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UDI Regulations Across the World "Harmonization" (internally and externally) is the Key to Success

Jay Crowley
VP, UDI Solutions and Services
jcrowley@usdm.com
+1-805-880-2591

USDM
Life Sciences

Jay Crowley

VP, UDI

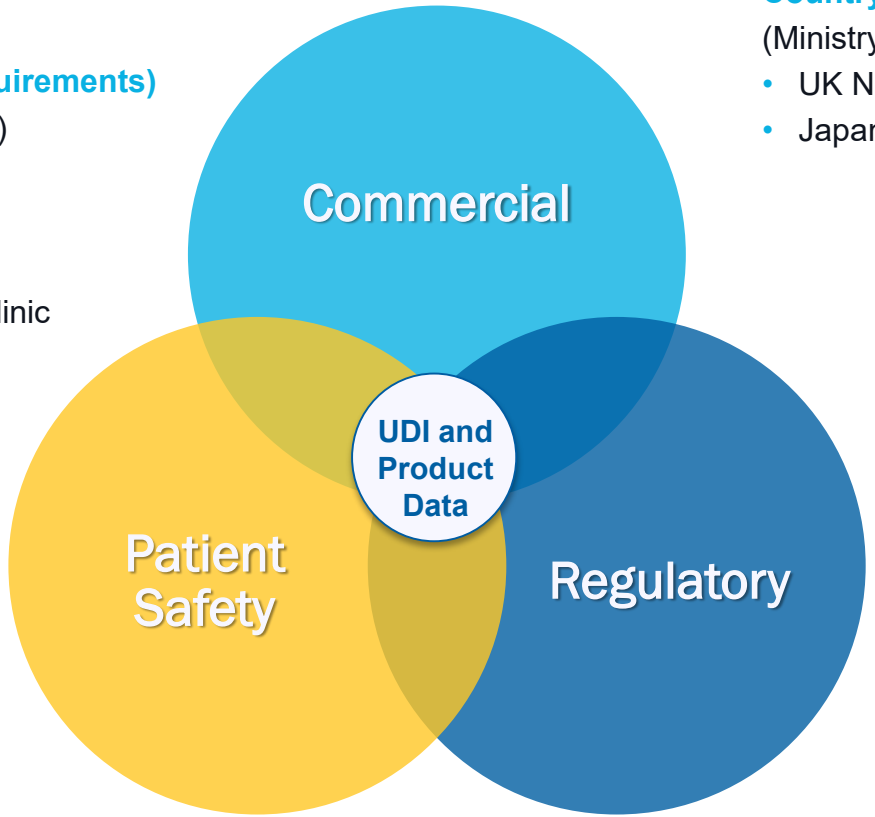
I am currently Vice President, UDI Solutions and Services, at USDM Life Sciences. Prior to joining the firm in January 2014, I was Senior Advisor for Patient Safety, in the US FDA's Center for Devices and Radiological Health. I held a variety of positions over my nearly 27 years at FDA. I had primary responsibility for the development and implementation of FDA's Unique Device Identification System and the development of the GHTF and IMDRF UDI guidance documents.

E-mail: jcrowley@usdm.com

The Evolving Global “UDI” Landscape

Commercial (Market Requirements)
- US IDNs (Kaiser, others)
- US GPOs
- US ONC/EHRs, CMS
- Canadian GPOs
- Abu Dhabi, Cleveland Clinic
- Qatar, Hamad Medical
- Netherland (implants)

Postmarket Requirements
- MDIC/`NEST
- RWD/RWE
- Case for Quality
- Registries, Sentinel
- EU MDR/IVDR



Country Requirements
(Ministry of Health Others)
- UK NHS
- Japan MHLW

Regulatory Requirements
- US
- EU
- China
- Saudi Arabia
- South Korea
- Taiwan
- India
- Australia

Traceability Requirements
- EU class III implants
- Turkey
- Saudi Arabia
- Brazil

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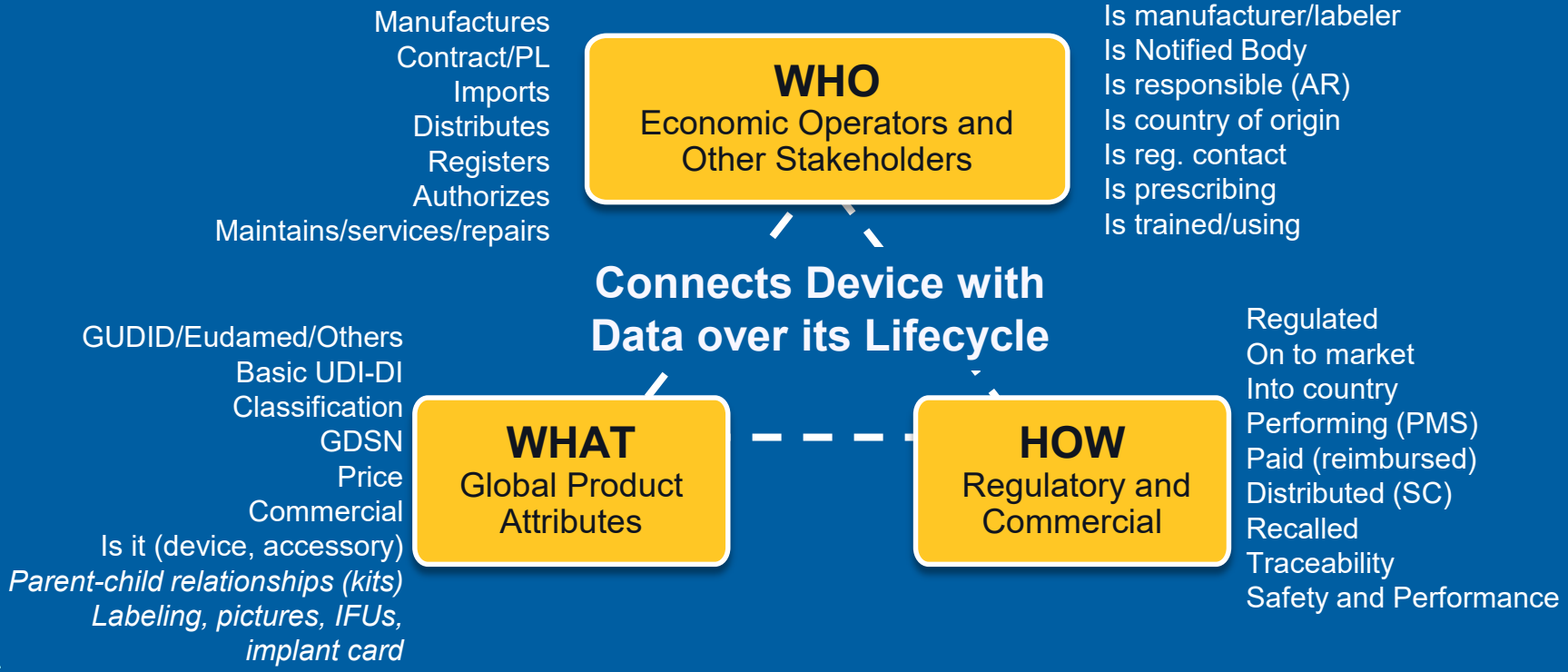
UDI – The Foundation for Visibility and Control



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Major (life-cycle) Harmonization Issues

1. Labeler, Manufacturer, Private Labeler, Contract Manufacturer
2. The Device's "Label" and other UDI location quandaries
3. "Barcode(s)" and HRI (UDI-PI(s) all on the label/package or just control?)
4. Direct Mark UDI-DI (reusable, vs reuse on multiple patients and re-processing)
5. Nomenclature(s?) (GMDN, EMDN, etc.) – purpose?
6. System, configurable devices, procedure pack (kit) (parent-child relationships)
7. Software
8. Devices, Accessories and "Components"
9. UDI Database(s) attributes (+ languages/translations) and New DI Triggers
10. Implementation and Use – including "exceptions/alternatives" (prospective regulatory development), timelines, and existing inventory (exception)

1. Labeler, Manufacturer and PL/OBL/CM

Who is responsible for developing and maintaining a device's UDI and associated data?

- Labeler – any person who causes a label of a device to be applied, replaced or modified with the intent that the device will be commercially distributed without any subsequent replacement or modification of the label…

- Manufacturer – a … person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark –

- "Legal" manufacturer – no such term or definition

- Private labeling/OBL and Contract manufacturer – not the labeler/manufacturer

2. The Device's "Label"

- [EU] 'label' means the written, printed or graphic information appearing either on the device itself, on the packaging of each unit, or on the packaging of multiple devices

- Label is where required information goes (e.g., EU MDR 23.2 – trade name, name and address of manufacturer, lot/serial number, etc.)

- [EU] UDI carriers shall be placed on the label of the device (…and on all higher levels of packaging)
  [US] The label of every medical device shall bear a UDI…
  [KSA] The UDI shall be placed on the label of the device …

3. “Barcode(s)” and HRI

- [KSA] If linear barcodes …. the UDI shall be concatenated into a single barcode
  [EU] If linear bar codes … DI and PI may be concatenated or non-concatenated
  [US] The UDI must be presented in [a form of] AIDC technology.

- 1D vs 2D barcode use/acceptance (POS vs Healthcare)

- [EU] The UDI carrier … means … conveying the UDI by using AIDC and its HRI.
  [US/KSA] The UDI must be presented in plain-text (also known as HRI)

- [All similar] If a lot number, serial number, software identification or expiry date appears on the label, it shall be part of the UDI-PI.

- Barcodes shall be verified according to the appropriate standard …

4. Direct Mark UDI-DI

- [EU] Devices that are reusable shall bear a UDI carrier [AIDC and HRI] on the device itself.

- [US] A device … must also bear a permanent marking UDI on the device itself if the device is intended to be used more than once and intended to be reprocessed [except cleaning alone] before each use…
  - AIDC or HRI
  - Same of different UDI

- [KSA] Reusable devices …shall also bear a DM UDI on the device itself.
  If the device's label is on the device itself and is permanent – a separate DM UDI is not required. However, the UDI label requirements will take precedent.

5. Nomenclature(ssss???)

What is the purpose of a nomenclature/classification…?

- [Globally harmonized?] generic term to identify a device type
- Used widely in (e.g.,) the pharma space to identify similar products, substitutes, manage data, support PMS, price, clinical decision support, etc. …
- Single vs multiple terms (systems, multiple indications)
- Management of term(s?) over time

6. Systems, configurable devices, kits

- Development and management of parent-child relationships – how and when are these relationships exposed and updated…?

- Agree on terminology and application:
  - System
  - Configurable device
  - “Kit” vs procedure pack/convenience kit
  - Non-homogenous packages
  - Accessories ↔ parent devices

- Management over time – e.g., “components” added/removed, changes in indications, “virtual” label

7. Software

- “Stand-alone” or Software as a Medical Device vs. “embedded” software (vs firmware) – does it matter?
- Is it a medical device?
- What does software version mean?
- Management (and communication) of changes
- Where do “wearables”, digital health fit in…?

8. Devices, Accessories and “Components”

- What (which?) is a device?
  Varies by region, regulation, risk class, combination products…

- What is an accessory
  [EU] means an article which, whilst not itself a medical device, is intended … to be used together with … medical device(s) to enable the device to be used ….

- Defintion of “component”…?
  [EU] Each component that is considered to be a device **and** is commercially available on its own shall be assigned a separate UDI…
  [EU/KSA] configurable device … consists of several components which can be assembled … in multiple configurations. The individual components may be medical devices themselves.

9. UDI Database(s)

Purpose and goals of country/region specific databases…?

Major issues include:

- Attribute definition(s?) and use(s?)
- Purpose/meaning of data [need feedback]
- Updates (timing and meaning)
- Corrections (internal vs external)
- Change rules
- New DI triggers
- Languages/translations

What happens if the data does not align across databases?

10. Implementation and Use

How do we decide (globally?) how UDI should apply to different devices/types:

- Device world very broad and heterogenous
- Did/could not foresee all possible implementations (or evolutions)
- Exceptions and alternatives processes key to implementation/convergence

- Implementation timelines and existing inventory (exception)

- How do we incorporate the needs of the various [and evolving] use cases (traceability, import control, costs/quality control, documentation in various clinical information systems, PMS/registries, …)?

None of this matters until/when (if?) UDI and its data attributes are consistently used throughout the device's lifecycle.

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Questions?

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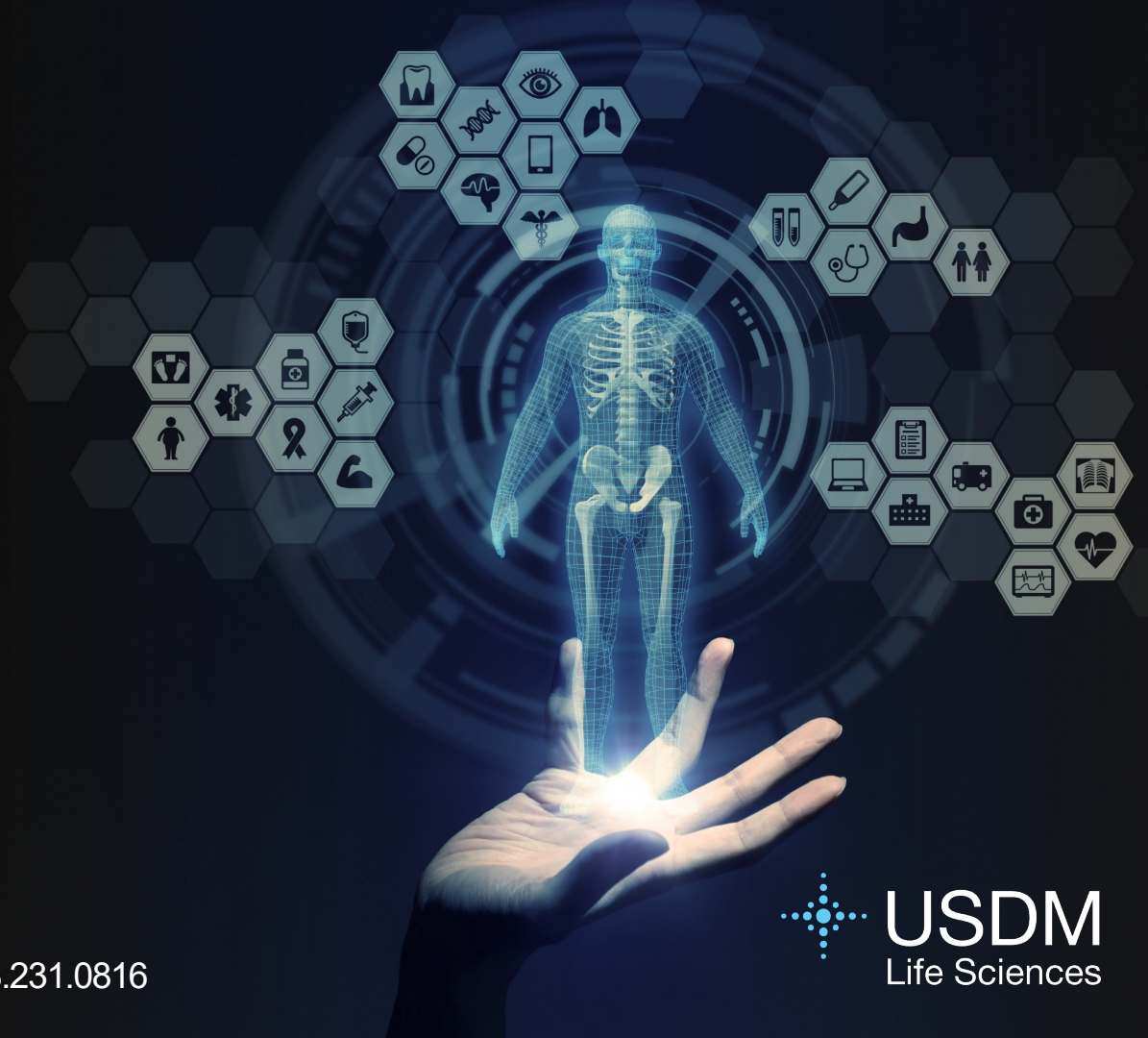
Thank you!

Jay Crowley

VP of UDI, USDM Life Sciences

jcrowley@usdm.com



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