IMDRF International Medical Device Regulators Forum

Session 5: Implementation and Challenges of UDI

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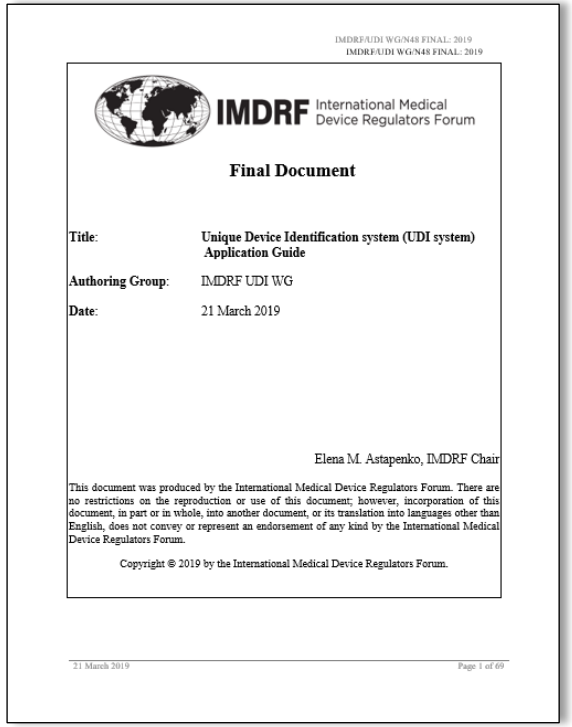
We are succeeding with the implementation of UDI

- **Device Labels:** Millions of labels modified to include UDI requirements
- **UDI Data:** is being created, published, and maintained in multiple countries
- **Process Modifications:** Including Regulatory, Quality, Supply Chain, Manufacturing, Sales, etc., continue to be implemented


IMDRF/UDI WG/N48 FINAL: 2019

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Final Document

Title:	**Unique Device Identification system (UDI system) Application Guide**
Authoring Group:	IMDRF UDI WG
Date:	21 March 2019

Elena M. Astapenko, IMDRF Chair

Much has been accomplished in the past 12 years!

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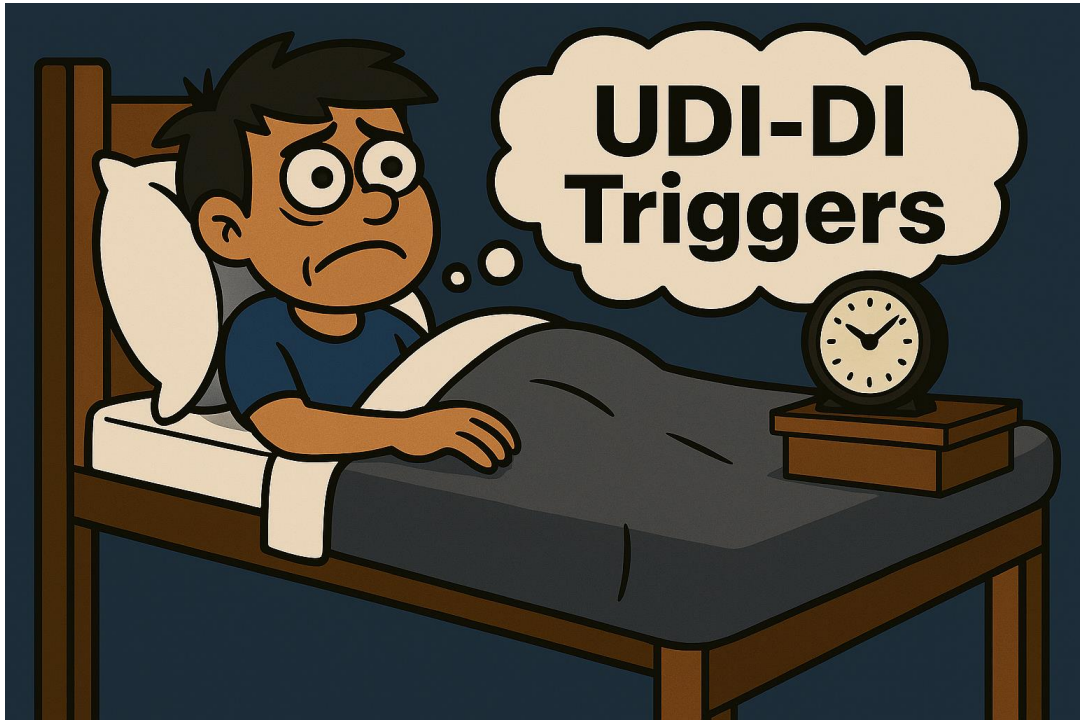
Long-Term UDI Sustainability (What keeps us awake at night)

- **UDI-DI Triggers:** Many disparate rules, locked data fields, and conditions that differ from IMDRF suggestions will cause frequent UDI-DI changes and decreased utility of UDI
  - Obstacle for healthcare providers
  - Safety/Surveillance challenge
  - Supply Chain confusion

- **Other Topics:** UDI for Software and Configurable Devices and UDI Data are worth exploring in future conversations



UDI-DI Triggers we can agree on include:

- A change from a medicated to a non-medicated stent
- Adding Latex and DEHP to a device
- Changing from a 22 Gauge to a 28 Gauge catheter size
- Sterile device converting to a non-sterile device

Examples of UDI-DI Triggers Challenges:

- A change in an alcohol swab (device/drug) in a procedure pack causes a classification change to a Combination Product and therefore a new UDI-DI.
- A change to a risk class of a device causes a new Basic UDI-DI and therefore a new UDI-DI.
- A locked field in a UDI Database in one jurisdiction requires us to change our UDI-DI for that device globally.
- If trace levels of DEHP are removed from a device, this is a UDI-DI Trigger in some jurisdictions. Not all jurisdictions have this requirement.

We should harmonize/rationalize UDI-DI Triggers requirements to align with IMDRF.