IMDRF International Medical Device Regulators Forum

PROPOSED DOCUMENT

International Medical Device Regulators Forum

Title: Use of UDI Data Elements across different IMDRF Jurisdictions

Authoring Group: IMDRF UDI WG

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Preface

The document herein was produced by the International Medical Device Regulators Forum (IMDRF), a voluntary group of medical device regulators from around the world. The document has been subject to consultation throughout its development.

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1.0 Introduction

The IMDRF UDI Guidance (IMDRF/WG UDI/N7Final:2013) provides a framework for the regulatory authorities that intend to develop their UDI Systems in a globally harmonized approach.

Since 2013, many jurisdictions worldwide have taken important steps forward in implementation of National UDI systems. IMDRF has recognized the need to supplement the IMDRF UDI Guidance (IMDRF/WG UDI/N7Final:2013) which was developed as a high-level conceptual framework, by providing principles for globally harmonized application of UDI system and tools for operators to identify how common IMDRF principles are translated into real-world terms.

Considerations related to submission of UDI core data elements to UDI databases is acknowledged as one key concern.

2.0 Scope

This information document, to be read in conjunction with the IMDRF UDI Application Guide (IMDRF/UDI WG/N48Final:2018) is intended to provide a UDI data elements dictionary containing descriptions of the data elements as collected in National UDI databases (UDID) across jurisdictions.

The objective of this information document is in particular to identify how common UDID data elements listed in Section 9.2 of the IMDRF UDI Guidance (IMDRF/WG UDI/N7Final:2013) are collected by the different jurisdictions and whether and how additional jurisdiction-specific UDI data elements are collected.

A data dictionary should be easily accessible to users and managers of a data system. Just as a typical dictionary helps convey the meaning of words, a data dictionary translates data elements into real-world terms.

It helps users submit data to the database.

3.0 Definitions

See Section 3.0 of the IMDRF UDI Application Guide (UDI WG(PD1)/N48).

4.0 Use of UDI Data Elements across different IMDRF Jurisdictions

This document contains one Annex in an Excel form.

This annex includes information from the jurisdictions that have defined the data fields in their respective UDID systems.

The file contains six sheets:
- Notes – explains the column headers of the UDI-DD and includes legend for the Compare summarization sheet
- IMDRF -2013 CDE – data elements listed in the IMDRF UDI Guidance (IMDRF/UDI WG/N7Final:2013)
- EU - EU specific data fields
- US - US specific data fields
- Compare – side by side comparison of EU and US data fields; sheet includes a field, "Grouper", that allows side by side comparison of fields with similar intent or meaning. Data elements without an assigned Grouper are specific to a jurisdiction and appear at the bottom of the worksheet
- Compare summarized - lists each data field in the side-by-side comparison and assigns a value of required, conditionally required, optional, auto-populated or not recognized.

5.0 Update of the document

The IMDRF Management Committee will consider whether and how the Annex to this document will be subject to regular review.