LexisNexis® Reed Tech®

UDI Product Data & EUDAMED Get onboard!

2022-January-27 at 1:00pm ET

Presenters: John Lorenc
Director Product Management Medical Devices – Life Sciences, Reed Tech
Gary Saner
Sr. Mgr. Information Solutions – Life Sciences, Reed Tech

greenlight guru

MEDICAL DEVICE QUALITY IS ALL WE DO, AND WE'RE ALWAYS AHEAD OF THE GAME.

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"Great eQMS Software..."

"The software is easy to use with little to no customization needed. It has been a great tool for developing our device through design control. The post-market additions have been amazing as well as tasks. **After using multiple types of eQMS software over the years, this is the best by far!"**

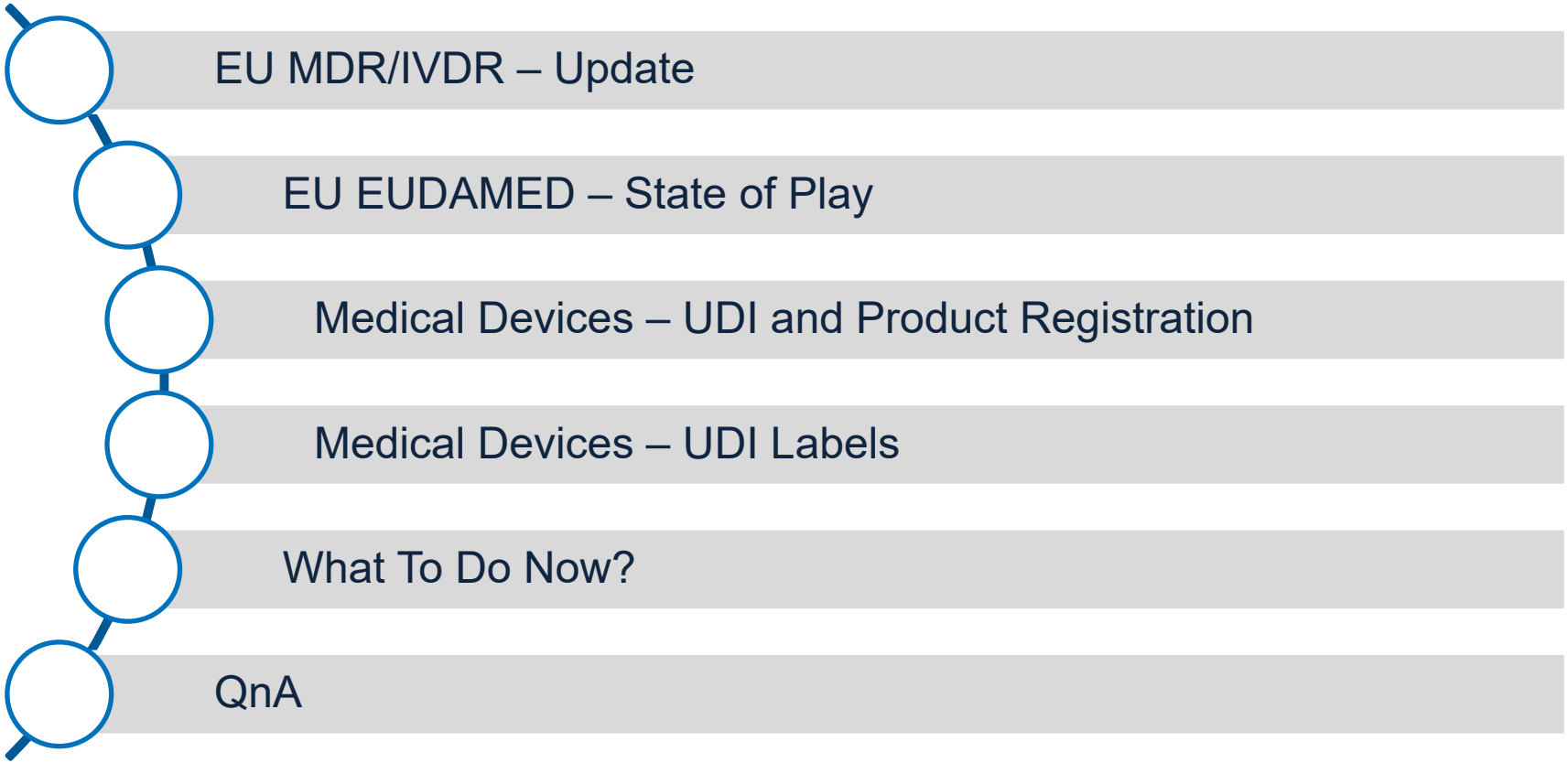
"My QMS is world class" ★★★★★

"Design controls lifesaver" ★★★★★

"One-stop shop" ★★★★★

"Fantastic product, even better team" ★★★★★

Discussion Topics



Speakers

Gary Saner

Sr. Manager, Information Solutions
Life Sciences
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John Lorenc

Director Product Management, Medical Devices
Life Sciences
Reed Tech

About Reed Tech

Preparation, Submission, and Lifecycle Data Management of Medical Device UDI product information

Industry Experts

18+ years of SPL knowledge (SPL-UDI since 2014); up-to-date SME knowledge from guidance, pilots, and trade groups (MedTech Europe committees, etc.)

Proven, Current, Compliant Systems (21 Part 11, Annex 11, Audit Trail)

730,000+ SPLs submitted to FDA GUDID; 2,500+ records to EU EUDAMED; Direct M2M (AS2/4, APIs) connections to HAs for auto, bulk submissions

Experienced, Major Industry Provider

32% of all FDA GUDID SPL records

Support US, EU, China, Korea; Roadmap for international UDIDs

Trusted Team Partner

450+ medical device customers since inception

Small (1 record) to large (250,000 records) customers

Flexible role assignments for in-country representatives and corporate users

LexisNexis® Reed Tech®

ISO 9001 Quality

ISO 27001 Security

HL7 Member since 2005

GS1 Solution Partner

1World Sync Alliance

RAPS PREMIUM SOLUTIONS PARTNER

MedTech Europe from diagnosis to cure

MedTech Europe Member

THE VISION COUNCIL

The Vision Council Consultant

DENTAL TRADE ALLIANCE

DTA Consultant

EU MDR/IVDR – Update

EU MDR/IVDR Description

Major EU Medical Device *Regulatory Reform* driven by:

- Recent incidents highlighting weaknesses in the framework
- New rules intended to restore confidence across the industry

EU Directives		***EU Regulations***
Varying implementations in EU MS		Legally binding across all EU MS
• **Medical Devices Directive** (MDD) 93/42/EEC • **Active Implantable Medical Device Directive** (AIMDD) 90/385/EEC	→	• **Medical Devices Regulation** (MDR) 2017/745
• **In Vitro Diagnostic Directive** (IVDD) 98/79/EC	→	• **In Vitro Diagnostics Regulation** (IVDR) 2017/746

Key MDR / IVDR Changes

Sweeping Changes to Process and Stakeholders

- All Notified Bodies need re-designation (new role)
- All Products need re-registration
- Some Products are up-classified
- Some Products need clinical re-evaluation
- All Products need UDI identification and registration
- All Products need updated Labeling content
- Revised Quality Management and Post-market Surveillance Systems
- Revised EUDAMED infrastructure

Issues to be addressed:

- Timelines
- Resources
- Systems
- Portfolio Evaluation
- Data (registration, UDI, etc.)
- Change Management

Much to Do !!!

1. Pre-Assessment
2. Gap Analysis and Actions
3. Quality Management System (QMS)
4. Legal Entities
5. Portfolio
6. Master Implementation Plan
7. Notified Bodies
8. Regulatory Training
9. **Execute Master Implementation Plan**
10. Review Efficiency and Effectiveness
11. Notified Body Submission
12. Ongoing Monitoring

Sub-Projects

- Clinical Evaluation
- Technical Documentation,
- Economic Operators' Relations
- Unique Device Identification
- Registration
- Labelling
- Post-market Surveillance
- Vigilance
- Reporting IT Systems

Source: EC Implementation Model for MDR Step by Step Guide

IVDR: More stringent rules. ~85% of all IVDs will need NBs oversight. New post-market performance follow-up, etc.

EU Reference – MDCG Guidance

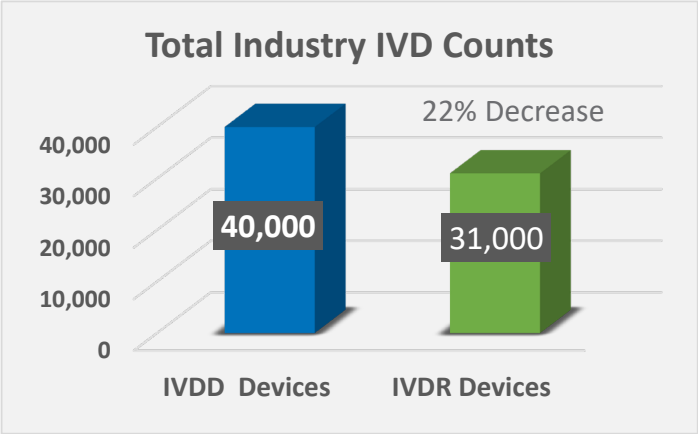
Medical Device Coordination Group (MDCG)

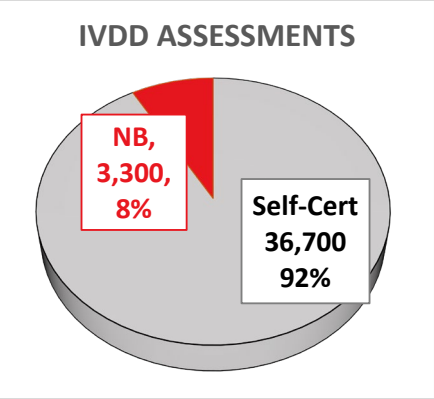
Guidance Documents List

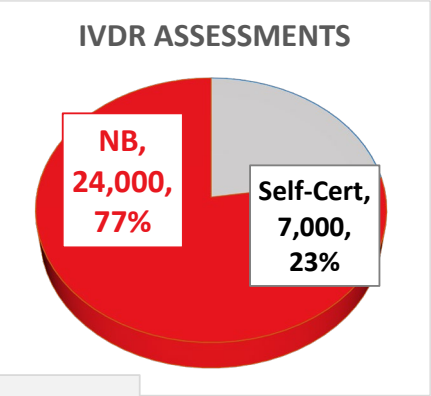
Partial UDI List

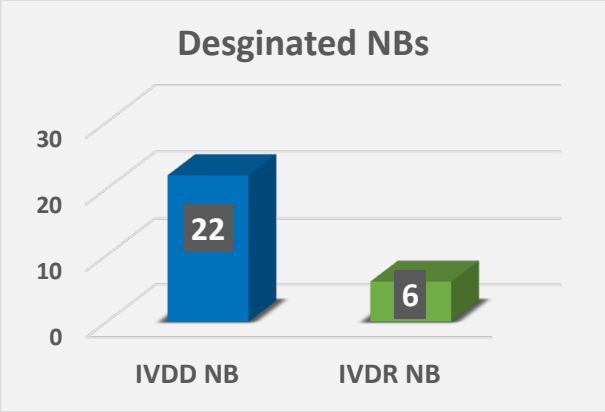
Reference	Title	Publication
MDCG 2021-19	Guidance note integration of the UDI within an organisation's quality management system	July 2021
MDCG 2021-10	The status of Appendixes E-I of IMDRF N48 under the EU regulatory framework for medical devices	June 2021
MDCG 2021-09	MDCG Position Paper on the Implementation of UDI requirements for contact lenses, spectacle frames, spectacle lenses & ready readers	May 2021
MDCG 2018-1 Rev.4	Guidance on basic UDI-DI and changes to UDI-DI	April 2021
MDCG 2019-18	MDCG Position Paper on UDI assignment for Spectacle lenses & Ready readers	December 2020

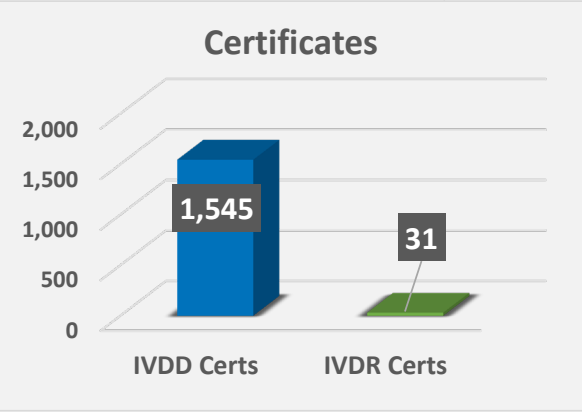
EU IVDR Pending Crisis











As of 2021-Oct

EU IVDR Amendment

Notice: 2021-Oct-14 EC IVDR Amendment Proposed

"If not addressed, this situation would lead to a significant disruption in the supply of a multitude of in vitro diagnostic medical devices on the market"

Provisions: 2021-Dec-15 EC IVDR Amendment Adopted

(targeted to enter into force before 2022-May-26)

- No change to IVDR DoA, still at 2022-May-26
- No change to IVDR Self-Certification by DoA for Class A (~20% IVDs)
- No change to IVDR compliance at DoA for "New" IVDs without Cert or DoC under IVDD
- No change to voluntary and mandatory UDI/Device Registration periods
- No change to UDI placed on product labels

- **Extend Legacy IVD transition period 1 year from 2024-May-26 to 2025-May-26**
- **Create transition schedule for IVDs w/o IVDD certificate that need IVDR certificates**

EU IVDR Amendment (2)

Provisions:

Applies to "**First Cert" IVDs** = IVDs on the market with an IVDD Declaration of Conformance (no Cert) prior to 2022-May-26 and require a NB conformity assessment for first time under IVDR

IVD Type	Place on Mkt	Sell Off*	Change
Directive IVD	2022-May-26	2025-May-26	None
Legacy IVD	2025-May-26	2026-May-26	**+1 year**
First Cert Class D	2025-May-26	2026-May-26	**New**
First Cert Class C	2026-May-26	2027-May-26	**New**
First Cert Class B & A/sterile	2027-May-26	2028-May-26	**New**

* "Sell Off" = Make Available on Market (supply chain) and Put into Service (patient use)

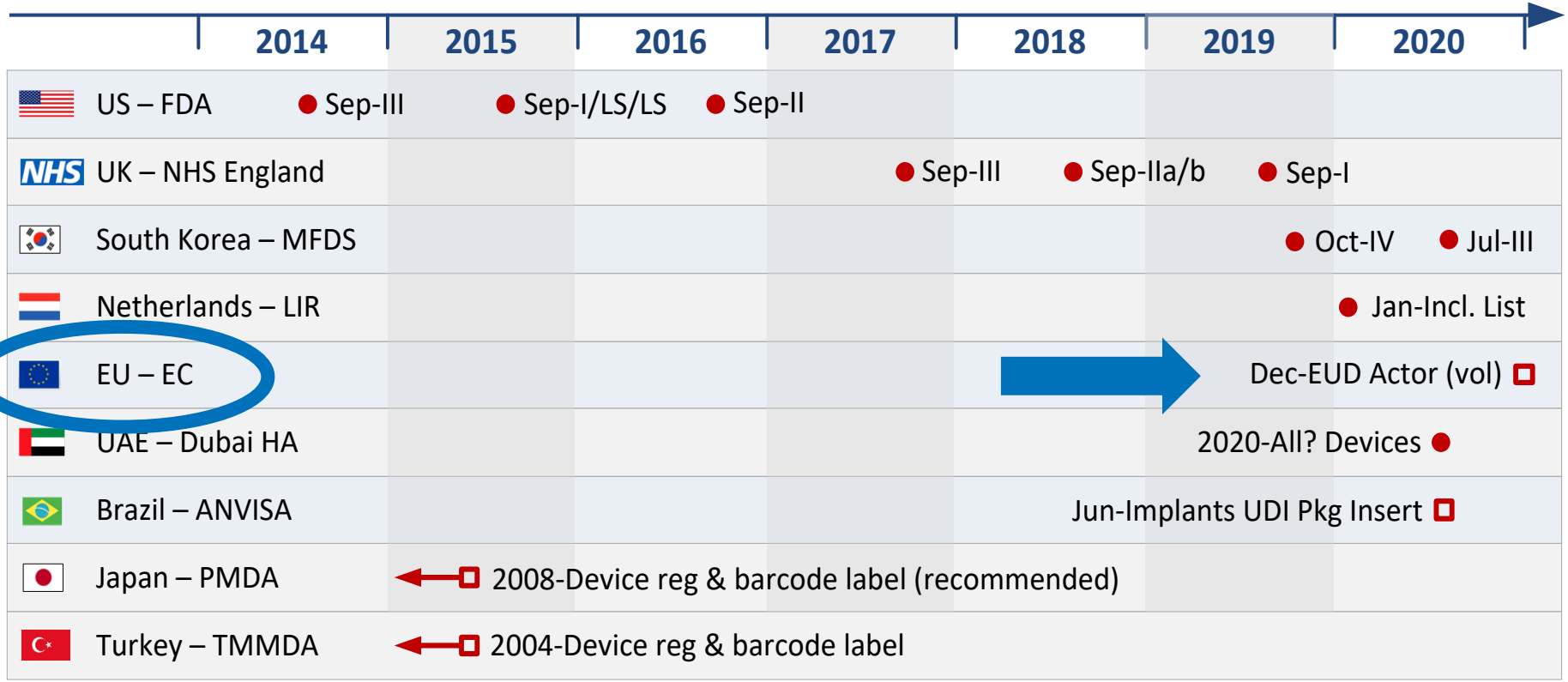
Legacy / Regulation Device

Characteristics	Legacy Device	Equivalent Device	MDR/IVDR Device
Design, intended use, functions, efficacy, safety, etc.	Original	Same	Different
Legislation / Evaluation	MDD/AIMDD/IVDD Directives	MDR/IVDR Regulations	MDR/IVDR Regulations
Registered	MS & EUDAMED (EUD-DI & EUD-ID)	EUDAMED (BUDI & UDI-DI)	EUDAMED (BUDI & UDI-DI)
Label	No UDI Reqm't	UDI, MD Symbol, (Warnings, etc.)	UDI, MD Symbol, (Warnings, etc.)

If changes include a different product version, i.e., significant changes to design, intended use, functions, efficacy, safety, etc., then a new MDR/IVDR device must be created

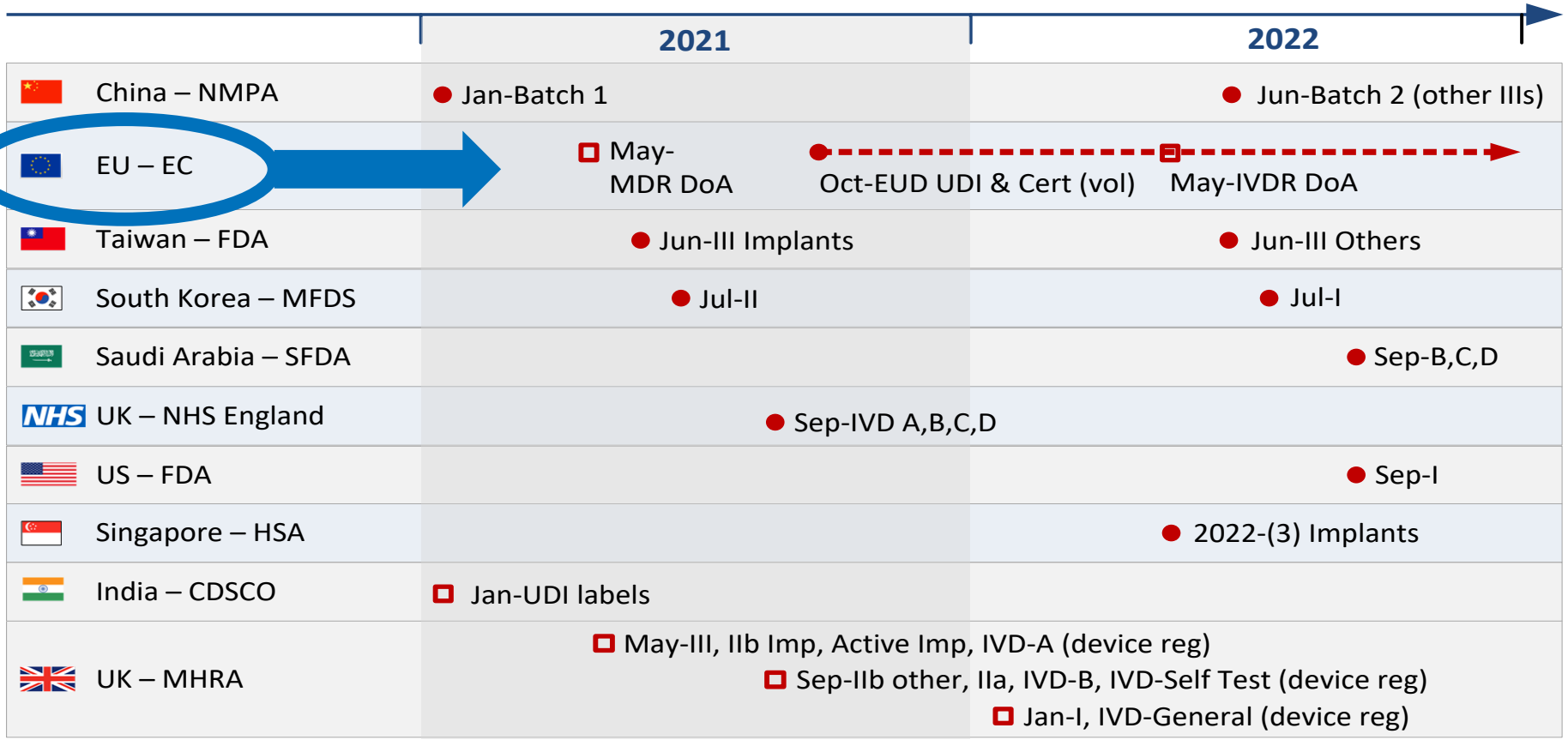
EU EUDAMED – State of Play

Past UDI Data Reporting Reqm'ts



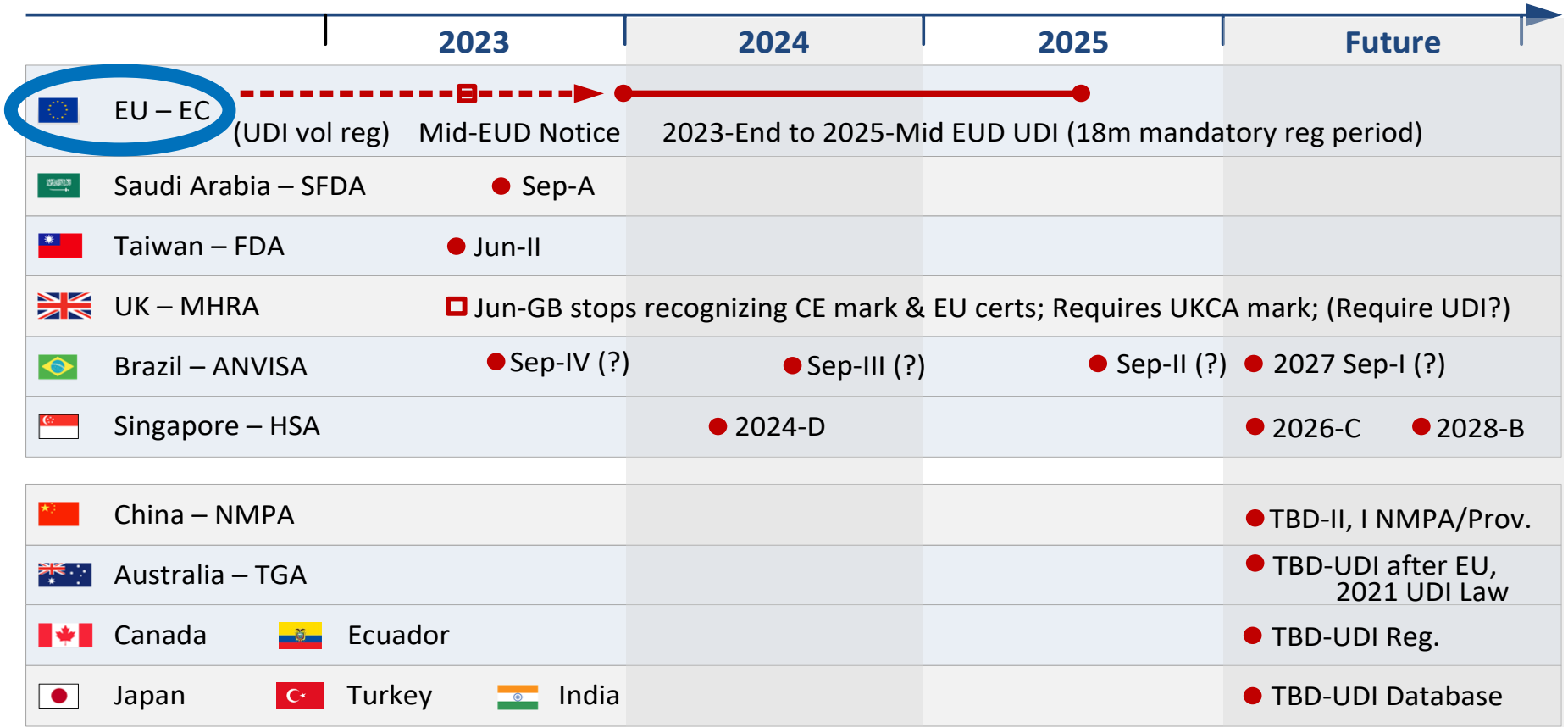
● UDI Submission Deadline, ☐ Milestone

Short-Term UDI Data Reporting Reqm'ts



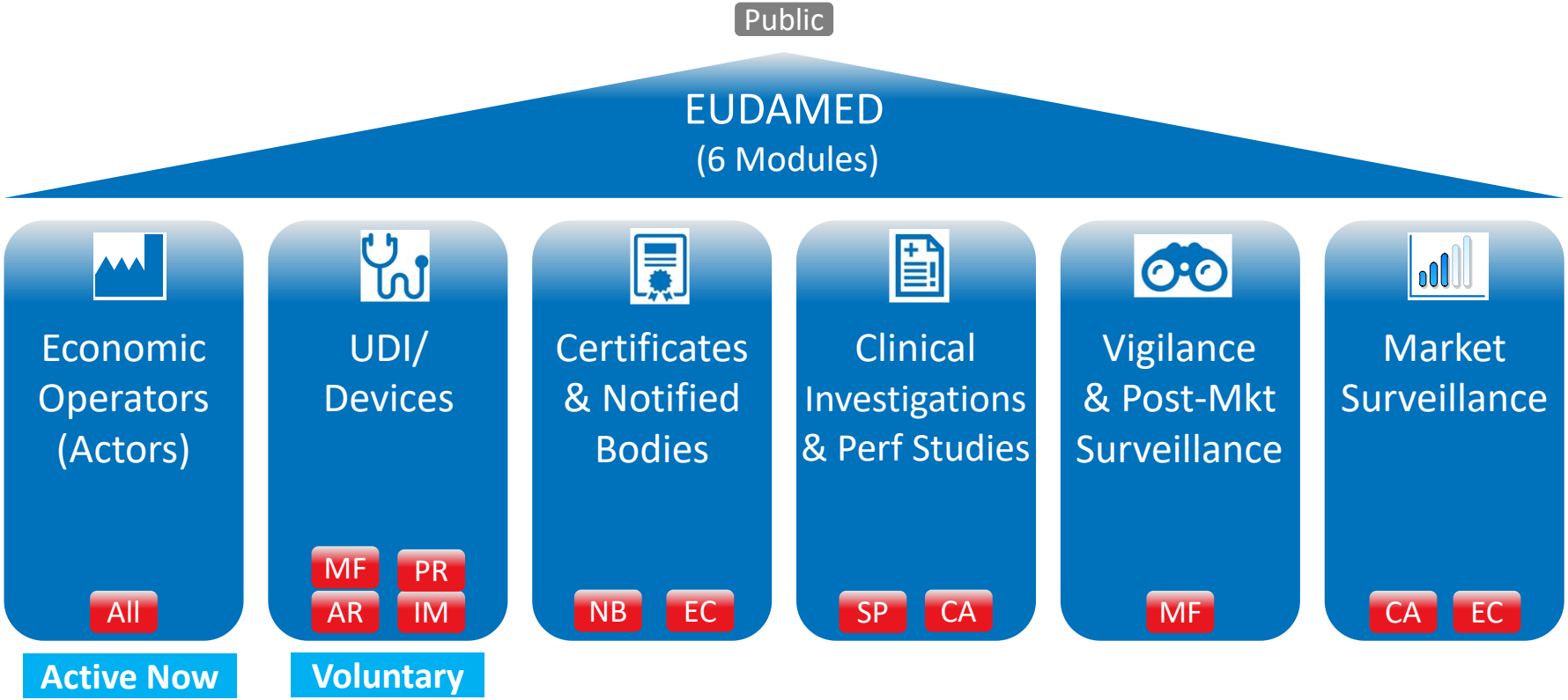
● UDI Submission Deadline, ☐ Milestone

Long-Term UDI Data Reporting Reqm'ts



● UDI Submission Deadline, □ Milestone

What is EUDAMED?

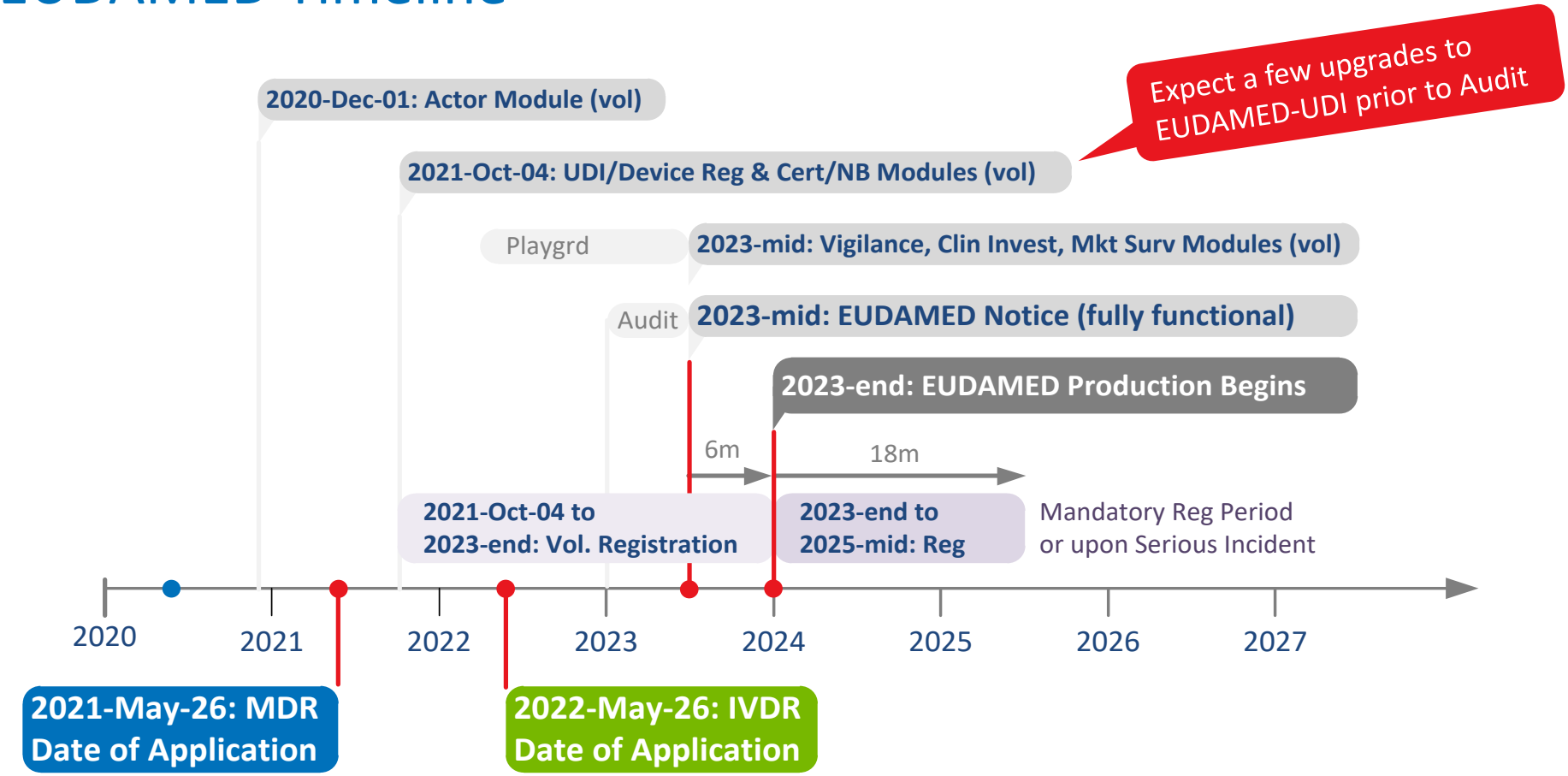


Note: Only primary associations are shown; AR - Authorized Representative, CA - Competent Authority, EC - European Commission, IM - Importer, MF - Manufacturer, NB - Notified Body, PR – (S/PPP) System/Procedure Pack Producer, SP - Sponsor

EU EUDAMED

Timing

EUDAMED Timeline



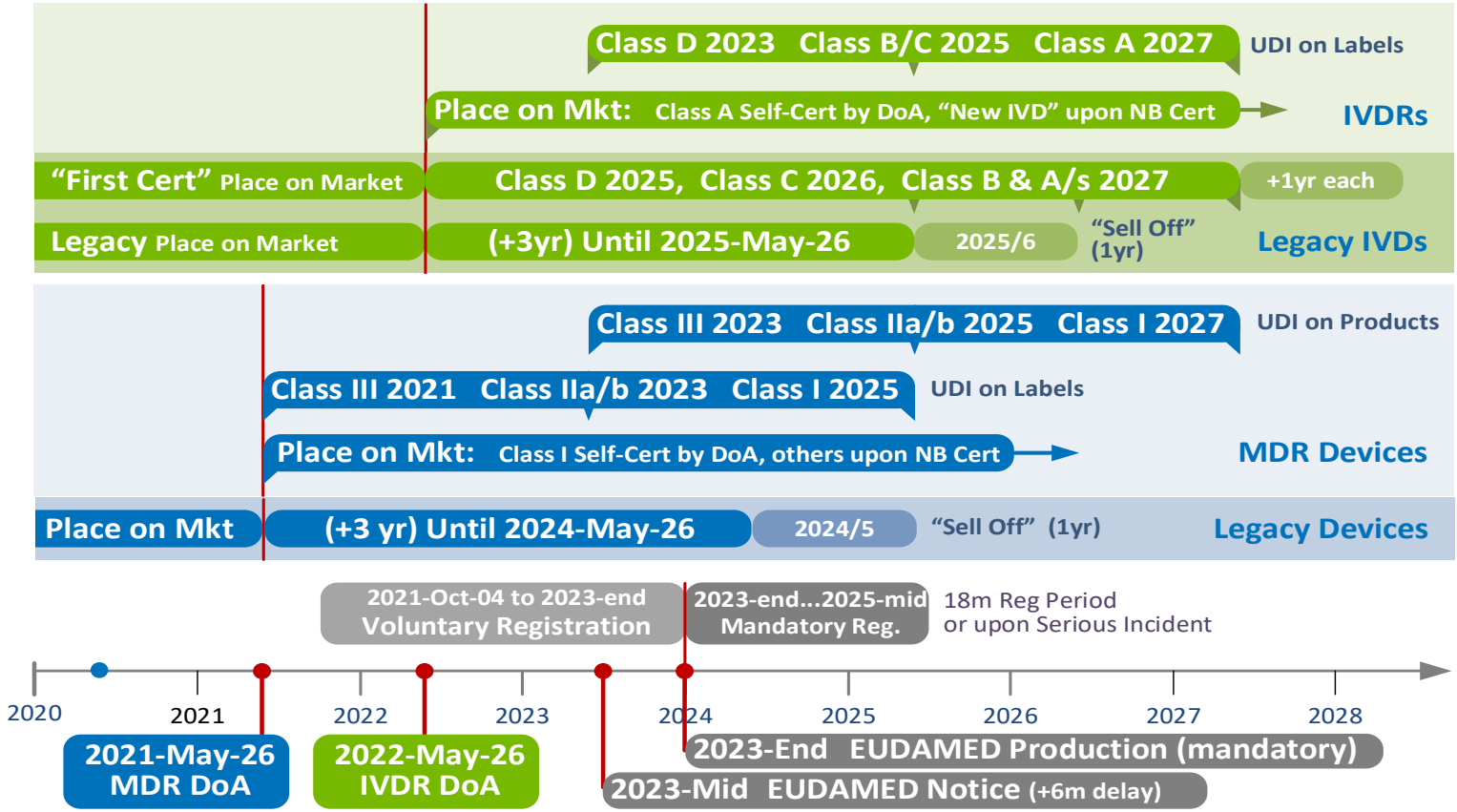
EUDAMED UDI Module

- **Work in Progress**
  - Bugs reported in previous iterations of “Playground” testing are still pending resolution
  - Multiple Playground and Production environment updates expected in 2022
  - Several data exchange services pending release
    - Add/update market information and container package
    - Improvements to bulk data exchange download of device information

- **Reminder:** initial EUDAMED go-live will be a **M**inimally **V**iable **P**roduct (MVP)

- **Implementation Timing TBD for Non-MVP Change Requests**
  - EUDAMED publication status receipt/updates via data exchange
  - Data exchange error message improvements

EU MDR/IVDR Timeline



Medical Devices

UDI and Product Registration

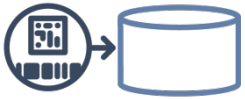
EU UDI Requirements

Label

- Add UDI (Device Id + Production Id) on Device Label & Pkg
- Present UDI in human-readable plain-text and Automatic Id and Data Capture (AIDC) technology (e.g., 1D/2D barcode, RFID)

Direct Marking (DM)

- Permanently mark UDI on reusable devices



EU UDI Database (EUDAMED)

- Submit DI and device attributes (102+ total) to EUDAMED

Reporting

- Include UDI in Annual Reports, Post Marketing Surveillance, Patient Implant Card

EU UDI – Components

The globally unique, numeric or alphanumeric UDI code consisting of two parts is generated by the owner per an approved Issuing Agency standard:

Device Identifier (DI)

Mandatory, fixed portion that identifies the labeler and the specific version or model of a device

00855361005016

Production Identifier (PI)*

Conditional, variable portion that identifies one or more of the following when included on a device label:

Manufactured Date	***2014-09-24***
Expiration Date	***2019-09-24***
Lot or Batch Number	***B35***
Serial Number	***S123***
Software ID	(if present on the label)

UDI = DI + PI

(01)00855361005016(11)140924(17)190924(10)B35(21)S123

GS1 UDI example

 * FDA adds DIN; EU Mfg conditional, adds Sfw ID

EU EUDAMED: UDI Data "MDR/IVDR Group" Basic UDI-DI (36 total)

Identification
Basic UDI-DI
Issuing Entity

Model Info
Device Model
Device Name
*System/Pack
**Kit (y/n)
Special Device

Organization
Mfr SRN
Auth Rep SRN

Regulatory
Legislation
Risk Class

Clinical Invest. #
Clinical Invest. Link
CI Non-EU Countries

Cert Type
Cert #
Cert Revision #
Cert Date
Cert Notified Body #

Characteristics
Animal Tissue/Cell (y/n)
Human Tissue/Cell (y/n)

*Active Device (y/n)
*Implantable (y/n)
*Measuring (y/n)
*Reusable Surgical (y/n)
*Admin Medicine (y/n)
*Medicinal Product (y/n)
*Human Blood/Plasma (y/n)
*Suture, Staple, Filling… (y/n)

**Reagent (y/n)
**Instrument (y/n)
**Companion Diagnostic (y/n)
**Near Patient Test (y/n)
**Patient Self Test (y/n)
**Professional Testing (y/n)
**Microbial Tissue/Cell (y/n)

Common 19
***MDR Only 9** (28 total)
****IVDR Only 8** (27 total)

EU EUDAMED: UDI Data "MDR/IVDR Device" UDI-DI (85 total)

Identification
Basic UDI-DI
UDI-DI
UDI-DI Issuing Entity
Sec UDI-DI, Iss Entity
UoU UDI-DI, Iss Entity
DM UDI-DI, Iss Entity
Related Legacy Device
Relationship Type

Device Info
Trade Name+
Reference/Catalog #
Product Description+
Info URL

Comm 52 + 5 Lang+ = 57
***MDR 22 + 5 Lang+ = 27**
****IVDR 1 + 0 Lang+ = 1**

Product Designer (Original Mfr)
PD SRN
PD Name
PD Street Name, #
PD Addr Complement
PD PO Box, City
PD Postal Code
PD Country
PD Phone, Email

Packaging
Base Device Quantity
Pkg UDI-DI, Iss Entity
Pkg Level Quantity
Pkg Contain UDI-DI
Pkg Status
Production ID Type

Regulatory
Device Status
Device Substatus, Start/End
Recall Precision+, Scope
MS Place on Mkt
MS(s) Made Available, Start/End Dates
Nomenclature Code
**New Device (y/n)
*Non-medical Purpose

Safety Info
Max # Reuses
Labelled Single Use (y/n)
Labelled Sterile (y/n)
Sterile Req'd For Use (y/n)
*Containing Latex (y/n)

Characteristics
*Clinical Size Type
*Clinical Size Precision
*Clinical Size Range Max, Min
*Clinical Size Value (single)
*Clinical Size Unit
*Clinical Size Text
*ClinSize Other Type Descrip+
*ClinSize Other Unit Descrip+
Storage & Handling Type
S&H Description+
*Medicinal Type, Name+, INN
Reprocessed SUD (y/n)

*CMR Type, Name+, CAS#, EC#
*Endocrine Name+, CAS#, EC#
Critical Warning/Contra-Indications Type, Text+

EU Basic UDI-DI

"BUDI-DI" is a product **group identifier** for related medical devices, i.e., a product family

- BUDI-DI "parent" identifier includes one or more "child" medical devices (UDI-DI)
- Each medical device child (UDI-DI) has only one BUDI-DI parent
- All BUDI-DI attributes are common for the product group, i.e., same intended purpose, risk class, design/mfg characteristics, certification

- **Creation**
  - EU MDCG format reqm'ts: max 25 characters & include check digit/character
  - Mfr creates BUDI-DI per Stds (GS1, HIBCC, ICCBBA, IFA) & independent of packaging

- **Use**
  - Used in EU Documentation for Device Registration, etc. and for Trade Item identification in EUDAMED
  - BUDI-DI is different from and does not replace UDI-DI
  - **NOT** used on any product labeling, physical marking, or AIDC data carrier

Basic UDI-DI – GS1 Implementation

GS1 "Global Model Number" (GMN) for Regulated Healthcare Medical Devices (BUDI-DI)

- GS1 General Spec – search "GMN"; EC-GS1-BUDI-DI – change notice for GMN
  GS1 GMN Generator – creates 2 check chars
- GMN created by brand owner, not to be reused, 25 max characters, no spaces,
  GS1 Company Prefix + Model Refer (alphanumeric, A-z/0-9, no special characters) + 2 check characters

GMN format

BUDI-DI (25 max)

0855361005	MyModelRef342	A7
GS1 Company Prefix	Model Reference	2 Check Char

No Barcode

Device Identifier format

UDI-DI (GTIN-14)

0	0855361005	01	6
Indicator Digit	GS1 Company Prefix	Item Ref	Check Digit

Basic UDI-DI Group Example

BUDI-DI: 0855361005MyForceps59

- **UDI-DI: 00855361005016 Forceps, Plastic**
  - **PKG-DI: 10855361005013 Forceps, Pouch - Qty 3**
    - **PKG-DI: 20855361005010 Forceps, Box - Qty 2**
- **UDI-DI: 00855361005023 Forceps, SS**
- **UDI-DI: 00855361005030 Forceps, SS, Locking**
- **UDI-DI: ...**

Medical Devices

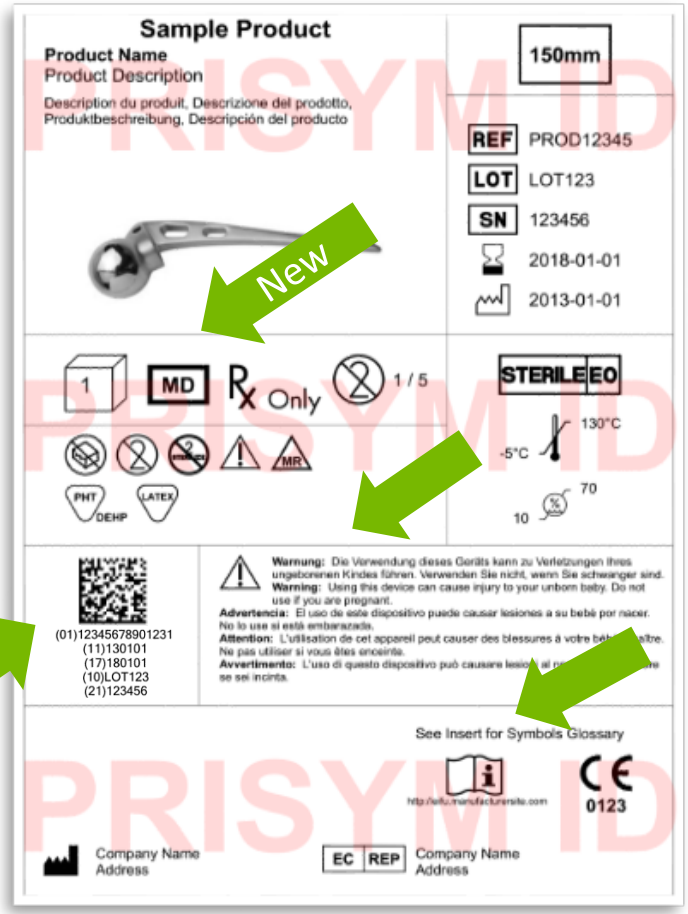
UDI Labels

EU MDR Label Sample

MDR Label Elements:

- “MD” symbol (new)
- Warnings
- eIFU URL
- UDI (new) …

UDI presented in human-readable plain-text and Automatic Id and Data Capture (AIDC) technology (e.g., 1D/2D barcode, RFID)



Enlarged views of PI and UDI

REF PROD12345
LOT LOT123
SN 123456
2018-01-01
2013-01-01

(01)12345678901231
(11)130101
(17)180101
(10)LOT123
(21)123456

Source: PRISYM ID

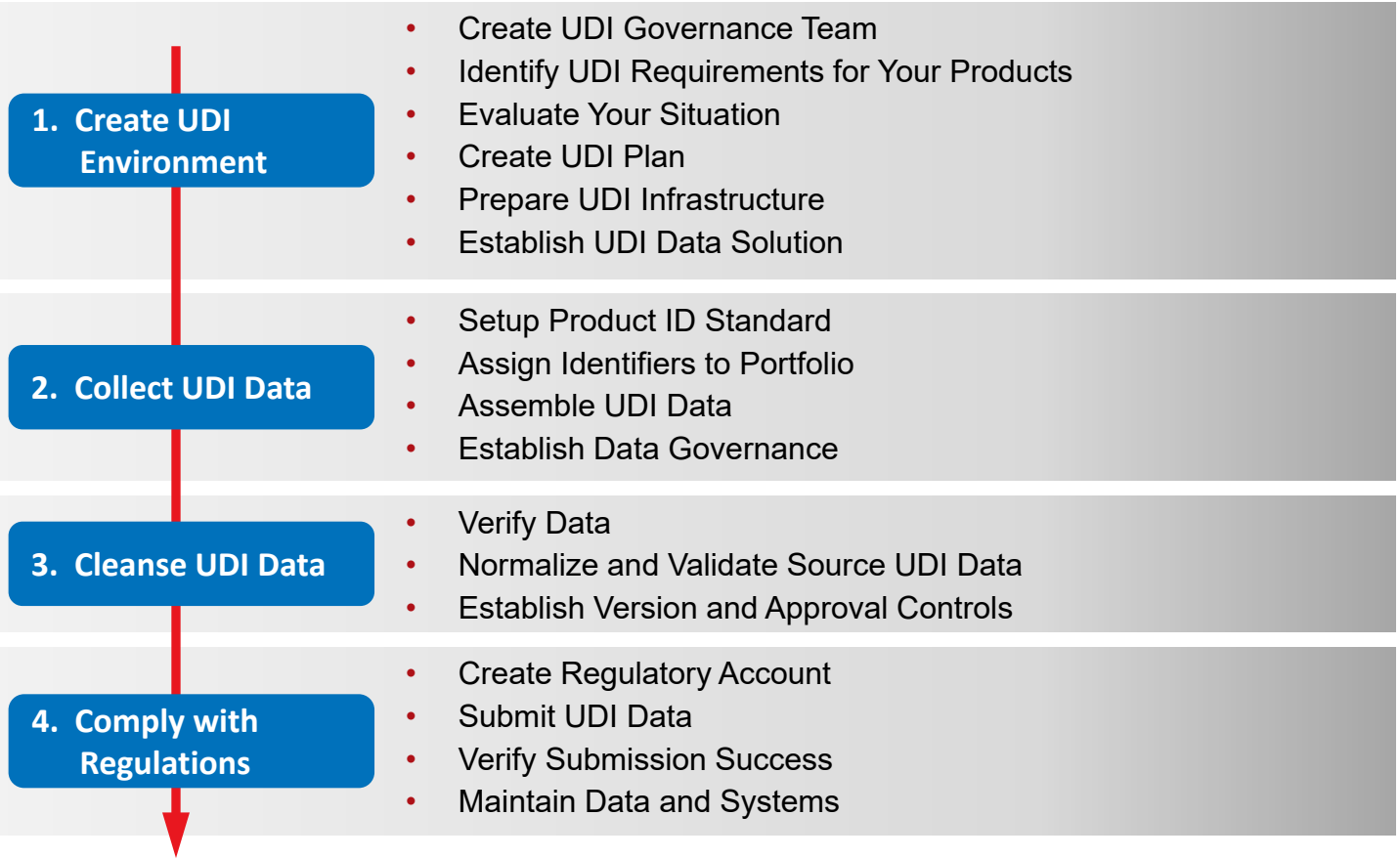
What To Do Now?

GET on Board!

4 C's of UDI/Device Registration

4. Comply with Regulations
3. Cleanse Data
2. Collect Data
1. Create Environment

EU UDI/Device Registration Summary



Reed Tech SSMD-EU Implementation Plan

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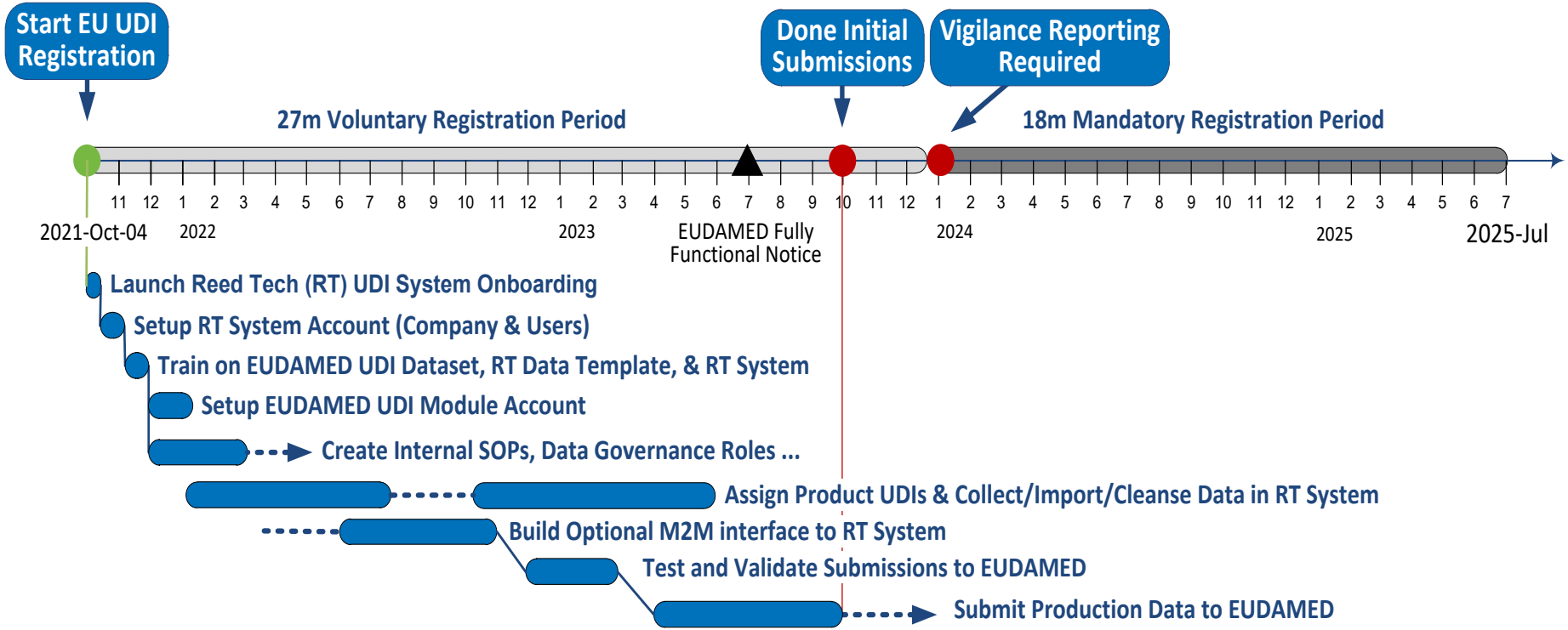
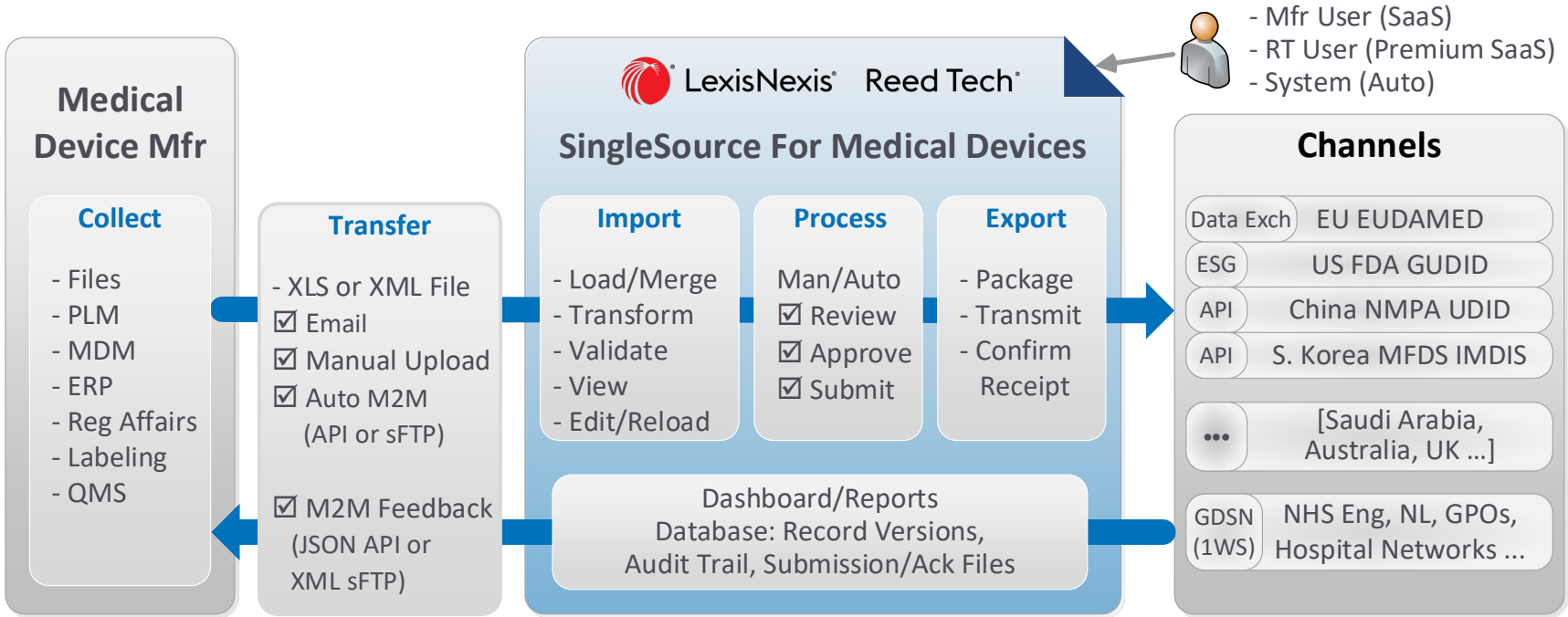
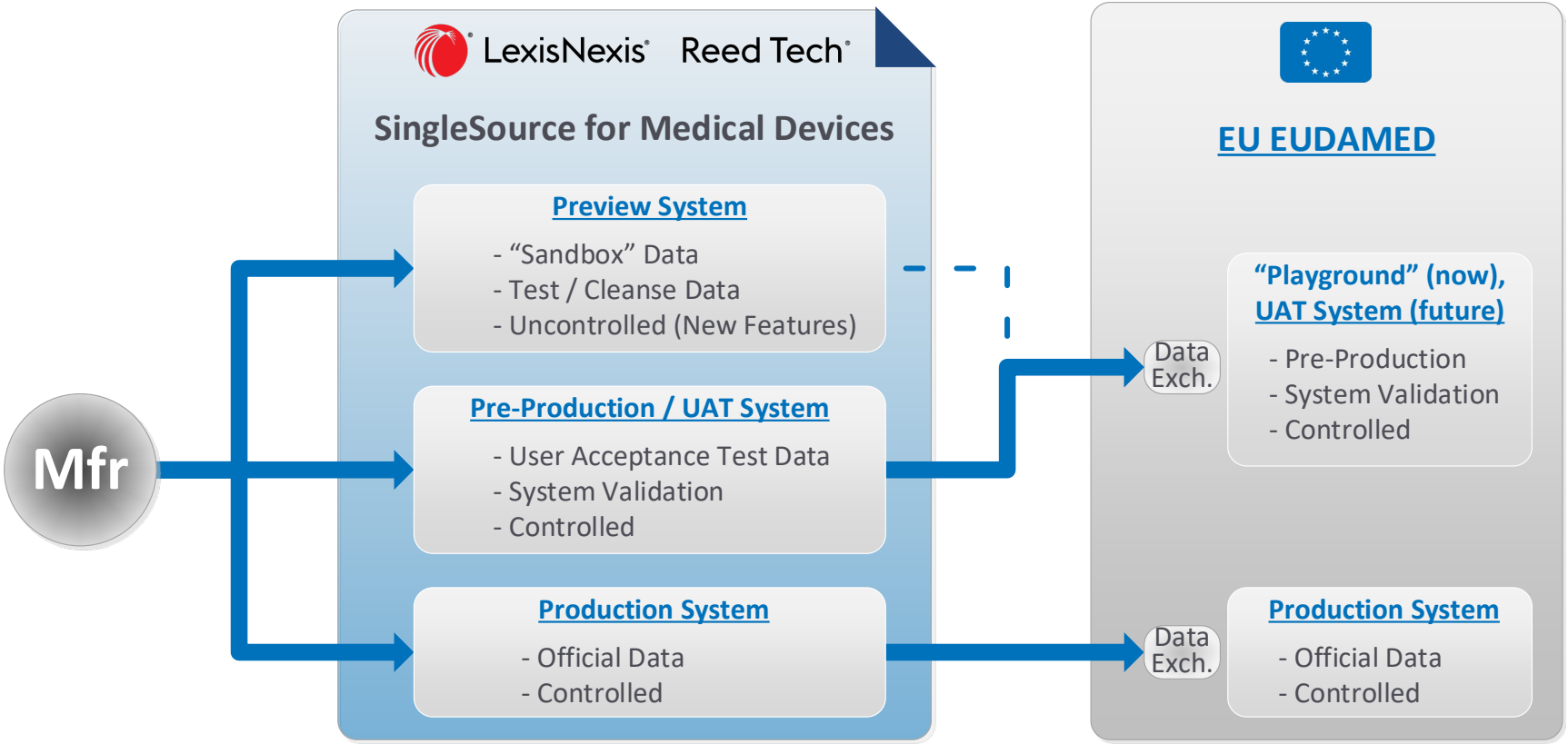
Sample Plan



SingleSource™ UDI Data Mgmt



SingleSource System Environments



UDI Lessons Learned / Best Practices

- **Think Globally**
  - Make EU part of your Global UDI Solution – avoid single-point solutions
  - Move to a master data solution that can expand to other Health Authorities, including HAs with local representation requirements

- **Start Early**
  - Learn EU MDR/IVDR policy, EUDAMED, UDI, your requirements/timing, etc.
  - By MDR Date of Application (DoA):
    - Assign Basic UDI-DI and UDI-DI to products
    - Self-certify MDR Class I devices
  - Create EUDAMED account – register in Actor Module now to receive SRN
    - Prepare/collect Docs before registering (AR must register before Non-EU Mfr)
  - Start product certification using NBs
  - Avoid expected backlog of EC and NB support; Do what you can based on published info; EC quote, “High number of devices on the market, Anticipated bottleneck in reviews by notified bodies, Ongoing need to interpret certain provisions of the Regulations”

UDI Lessons Learned / Best Practices (cont'd)

- **Watch for Updates**
  - EC MDR/IVDR implementation is subject to change!
  - Expect EC and MDCG to frequently update timing and add guidance

- **Prepare Infrastructure and UDI Data**
  - System upgrades can be time consuming
  - EU UDI dataset has twice the number of US UDI attributes and is more complex
  - Data collection and cleansing always seems to take longer than expected
  - Prepare to leverage EUDAMED Playground once it opens to additional Mfrs

- **Reed Tech can Help**
  - Access SME UDI knowledge, training, and industry news
  - Collect and cleanse EU data using Reed Tech UDI templates and system
  - Engage a global UDI data management and submission data hub

Questions?

Resources

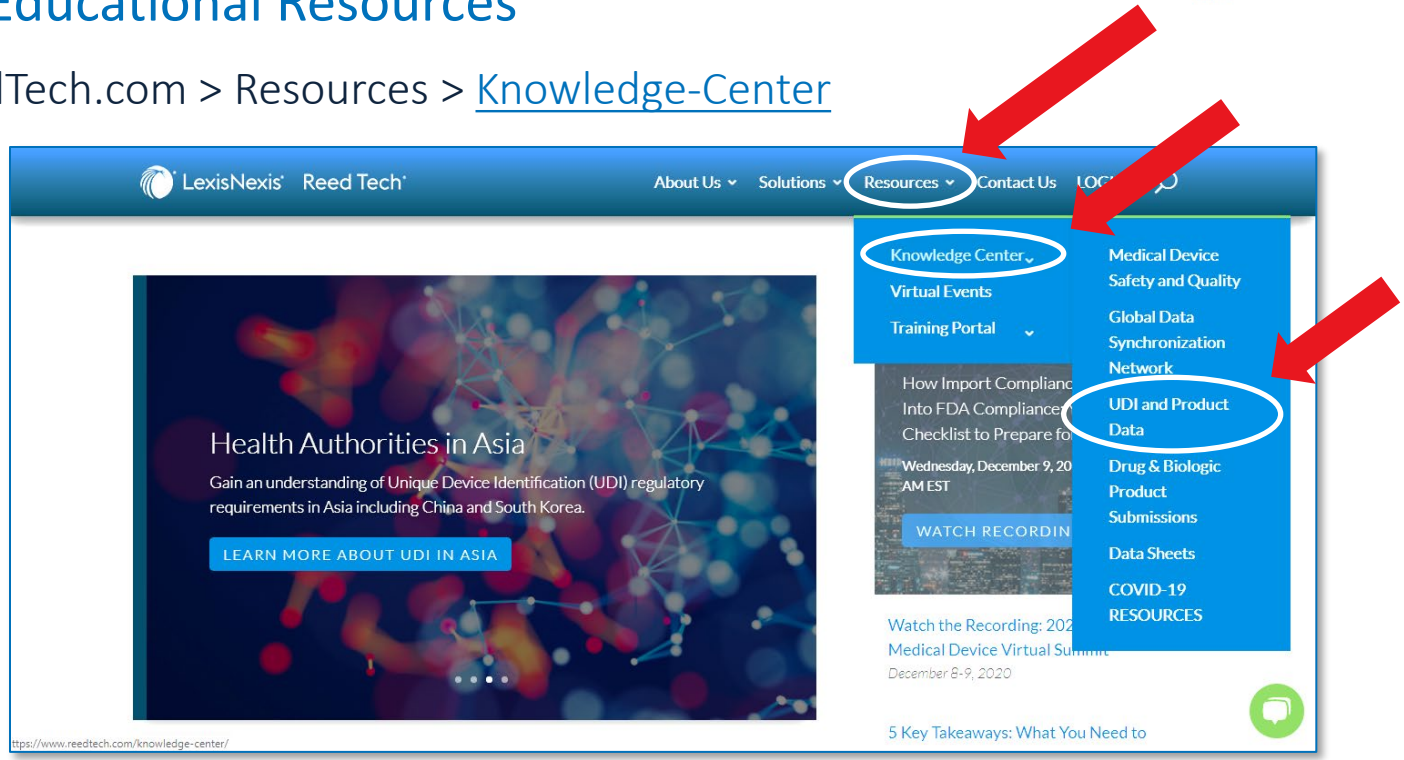
For more information, contact:

Reed Tech Life Sciences Team

MedDevice@ReedTech.com
+1-215-557-3010
www.ReedTech.com

Reed Tech Educational Resources

ReedTech.com > Resources > Knowledge-Center



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Thank you !

Appendix

EU – EC

Events

2021-May-26	MDR DoA
2022-May-26	IVDR DoA
2023-mid	EUDAMED “Functional” Notice (6 modules fully functional)

Compliance Timing

2020-Dec-01	Actor Vol Registration
2021-May-26	Class I Self-cert req’d
2021-Oct-04	UDI/Device & Cert/NB Vol Reg
2023-end	Legacy, MD, IVD: UDI/Device Registration Mandate (notice+6m)
2025-mid	Legacy, MD, IVD: UDI/Device Registration Deadline (notice+24m)

Description

- ***Approach***: **new regulations** for approval, reg, UDI data/labels, vigilance, etc.; rules & timing for Legacy Directive, MDR, IVDR devices
- ***Database***: EUDAMED 3 modules open (Actor, UDI, Cert); 3 future (Vigilance, CI, Mkt Suv)
- ***Data***: 117+ attributes; new **BUDI-DI** “device group” concept
- ***Sub***: website entry/XML upload or M2M XML transfer via Data Exchange (DTX)
- ***Label***: HRI & AIDC by class (2021,2023,2025) Direct Mark by class (Label + 2y)
- ***STD***: GS1/HIBCC/ICCBBA/**IFA**; **SRN**; **EMDN** (CND)
- ***Info***: EC Reg, UDI

EC – European Commission