The Global Language of Business

Discusion Paper on Machine-to-Machine (M2M) Unique Device Identification (UDI) data connection

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Audience

The main target audience of this discussion paper is regulators developing UDI requirements, in particular related to the UDI Database.

Scope

The UDI systems – as defined by the International Medical Device Regulators Forum (IMDRF) Application Guide[1] - that are being developed worldwide imply the submission of required data to UDI regulatory databases by the relevant stakeholders. Manufacturers may have several options for data submission to a UDI regulatory database.

Purpose

This discussion paper aims at highlighting the importance of proposing a Machine-to-Machine (M2M) connection option to submit data and presents the benefits that the GS1 standard Global Data Synchronisation Network (GDSN) brings in that context.

M2M data connection for better data quality

Unique Device Identification data intends to be used and integrated into several electronic data sources throughout the healthcare system (supply chain, electronic health records, registries, etc.). Data quality is therefore of utmost importance to accomplish the benefits of UDI, so that data can be trusted and widely used by the healthcare stakeholders.

M2M submission systems enable medical device manufacturers to better control the quality of the data submitted to a UDI regulatory database as it leads to less errors than manual entry of data. Furthermore, when using M2M submission systems, strict validation processes of the data submitted can be implemented (data quality checks and procedures, data management process and policies, enterprise-wide data governance policies, etc.).

M2M submission systems ensure automated synchronization of up-to-date data between the manufacturers' Information System and a UDI regulatory database, whereas manual maintenance management processes are not so reliable to ensure that data are effectively updated using manual submission systems. Manual data entry processes introduce significantly more data errors than automated ones.

Furthermore, given the UDI requirements development pace in the world today, it would be challenging for manufacturers to manage several UDI data sets for each local context, also given the number of data attributes required. Harmonisation of data elements and definitions is therefore also key to ensure consistent and accurate data across UDI databases worldwide.

Last, to ensure that the benefit of the submission using M2M system, the sender of a data submission must always receive a response message acknowledging his submission, regardless whether the submission was successful or not. It is important for the regulators establishing the specifications to plan for a complete loop of messaging as part of the MéM submission process.

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[1] A system that is intended to provide single, globally harmonized positive identification of medical devices through distribution and use, requiring the label of devices to bear a globally unique device identifier (to be conveyed by using AIDC and, if applicable, its HRI) based upon standard, with the UDI-DI of that unique identifier being also linked to a jurisdiction-specific public UDI database. For more information on the fundamental concepts of the unique device identification system, see IMDRF/WG UDI/N7Final:2013.

GS1 standards for M2M connection: Global Data Synchronisation Network (GDSN®)

Normalised, standardised product data will help drive higher quality data for regulatory agencies. The Global Data Synchronisation Network (GDSN®) enables manufacturers, distributors, and providers to share accurate product information electronically. When M2M connection option is possible as well as the use of GDSN standard, **the GDSN provides a secure and easy way for manufacturers to register their product data in a UDI regulatory database via certified data pools.**

It is critical to emphasize that the GDSN is a mean of moving data from one point to another and that data quality is to be achieved before the data is sent through the GDSN, even more given that UDI related data are not only used for regulatory compliance but also by hospitals to support patient care. Achieving data quality implies a series of internal processes (e.g. data creation, data collection, data revision, data maintenance) managed by the manufacturer to ensure accuracy and completeness. Once data quality is ensured, the GDSN can be used to facilitate publication[2] of standardised product data to regulatory UDI databases.

GDSN standard attributes have been used to support successful registration of regulated product data in the U.S. FDA UDI database since 2012.

Useful information:

How GDSN enables UDI

Leveraging GDSN for the FDA Global Unique Device Identifier Database (GUDID) Implementation Guideline

IMDRF UDI Application Guide

[2] Final loading of product data into a specific UDI database may require additional steps - e.g. before being loaded into the US FDA UDI database, data had to be converted to an HL7 format.