

Global IMDRF UDI workshop

Convened on 9 June 2026



Purpose of workshop

The International Medical Device Regulators Forum (IMDRF) Unique Device Identification (UDI) framework was developed to improve patient safety, support rapid device identification, enhance supply chain efficiency, reduce regulatory burden and enable global interoperability.

Following feedback from regulators, industry, UDI issuing agencies, and other stakeholders on the challenges of global UDI implementation, the IMDRF Management Committee requested that a workshop be held to explore the key drivers of divergence and identify opportunities to improve alignment. The workshop brought together regulators, industry representatives, UDI issuing agencies and international organisations.



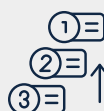
Key findings

Participants agreed that UDI divergence remains a significant global challenge despite the common IMDRF framework. Different implementation approaches across jurisdictions continue to create complexity for regulators, industry and healthcare.

The key causes of divergence identified were:

- different interpretations of UDI requirements and concepts
- jurisdiction-specific requirements
- variations in UDI-DI trigger rules
- differences in data definitions, structured fields and database design
- emerging technologies such as software, AI/ML and configurable devices.

These differences increase regulatory burden, reduce interoperability, and limit the full benefits of UDI.



Priority areas identified

Participants prioritised several areas that offer the greatest opportunities to reduce global UDI divergence and improve consistency.

Priority areas include:

- UDI-DI triggers
- look-alike fields
- terminology, categorisation and nomenclature
- lists of values (LOVs) and structured data
- locked fields.



Proposed activities

The workshop identified a combination of short-term and longer-term activities to support improved alignment.

Short-term priorities focus on practical improvements that can deliver early benefits:

- aligning look-alike fields and structured data
- reviewing key data definition inconsistencies
- reducing variation in UDI databases.

Medium to long-term priorities require greater collaboration and alignment:

- aligning UDI-DI trigger rules
- developing guidance for software and configurable devices
- addressing complex use cases such as mergers and acquisitions.



Proposed strategic activities

To support advancing global alignment, participants proposed:

- developing practical guidance on high-priority topics
- creating a global repository of UDI rules, UDI triggers, definitions and data elements
- aligning common data attributes across UDI databases
- continuing collaboration between regulators, industry, UDI issuing agencies and healthcare stakeholders.



Key takeaway

There is strong international consensus that greater UDI harmonisation is needed. Practical short-term activities provide an opportunity to deliver early value, while longer-term collaboration will be required to address more complex areas of divergence and support a more globally interoperable UDI system.