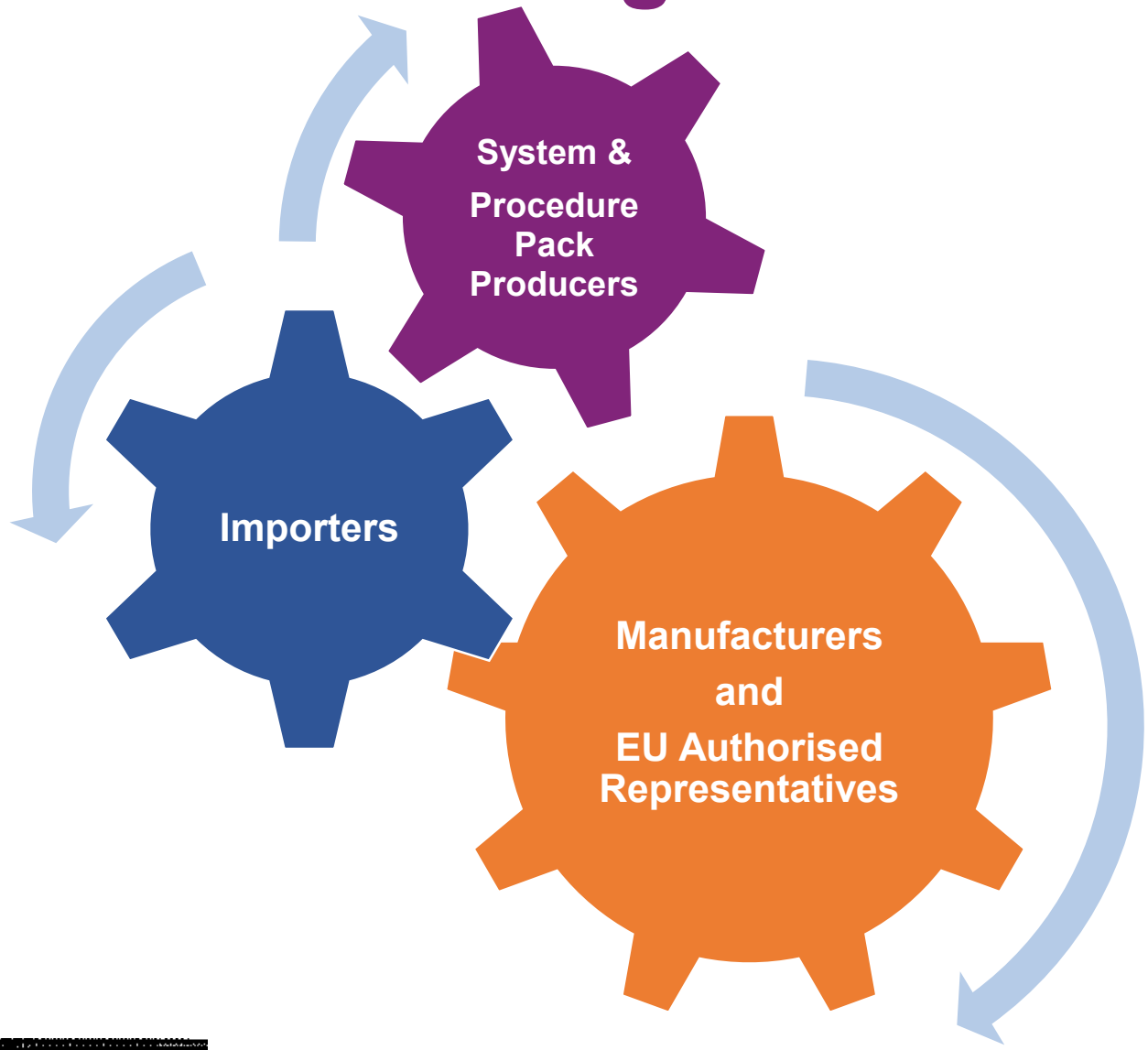
EUDAMED Device Nomenclature

- You must always use the lowest level EMDN

  EMDN Full Download List - https://webgate.ec.europa.eu/dyna2/emdn/

CODE	LEVEL	BOTTOM LEVEL YES/NO	EN CATEGORY DESCRIPTION	EN DESCRIPTION
A	1	NO	DEVICES FOR ADMINISTRATION, WITHDRAWAL AND COLLECTION	DEVICES FOR ADMINISTRATION, WITHDRAWAL AND COLLECTION
A01	2	NO	DEVICES FOR ADMINISTRATION, WITHDRAWAL AND COLLECTION	NEEDLES
A0101	3	NO	DEVICES FOR ADMINISTRATION, WITHDRAWAL AND COLLECTION	NEEDLES FOR INFUSION AND SAMPLING
A010101	4	NO	DEVICES FOR ADMINISTRATION, WITHDRAWAL AND COLLECTION	HYPODERMIC NEEDLES
A01010101	5	NO	DEVICES FOR ADMINISTRATION, WITHDRAWAL AND COLLECTION	HYPODERMIC SYRINGE NEEDLES
A0101010101	6	YES	DEVICES FOR ADMINISTRATION, WITHDRAWAL AND COLLECTION	SYRINGE HYPODERMIC NEEDLES, WITH SAFETY SYSTEMS
A0101010102	6	YES	DEVICES FOR ADMINISTRATION, WITHDRAWAL AND COLLECTION	SYRINGE HYPODERMIC NEEDLES, W/O SAFETY SYSTEMS

EUDAMED Registration

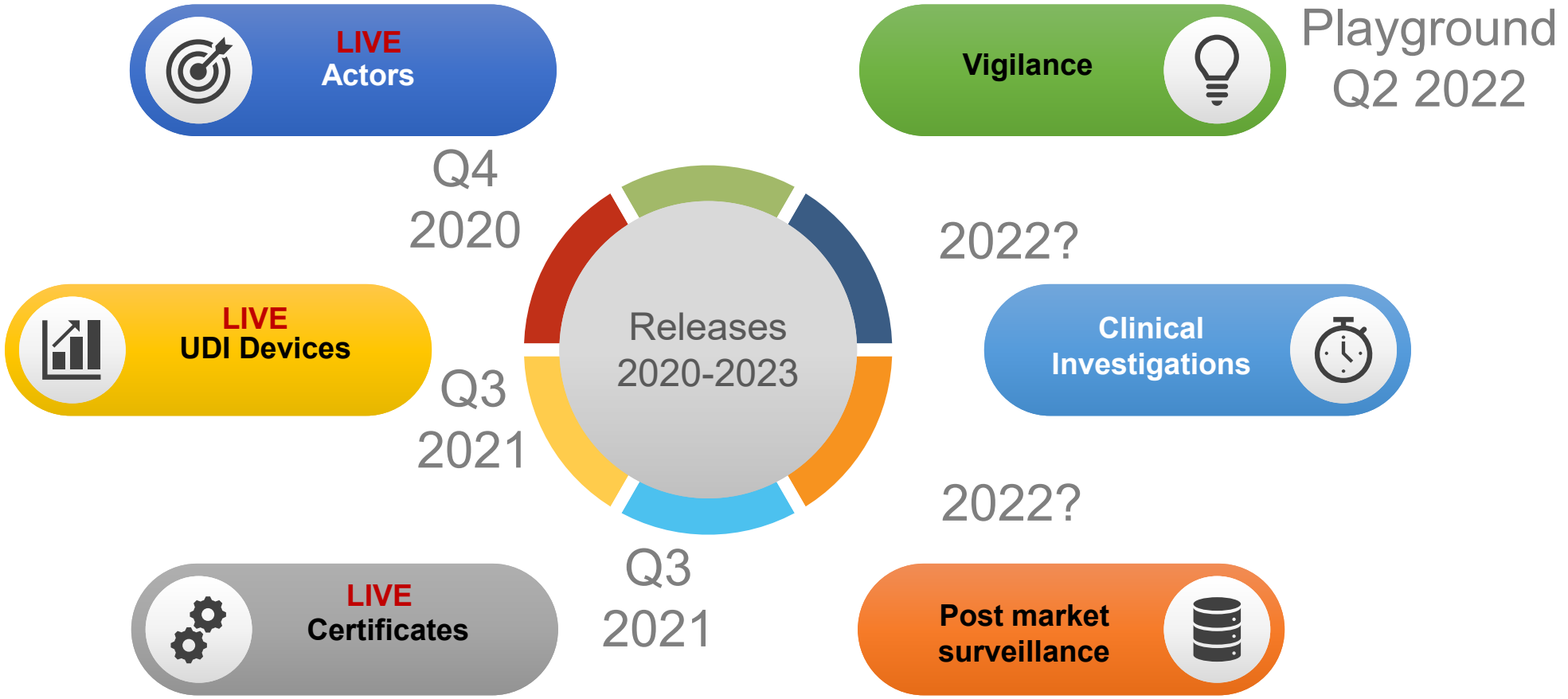


Registrations required from May 26, 2022

Early registrations from 1st December 2020

Possible Multiple SRN's
(Single Registration Number)

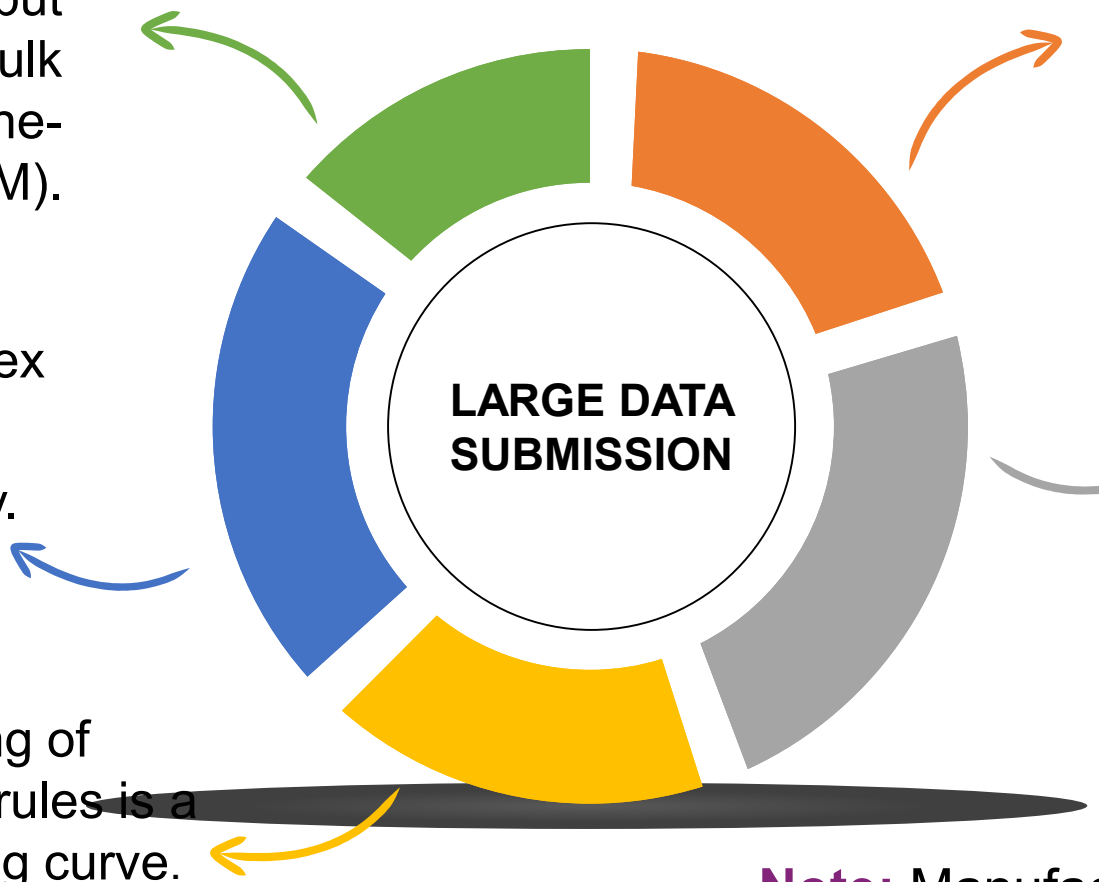
EUDAMED Releases



What is so special about EUDAMED?

Multiple data input options – Web, Bulk upload and machine-to-machine (M2M).

Each company will require a full IT and change management project.



Data uploads complex format. Common understanding is key.

Data validation and business rules are extensive.

Achieving an understanding of formats and rules is a steep learning curve.

Note: Manufacturers are responsible for submitting their data to EUDAMED

EUDAMED

EUDAMED Time line

Development
Contingency

The European Commission targets

Q4 2022	Q1-Q2 2023	Q2 2023	Q2 2023	Q4 2023	Q2 2025
End of the EUDAMED MVP[1] development for all six modules	Independent **Audit**	Audit results presented to the Medical Devices Coordination Group (MDCG)	EUDAMED has achieved full functionality following the outcome of the Audit **Publication of a Commission notice** in the *Official Journal of the European Union* **(OJEU)** The full EUDAMED system is ready Only the first 3 modules, with features available on voluntary basis, are in production	End of 6 months transitional period after publication of the notice in the OJEU Fully functional EUDAMED (all 6 modules) goes live The use of **EUDAMED** becomes **mandatory** as regards obligations and requirements related to **Actors, Vigilance, Clinical Investigation & Performance Studies and Market Surveillance modules**	End of 24 months transitional period after publication of the notice in the OJEU The use of **EUDAMED** becomes **mandatory** as regards obligations and requirements related to **UDI/Device and NB & Certificate modules**

EUDAMED

Moral of the story:

Do not underestimate the time needed nor the complexity of the required EUDAMED project.

By maintaining a similar database Swiss Medic will reduce the burden on manufacturers.

Reference links:

EUDAMED data preparation, management, & UDI submission solutions:

https://eudamed.com/index.php/eudamed-saas/

https://eudamed.com/index.php/eudamed-plus/

EUDAMED Training:

https://eudamed.com/index.php/eudamed-training/

EUDAMED Software solutions infographic:

https://eudamed.com/eudamed_infographic.pdf

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Thank you.

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