IMDRF International Medical Device Regulators Forum

Final Document

International Medical Device Regulators Forum

Title: Common Data Elements for Medical Device Identification

Authoring Group: IMDRF RPS Working Group

Date: 24 March 2016

Fabio Pereira Quintino, IMDRF Chair

Contents

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.

1 Introduction

The International Medical Device Regulators Forum (IMDRF) was conceived in February 2011 as a forum to discuss future directions in medical device regulatory harmonization. It is a voluntary group of medical device regulators from around the world who have come together to build on the strong foundational work of the Global Harmonization Task Force (GHTF). The Forum will accelerate international medical device regulatory harmonization and convergence.

Regulators require submission of device identification information at different points in the regulatory life cycle of a medical device. Structured device identification information is now or expected in the future to be included as part of pre-market submission, post-marketing distribution and use (disposal and discard), adverse event/vigilance reporting, and recall.

Once the medical device is commercially available, a Unique Device Identification (UDI) system is expected to capture the device identification data elements at the level of a particular medical device. However, at the point of initial regulatory submission, specific medical device identification data elements are not always assigned. Therefore it would be useful to establish common data elements, for which they can be defined throughout the life cycle. Currently these data elements have not been identified resulting in the lack of a consistent nomenclature, definitions and structure for submission of this identifying information. Each type of submission may reference the product differently. For example, a regulatory submission may refer to the medical device's trade name, the data attributes associated with UDI may contain brand name and a recall may refer to proprietary name – all referring to the same medical device. The identification information is also often submitted as part of unstructured medical device regulatory submission forms and other unstructured documents. The combination of different ways to identify a medical device and the unstructured way medical device information is submitted make it difficult over time to reconcile references to the same medical device.

Inconsistency in the format used to identify medical devices as part of submissions and the lack of a harmonized nomenclature and structure for medical device identification information, currently result in multiple submissions of data, inconsistencies in submitted information, and ultimately an inability to compile effective market surveillance information about a medical device. Lack of a common definition for medical device identification information also increases the risk that, for regulatory purposes, a medical device may be referenced differently in different countries, which limits the ability to compile data or make comparisons across countries.

Consistent use of standardized structured data elements for submission of regulated medical device identification information will aid in long-term regulatory convergence by providing a common way for regulators to refer to what is regulated and enables tracking and reporting unambiguously on the regulatory marketing status of a medical device around the world.

2 Scope

This document outlines the common data elements for medical device identification that may be used through regulatory activities or processes, including the future possibility of electronic regulatory submission of device identification information. This document will cover the harmonization of terms and their definitions.

3 References

The following references were used in the development of this document:

- GHTF/SG1/N70:2011, Label and Instructions for Use for Medical Devices;
- GHTF/SG1/N71:2012, Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device';
- GHTF/SG1/N78:2012, Principles of Conformity Assessment for Medical Devices;
- GHTF/SG2/N87, An XML Schema for the electronic transfer of adverse event data between manufacturers, authorised representatives and National Competent Authorities (Based on GHTF/SG2/N54: 2006);
- IMDRF/RPS WG/N9FINAL:2014, Non-In Vitro Diagnostic Device Market Authorization Table of Contents (nIVD MA ToC);
- IMDRF/RPS WG/N13FINAL:2014, In Vitro Diagnostic Medical Device Market Authorization Table of Contents (IVD MA ToC);
- IMDRF/SaMD WG/N10FINAL:2013, Software as a Medical Device (SaMD): Key Definitions;
- IMDRF/UDI WG/N7 FINAL:2013, UDI Guidance - Unique Device Identification (UDI) of Medical Devices.

4 Definitions

Accessory to a medical device: means an article intended specifically by its manufacturer to be used together with a particular medical device to enable or assist that device to be used in accordance with its intended use. *GHTF SG1/N071:2012*

Applicant: means any natural or legal person[1] who is legally responsible for the medical device regulatory submission under the country or jurisdiction's legislation.

Manufacturer: means any natural or legal person[2] with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s) [GHTF SG1/N55:2009]. This includes reprocessors and remanufacturers that take responsibility for the device and reintroduce it into commercial distribution. *IMDRF/UDI WG/N7 FINAL:2013*

Medical Device: means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by

[1] The term "person" that appears here includes legal entities such as a corporation, a partnership or an association.
[2] Ibid.

the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices,
- providing information by means of in vitro examination of specimens derived from the human body;

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means. **Note:** Products which may be considered to be medical devices in some jurisdictions but not in others include:

- disinfection substances,
- aids for persons with disabilities,
- devices incorporating animal and/or human tissues,
- devices for in-vitro fertilization or assisted reproduction technologies.

GHTF SG1/N071:2012

Regulatory Authority (RA): A government body or other entity that exercises a legal right to control the use or sale of medical devices within its jurisdiction, and that may take enforcement action to ensure that medical products marketed within its jurisdiction comply with legal requirements.

GHTF/SG1/N78:2012

Software as a Medical Device (SaMD): is defined as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.

NOTES:

- SaMD is a medical device and includes in-vitro diagnostic (IVD) medical device.
- SaMD is capable of running on general purpose (non-medical purpose) computing platforms[3]
- "without being part of" means software not necessary for a hardware medical device to achieve its intended medical purpose;

[3] "Computing platforms" include hardware and software resources (e.g. operating system, processing hardware, storage, software libraries, displays, input devices, programming languages etc.).
"Operating systems" that SaMD require may be run on a server, a workstation, a mobile platform, or other general purpose hardware platform.

- Software does not meet the definition of SaMD if its intended purpose is to drive a hardware medical device.
- SaMD may be used in combination (e.g., as a module) with other products including medical devices;
- SaMD may be interfaced with other medical devices, including hardware medical devices and other SaMD software, as well as general purpose software
- Mobile apps that meet the definition above are considered SaMD.

IMDRF/SaMD WG/N10FINAL:2013

5 Data Elements Used for Device Identification and Regulatory Activities

This document identifies preferred data elements that may be used to identify a medical device through its life cycle. The data elements resulted from consensus discussions and are subject to specific regional considerations that are not included in this work item.

5.1 Overview

The RPS Common Data Elements Working Group has developed this document to describe preferred medical device terminology to facilitate the interchange of information and minimize re-work when operating across jurisdictions. The list is not prescriptive but it represents a step in the evolution of harmonized terminology and adoption by stakeholders over time will simplify the development and exchange of information.

The Working Group discussed related terms not described here (including device characteristics and regulatory tracking information) that would be useful in the exchange of information between Regulatory Authorities and Regulated Entities. One of the examples is device image. The element may be considered in future regional implementations as it was accepted by a majority of regulatory authorities citing that it would provide additional information that may be used when identifying a medical device. Future work may result in the development of further harmonized terms and definitions.

Please note that regional requirements need to be followed. This document serves as a reference document so that, where possible, stakeholders can work towards common data elements and definitions.

5.2 Stakeholders

The stakeholders involved in the exchange and/or use of data elements to identify a medical device include, but are not limited to the following:

- Regulatory Authorities;
- Regulated Entities (e.g., Sponsors, Applicants, Manufacturers, Labelers, Suppliers and Distributors, Maintenance/Servicing);
- Users of Medical Devices (e.g., Hospitals, Physicians, Patients, Consumers).

5.3 Common Data Elements across the Medical Device Life Cycle

Common data elements may be reported by Regulated Entities or assigned by Regulatory Authorities to support various regulatory activities during the life cycle of a medical device. Prior to placing a medical device on the market, the following regulatory activities may occur: submission requesting regulatory feedback; submission to conduct clinical studies, submission of regulatory information to support an application or notification of marketing a medical device (e.g., submissions of data to ensure safety and effectiveness, labeling information, etc.), and any relevant registration or listing information.

Once the medical device is commercially available, there are certain requirements and regulations that should be met to ensure safety, performance and effectiveness. Regulated Entities as well as other firms involved in the distribution of devices are responsible for reporting device malfunctions, serious incidents and adverse events. Regulatory Authorities are responsible for surveillance that may include signal detection, signal assessment, authorizing risk management activities and review of post market commitments.

Based on the surveillance activities, the Regulated Entities are responsible for complying with regulatory requirements for the medical device in the countries or jurisdictions where it is intended to be made available or sold, and includes monitoring and auditing activities. When a Regulated Entity fails to comply with these requirements they may either take voluntary actions to correct the violation (e.g., product withdrawal), or regulatory action may be taken that may include changes in marketing status, risk communications, warning letters and corrective actions (e.g., recalls).

5.4 Common Data Elements Groupings

The data elements provided in this document appear in the order presented in

Table 1: Data Element Groupings. In addition, the data elements presented do not imply a "requirement" for the exchange and/or use of the data, but only the potential to identify a medical device at each life cycle phase based on the regulatory requirements in each of the jurisdictions.

Table 1: Data Element Groupings

Data Elements/Grouping	Purpose

Medical Device Primary Identity Information
• Medical Device Name (Brand/Trade/Proprietary or Common name)
• Model
• Catalog/Reference (REF)
• Catalog/Reference (REF) Description
• Version (Software or Firmware)
• Unique Device Identifier (UDI)
  ○ Device Identifier (DI)
  ○ Production Identifier (PI)
  ▪ Serial Number
  ▪ Lot or Batch Number
  ▪ Manufacturing Date
  ▪ Expiration Date
	The value of the data elements are assigned by the Regulated Entity for the purposes of identifying and tracking the medical device throughout its life cycle.

Regulated Entity • Name • Address • Identifier • Type	These data elements as specified by the Regulatory Authority and the values provided by the Regulated Entity are for the purposes of identifying the legal party involved in a regulatory activity.
Kit	These data elements provide an indicator used to differentiate the grouping of different medical devices and/or accessories for the purpose of placing it on the market.
Medical Device System	
Contains Biological Materials	This data element provides an indicator for the existence of specific biologic materials in the medical device for safety purposes.
Medical Device Usage • Single Use Device • Reusable - Single Patient Use Device • Reusable - Multi-Patient Use Device	The values of the data elements are determined by the Regulated Entity for the purposes of managing risks associated with multiple use of the medical device.
Sterilization Information • Supplied Sterile • Needs Sterilization before use • Method of Sterilization	The values of the data elements are determined by the Regulated Entity for the purposes of managing risks associated with sterilization.
Regulatory Information • Medical Device Type • Medical Device Risk Classification • Submission Number • Regulatory Authorization or Marketing Number • Regulatory Authorization or Marketing Status	The values of the data elements are assigned by the Regulatory Authority for the purposes of identifying and tracking regulatory activities for a medical device through its life cycle.

Note: The values assigned to the data elements may change at any point in time and may require reporting to the Regulatory Authority.

5.5 Harmonized Common Data Elements

The following sections are organized by individual common data elements, and provide the harmonized description of each data element, the life cycle (i.e., usage). Some of the data elements will include a "type" attribute when it needs additional information to fully describe the value.

5.5.1 Medical Device Primary Identity Information

Includes the data elements that identify the medical device by its name, model, catalog/reference, or version numbers.

5.5.1.1 Medical Device Name (Brand/Trade/Proprietary or Common name)

A name used to assist in the identification of the regulated medical device.

Type
Indicates the type of name that identifies the regulated medical device. It may be Brand, Trade/Proprietary or Common name.

5.5.1.2 Model

The value used to represent one medical device or a family of medical devices to group many variations that have shared characteristics.

5.5.1.3 Catalog/Reference (REF)

The value given by the Regulated Entity to identify the specific medical device as it relates to its form/fit, function and process (i.e., manufacturing processes requiring differentiation for distribution control (e.g., sterilization, component material, reprocessing, etc.).

5.5.1.4 Catalog/Reference (REF) Description

Text describing or differentiating the variant of the medical device.

5.5.1.5 Version (Software or Firmware)

The value given by the applicant to identify a specific revision of the software or firmware (including SaMD).

5.5.1.6 Unique Device Identifier (UDI)

A series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard. It allows the unambiguous identification of a specific medical device on the market. The UDI is comprised of the Device Identifier and Production Identifier.

Note: The word "Unique" does not necessarily imply serialization of individual production units, but does allow tracking of medical devices through the supply chain.

Reference/Citations: IMDRF/UDI WG/N7 FINAL:2013

5.5.1.6.1 Device Identifier (DI)

A unique numeric or alphanumeric value specific to a model or version of a medical device.

Reference/Citations: IMDRF/UDI WG/N7 FINAL:2013

5.5.1.6.2 Production Identifier (PI)

A numeric or alphanumeric code that identifies the unit of device production. The different types of Production Identifier(s) include serial number, lot/batch number, manufacturing date, and/or expiration date.

Reference/Citations: IMDRF/UDI WG/N7 FINAL:2013

5.5.1.6.2.1 Serial Number

A unique sequence of numbers or letter in a series used to identify an individual unit of a medical device.

5.5.1.6.2.2 Lot or Batch Number

A value that represents one or more components or finished devices that consist of a single type, model, class, size, composition, or software version that are manufactured under essentially the same conditions and are intended to have uniform characteristics and quality within specified limits.

5.5.1.6.2.3 Manufacturing Date

A date determined by the Regulated Entity in which the medical device is considered manufactured.

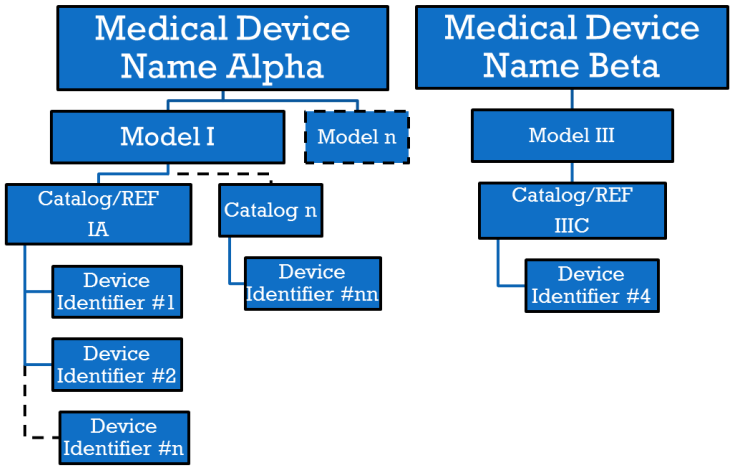
5.5.1.6.2.4 Expiration Date

A date based on the results of studies which demonstrate that the medical device will perform as intended and will meet its specifications until that date.

5.5.1.7 Relationship of Medical Device Primary Identify Information Data Elements

In addition to defining these data elements, there are relationships across them that describe the hierarchical relationship between data elements. Figure 2 below depicts these relationships.

Figure 1: Medical Device Identity



5.5.2 Regulated Entity

The responsible party involved in a regulatory activity. The Regulated Entity may be identified by specific information to include a name, address, and identifier of regulated entity.

Type
Indicates the value assigned to identify the type of Regulated Entity. For example, it may be Manufacturer or Distributor.

5.5.2.1 Name

The text value used to identify the Regulated Entity.

5.5.2.2 Address

The physical and/or mailing/postal location of the Regulated Entity.

5.5.2.3 Identifier

The alphanumeric value used to identify the Regulated Entity.

5.5.3 Kit

A collection of products, including medical devices, that are packaged together to achieve a common intended use and is being distributed as an in vitro diagnostic medical device, or for the convenience of the user.

Reference/Citations: Modified from IMDRF/UDI WG/N7 FINAL:2013

5.5.4 Medical Device System

A medical device comprising a number of components and/or accessories intended to be used together to fulfill some or all of the medical device's intended functions, and is placed on the market as specified by its manufacturer (e.g., under a single name, or sold as one item).

5.5.5 Contains Biological Material

A value that indicates if the medical device is coated, impregnated or combined with biological materials such as cells, tissues or other materials (which may be of human, animal or microbial origin) that are intended for implantation, transplantation, infusion, or transfer into a human recipient.

5.5.6 Medical Device Usage

Describes the use and reuse of the medical device with respect to reprocessing. The type could be single use (SUD), reusable – single patient use, reusable – multi patient use or other (e.g., reprocessed SUD).

5.5.6.1 Single Use Device

A medical device intended by the manufacturer to be used on an individual patient during a single procedure.

5.5.6.2 Reusable - Single Patient Use Device

A medical device intended by the manufacturer to be used on a single patient with reprocessing (e.g. cleaning, disinfection or sterilization) between uses.

5.5.6.3 Reusable - Multi-Patient Use Device

A medical device intended by the manufacturer to be used on multiple patients with reprocessing (e.g. cleaning disinfection or sterilization) between uses.

5.5.7 Sterilization Information

The sterilization information for a medical device includes whether or not it is supplied sterile, needs sterilization before use and the method(s) of sterilization used.

5.5.7.1 Need for Sterilization Before Use

The manufacturer specifies whether or not the medical device must be sterilized before use. This is applicable to medical devices which are supplied sterile and intended for multiple use, or that require sterilization before first use and any intended subsequent use.

5.5.7.2 Supplied Sterile

The manufacturer specifies whether or not the medical device is supplied sterile.

5.5.7.3 Method of Sterilization

The manufacturer specifies the method(s) of sterilization if the medical device needs sterilization before use.

5.5.8 Regulatory Information

The regulatory information related to the medical device including medical device type, medical device risk classification, submission and regulatory authorization or marketing numbers, and regulatory authorization or marketing status.

5.5.8.1 Medical Device Type

The value assigned to describe the device type by a nomenclature system.

Type of Nomenclature
Indicates the code system used to specify the medical device type.

5.5.8.2 Medical Device Risk Classification

A classification based on rules derived from the potential of a medical device to cause harm to a patient or user (i.e., the hazard it presents).

Type
Indicates the Regulatory Authority under which the device risk is classified.

5.5.8.3 Submission Number

A tracking number which is assigned to the regulatory activity when submitted by the applicant.

Type
Indicates the Regulatory Authority assigning the Submission Number.

5.5.8.4 Regulatory Authorization or Marketing Number

A number issued when the medical device can be legally marketed.

Type
Indicates the Regulatory Authority assigning the Regulatory Authorization or Marketing Number.

5.5.8.5 Regulatory Authorization or Marketing Status

A decision or action assigned by the Regulatory Authority that indicates the marketing availability of the medical device.

Type
Indicates the Regulatory Authority assigning the Regulatory Authorization or Marketing Status.

Index