### Industry suggestions for the implementation of EUDAMED

### Provided by MedTech Europe

*Updated version of 18 February, 30 June 2020 and 26 May 2021 submissions*

### Introduction

**MedTech Europe members implementing EUDAMED involved in automated data submission would like to reflect on the recent state of the EUDAMED implementation.**

**We would like to summarise the essential points in this document that we find important for a successful EUDAMED project from a manufacturer perspective. Those solutions aim at optimizing the data quality in EUDAMED which is of paramount importance for the European Commission, the manufacturers, and all external parties accessing data available in EUDAMED. This is consistent with the obligations of manufacturers under MDR Article 31 and will result in a decreased workload of the EUDAMED helpdesk.**

**Thank you for the useful answers you provided on our submission of 26 May 2021 about the technical aspects of the system. We have a few follow-up points, clarifications highlighted below.**

### Recommendations/questions

1. **Fixing errors / correction feature (incl. non-updatable fields)**

* Please confirm if the correction to Basic UDI-DI and UDI-DI data via M2M and through the User Interface will be available in the in the July playground and/or September release of the UDID module. Also, if it will work both in “Submitted” and in “Registered” status.

This will not be possible. EUDAMED is an integrated system. Changes to BUDI and UDI-DI could trigger problems if they are used/linked already in other modules of EUDAMED (e.g. certificate module). In the context of MVP, this cannot be included.

We remind the following delete/discard options available for Devices / System and Procedure Packs through EUDAMED User Interface:

* Device in status Submitted: Delete operation for UDI-DIs – once the last UDI linked to the Basic UDI is Deleted also the Basic UDI is Deleted;
* Device/System or Procedure Pack in status Registered: Discard operation available for UDI-DIs – once the last UDI linked to the Basic UDI is Discarded also the Basic UDI is Discarded;
* Please confirm if manual “discard” and resubmission via M2M (reuse of the Device Identifiers allocated for the Discarded Device) will be the only option to correct information.

Indeed, at the moment this is the only option foreseen.

* US FDA offers a grace period per regulation as well as an unlock function. This functionality is for error correction, **which includes the ability to change all data elements with the exception of the publish date. This includes UDI-DI triggers**. Using the FDA coordinator account, FDA allows to unlock data and correct it for errors or omissions. Unlocking data only works manually through the User Interface. Once unlocked, an update can be made manually or via M2M electronic submission.

See first paragraph. It is easier to do for the US FDA GUDID database that is a stand-alone database on UDI only, while EUDAMED is an integrated system.

1. **Update updatable fields**

* We would need a response message to be created if new submitted data does not match the content of the registered data. The FDA GUDID sends a response message if the manufacturer tries to update via M2M a non-updatable field (a field that triggers a new record/a new UDI-DI when updated). Currently, EUDAMED has no validation and sends no ERROR response regarding non-updatable fields. If a manufacturer sends changed items with changed data for non-updateable fields, the message in EUDAMED will be recorded only for updatable fields (which then are changed in the EUDAMED Web User Interface). **The sender receives an ACK Success without any error and will not know that some data have not been integrated into EUDAMED**. As a consequence, the databases between the manufacturer and EUDAMED become inconsistent, with potentially EUDAMED displaying wrong information to users. We understand from the last feedback from the Commission, that when updated info is being submitted, EUDAMED will check if non-updateable content is the same as in EUDAMED and if not, will refuse the transaction and will throw an error message. Will this functionality be already available in the July playground and/or in the September go-live?

The services for updating the Basic UDI take into account a consistency check over the following properties submitted:

* Is it a System which is  a Device in itself, Procedure pack which is a Device in itself
* Is it a Kit
* Special Device Type (Flag Yes/No and the type of special Device selected)
* Risk Class
* Active Device
* Device Intended to administer and/or Remove medicinal product
* Implantable
* Is it Device a suture, staple, dental filling, dental brace (...)?
* Measuring Function
* Reusable Surgical Instruments
* Companion Diagnostic
* Near Patient Testing
* Patient Self Testing
* Reagent
* Professional Testing
* Instrument
* Tissues and cells - presence of human tissues or cells, or their derivate
* Tissues and cells - Presence of animal tissues or Cells, or their derivate
* Tissues and cells - Presence of cells or substances of microbial origin
* Presence of a substance which , if used separately, may be considered to be a medicinal product derived from human blood or plasma
* Presence of substance which, if used separately, may be considered to be a medicinal product

The services for updating the UDI-DIs take into account a consistency check over the following properties submitted:

* Quantity of Device
* Type of UDI-PI
* Containing latex
* Labelled as single use
* Maximum number of reuses
* Device labelled sterile
* Need for sterilisation before use
* Reprocessed single use device
* Intended purpose other than medical (Annex XVI)
* New Device (could change later, see below in table for UDI triggers)

The consistency check will return an error if the submitted properties have different values than the ones already stored in EUDAMED. The error will impede the upload of the Device update.

* It appears ‘delete’ can be used for ‘draft’ and ‘submitted’ UDI-DI records. The latest UDID Business rules document does not contain rules on updates. Will the next version of the Business rules document contain rules on updates?

In the Data Dictionary (DD) it is written which field is updatable and which is not. If the info is in the DD, we do not repeat it in the BR except to provide extra conditions.

* Can a table/overview be produced which action/use case (correction, update) can be performed in which status and in UI or M2M? - e.g. in the following proposed format:

No ‘correction’, only discard option.

Modifications possibilities are described in the following table:

N – means that operation is not possible for the mentioned state;

N/A – means that the mentioned functionality is not relevant and/or not implemented at all;

As a remark, there are no differences in the rules between Regulation devices, Legacy devices and System/Procedure packs.

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| --- | --- | --- | --- | --- | --- |
| **Related UDI** | **Workflow State** | **In User Interface (manual)** | | **Through an access point (via M2M)** | |
| Correction (Y/N or N/A) | Updates (Y/N or N/A) | Correction (Y/N or N/A) | Updates (Y/N or N/A) |
| Regulation Device | | | | | |
| Basic UDI-DI | DRAFT | Y | Y | N/A | N/A |
| SUBMITTED | Y(Delete – by deleting the last UDI-DI) | N | N/A | N |
| REGISTERED | Y(Discard - by discarding the last UDI-DI) | Y | N/A | Y |
| DISCARDED | N/A | N/A | N/A | N/A |
| UDI-DI | DRAFT | Y | Y | N/A | N/A |
| SUBMITTED | Y(Delete) | N | N/A | N |
| REGISTERED | Y(Discard) | Y | N/A | Y |
| DISCARDED | N/A | N/A | N/A | N/A |
| Legacy Device | | | | | |
| EUDAMED-DI | DRAFT | Y | Y | N/A | N/A |
|  | REGISTERED | Y(Discard) | Y | N/A | Y |
|  | DISCARDED | N/A | N/A | N/A | N/A |
| UDI-DI/ EUDAMED ID | DRAFT | Y | Y | N/A | N/A |
|  | REGISTERED | Y(Discard) | Y | N/A | Y |
|  | DISCARDED | N/A | N/A | N/A | N/A |
| System or Procedure Packs | | | | | |
| Basic UDI | DRAFT | Y | Y | N/A | N/A |
|  | REGISTERED | Y(Discard - by discarding the last UDI-DI) | Y | N/A | Y |
|  | DISCARDED | N/A | N/A | N/A | N/A |
| UDI-DI | DRAFT | Y | Y | N/A | N/A |
|  | REGISTERED | Y(Discard) | Y | N/A | Y |
|  | DISCARDED | N/A | N/A | N/A | N/A |

1. **Messages ‘are all or nothing’**

* At the current stage of the EUDAMED development, when many device records are sent in one message, if any of the records have an error, the entire message is failed and only the first error encountered is reported to the submitter. EUDAMED should accept and process the entire message, publish all correct records or reject those with errors and report all errors back to the submitter. This would also help reducing the data traffic to EUDAMED. This is also the approach that FDA implemented. We understand that error statement will highlight all errors in the file however this could not be tested as does not seem to be implemented yet. Will this feature be implemented in the July playground and/or September release?

*Example:* If 1000 records are sent in one message, we propose that all 1000 are examined for errors and that a complete list of errors specified is sent back. In this way each one gets its own pass or failure message.

The system tries to report all errors (system has been improved) but it can still happen some errors are not reported in complex cases due to technical limitations/difficulties (progressively improved).

Remark: it is better having smaller content per transaction and more transactions than the opposite.

1. **M2M acknowledge message**

* After a successful registration of data there should be a M2M acknowledge message received by EUDAMED confirming the status change from ‘submitted’ to ‘registered’. It needs to be clearly and consistently related to the original submission ID – as implemented by US FDA. Receiving email notification (email as for records manually registered in the User Interface) instead of automated M2M acknowledgement defeats the purpose of M2M communication. Data in EUDAMED being consistent with the data managed by manufacturers in their internal system is critical for applying the manufacturers’ quality management. As the whole cycle from data submission to data status change is not foreseen to be provided in the first release, that makes applying the regulatory requirements (e.g. conduct the QMS) overly burdensome. Thank you for planning the implementation of such M2M synchronization of status (what the correct data and its status are in EUDAMED) between manufacturers’ internal system and EUDAMED.

Not MVP. Your responsibility to double-check the system. There is no risk you re-submit successfully data that would change a ‘submitted’ set of data, EUDAMED will not allow the change. So from security point of view and accuracy of data in EUDAMED, it is not required, therefore, not MVP. Could be considered only later.

* Also, a document describing all possible error messages is key for aligning industry’s internal system with EUDAMED. This is essential to industry to help the data quality and consistency to be provided to EUDAMED.

The document with errors messages (and their associated codes) will be provided when mature enough (work in progress).

1. **Sequence of data entry**

* At the current stage of the EUDAMED development, the order of processing the submitted data is not guaranteed. The advantage of M2M communication is to submit data in mass which with the missing sequencing it is not possible. If two files that are related need to be processed in a specific sequence, it would be beneficial that EUDAMED guarantees the proper integration sequencing, for instance by integrating files following publication date and time, or by integrating the second file once the first file has been integrated with SUCCESS. This function is not critical for the September go-live, but we appreciate to have this feature to be available in a later edition.

The sequence order cannot be managed in the queuing system.

* The Commission’s suggestion is to combine all devices with the Basic UDI-DI (all at once as much as possible) for the initial registration. If the submission fails, the **response/error message is not referencing the UDI-DIs, so sending more than one UDI-DI in one message is not efficient for reading the responses**. We recommend improving the response feedback content.

There are some errors treated from the transformation layer which are not returning an entity ID with regards to the item having the mentioned issue. This is due to technical limitations/difficulties (it will improve with time).

1. **Comprehensive list of EU UDI-DI triggers**

* **Since EUDAMED offers a versioning feature of keeping track of changes of the database records, we would like to request the Commission to consider using this versioning option whenever the change of data purely serves regulatory purposes and does not affect the identification, traceability or the safety and performance of the device** and not to implement these changes as de-facto UDI-DI triggers.

Noted. Correction is different from Update.

* The creation of a new device identification leads to the disconnect from the previous regulatory record. **The creation of country / region-specific UDI-DIs for a device puts the identification and traceability of devices globally at risk.** The benefits of the UDI system can only be achieved if a consistent approach is pursed by regulators at the global level.

Acknowledged.

* Immediate clarification of **which data elements are updatable** in the UDID Data Dictionary is fundamental before manufacturers assign UDI-DI under MDR/IVDR to understand the conditions when a change will be imposed. **Please indicate in the “Updateable” column of the UDID Data Dictionary if a field is not updatable (N), thus it is a UDI trigger if changed.**

Issuing entities and UDI WG/UDI Guidance should elaborate and define which ones are the triggers. EUDAMED should be aligned with that and should not define triggers but what is updatable or not. EUDAMED should be in general more flexible to allow possible adjustments.

In case of conflict, it should be reported to EUDAMED support team for possible change requests.

* EUDAMED database design creates additional UDI-DI triggers compared to MDR/IVDR requirements. **We call the Commission to ensure that the database design follows the legal requirements and is aligned with the MDR and IVDR as well as with the corresponding MDCG guidance documents. These DI Triggers are not consistent with the international standards established by the Issuing Entities or the IMDRF.**

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| --- | --- | --- | --- |
| **UDI-DI** | **UDI-DI Attributes Data Dictionary 7.0V** | **MDR/IVDR UDI-DI triggers**  **Annex VI Part C Section 3.9** | [**MDCG 2018-1 Rev. 4 triggers**](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2018-1_guidance_udi-di_en.pdf) |
| **Unit of Use DI** | UDI-DI Trigger  Not updatable because would mean to change an identifier.  UDI WG will be consulted to determine if can be updatable for same UDI-DI | Not a trigger by law | Not a trigger in this doc |
| **Member State of the placing on the EU market of the device** | UDI-DI Trigger Conditionally  (Can be provided later on if the Device is subject to a change of state from Not intended to be placed on EU market to On the EU market)  If you don’t provide that data because device not intended for EU market, you can provide it later. But if you provide such data, then you cannot change it. The only reason why it could be updatable after having provided the data would be for adjustment/correction (better knowledge on where was first placed on the market).  UDI WG will be consulted to determine if can be updatable. Not a UDI trigger, just that such information is not supposed to change when specified. | Not a trigger by law | Not a trigger in this doc |
| **Type of UDI-PI** | UDI-DI Trigger  UDI WG will be consulted to confirm it can be updatable, seems sensible. | Not a trigger by law | Not a trigger in this doc |
| **New Device (IVDR only)** | UDI-DI Trigger  Flag at UDI-DI level for IVDR Devices - Not updatable  UDI WG will be consulted to determine when could be updatable, seems sensible after some time (should not stay forever New device). Not really required at beginning (MVP). | Not a trigger by law | Not a trigger in this doc |
| **Related Legacy Device** | If the link between the Regulation and Legacy Device is made manually it can be updated (can be deleted)  If not made manually, is it a trigger (not updatable)  As mentioned, if both Devices have the same UDI-DI a link is automatically created. Clearly if they share same UDI-DI, they must be linked. If one of the Devices have been entered by mistake the Discard possibility exists. In case of manual link with EUDAMED ID (not MVP functionality yet)– it will be updatable; Not a UDI trigger; | Not a trigger by law | Not a trigger in this doc |
| **Recall Precision** | UDI-DI Trigger  It has been defined as a possible option in the Device Module in order to allow the manual registration of the Sub statuses for Devices (due to late implementation of Vigilance Module). Will be managed from Vigilance module;  Not a UDI-DI Trigger, it is updateable; | Not a trigger by law | Not a trigger in this doc |
| **Scope of Recall** | UDI-DI Trigger  Same as Recall Precision  Not a UDI-DI Trigger; | Not a trigger by law | Not a trigger in this doc |

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| --- | --- | --- | --- |
| **Basic UDI-DI** | **UDI-DI Attributes Data Dictionary 7.0V** | **MDR/IVDR UDI-DI triggers**  **Annex VI Part C Section 3.9** | [**MDCG 2018-1 Rev. 4 triggers**](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2018-1_guidance_udi-di_en.pdf) |
| VAT/EORI (from Actor module) | UDI-DI Trigger  This is actor data, not managed from Device module. They are considered as identifiers of the actor. | Not a trigger by law | Not a trigger in this doc |
| Legal Manufacturer SRN | UDI-DI Trigger potentially a problem for uniqueness of BUDI.  UDI WG will be consulted to determine if can be updatable | Not a trigger by law | Not a trigger in this doc |
| Is it a System which is a Device in itself, Procedure pack which is a Device in itself or Kit | UDI-DI Trigger  Attached to a specific device type, such change would mean necessarily another (type) device | Not a trigger by law | Not a trigger in this doc |
| Special Device Type | UDI-DI Trigger  Attached to a specific device type, such change would mean necessarily another (type) device. | Not a trigger by law | Not a trigger in this doc |
| Risk Class | UDI-DI Trigger  Such change would mean different obligations. Could be only considered in the context of correction after NB involvement (discard option).  To discuss with UDI WG | Not a trigger by law | Not a trigger in this doc |
| Certificates linked to the Device | UDI-DI Trigger  Cannot be updated from UDI-Device Module – link is created automatically from the Certificate module (Not a UDI trigger, it is updatable) | Not a trigger by law | Not a trigger in this doc |
| Clinical Investigation/Performance study reference Number | UDI-DI Trigger  Not a UDI trigger. Indeed a Clinical Investigation once added to the Device cannot be updated (data stored about that Clinical Investigation cannot be updated), but can be inactivated | Not a trigger by law | Not a trigger in this doc |
| Countries outside EU where Clinical Investigation is performed | UDI-DI Trigger  Not a UDI trigger. Indeed a Clinical Investigation once added to the Device cannot be updated (data stored about that Clinical Investigation cannot be updated), but can be inactivated | Not a trigger by law | Not a trigger in this doc |
| Certificate Type (Technical Documentation, Type Examination, etc.) | UDI-DI Trigger  Generic information provided by the Manufacturer about the Certificate. Does not impede the NB to enter the correct data and link it to the Device. Not a UDI trigger. An issue only in case of a mistake on legacy device registration. | Not a trigger by law | Not a trigger in this doc |
| Revision Number | UDI-DI Trigger  Generic information provided by the Manufacturer about the Certificate. Does not impede the NB to enter the correct data and link it to the Device. Not a UDI trigger. An issue only in case of a mistake on legacy device registration. | Not a trigger by law | Not a trigger in this doc |
| Notified Body | UDI-DI Trigger  Generic information provided by the Manufacturer about the Certificate. Does not impede the NB to enter the correct data and link it to the Device. Not a UDI trigger. An issue only in case of a mistake on legacy device registration. | Not a trigger by law | Not a trigger in this doc |

1. **Data quality by Data Dictionary Precisions**

* It is not only important to know whether the field can be updateable (Y/N), but manufacturers need to know the manner in which the field is allowed to be updated. **We request the indication of more specific edit rules such as ADD, DELETE, EDIT** **for the updatable fields** as this is done in the US FDA GUDID. (ADD address the possibility to include something but not change if it was already included. EDIT includes ADD as here there is the possibility to remove.)
* The impact of not having this clarification, can be tremendous if manufactures only learn when registering a device that certain edit rules do not apply and can only be resolved by changing the DI for the device. **Changing the DI can cause proliferation of DIs, new labeling for the same device new device and re-registrations worldwide.**
* Also, as providers and distributors use the DI in their Enterprise resource planning (ERP) systems, which typically are capable of holding only one DI, the proliferation, is overly burdensome for all parties: for the Commission, Notified Bodies, Manufacturers as well as end-users. Proliferation of DIs further counters effective traceability measures. Changing of the device’s UDI-DI causes confusion for the users: it leads to scanning errors and hurdles in the workflows for hospitals in the US.

See related report here: <https://www.ahrmm.org/sites/default/files/ahrmm/multiple-device-identifier-work-group-report-031919.pdf>

*Example*:

|  |  |  |
| --- | --- | --- |
| **Data Dictionary attribute** | **Data Dictionary Updateable Description** | **Revisions (Precision) to the Updateable Description (ADD, EDIT, DELETE)** |
| Direct Marking UDI-DI code | Y (conditionally)  Can be provided later on if initially not provided  Modify to include: However, once “Is the Device Directly marked” is Y, it cannot be set back to N. | ADD |
| Member State of the placing on the EU market of the device | Y (conditionally)  Can be provided later on if the Device is subject to a change of state from Not intended to be placed on EU market to On the EU market | ADD, EDIT |
| Device Status | Y | EDIT |
| Critical warnings or contra-indications Description | Y | ADD |
| List of Storage and Handling Conditions | Y | ADD |
| Member State where the device is or is to be made available | Y (conditionally)  New Countries can be added (existing countries can be marked with an end-date) | ADD, EDIT |
| Clinical Sizes | Y | ADD |
| List of CMR Substances associated to Device | Y | ADD |
| List of Endocrine Substances associated to Device | Y | ADD |
| List of Medicinal product substances associated to the Device | Y (conditionally)  If ***initially*** have been marked as applicable (at Basic UDI-DI level) | ADD |
| Container Package Status | Y | ADD, EDIT |
| Basic UDI-DI and UDI-DI | N | EDIT if Basic UDI-DI and UDI-DI in DRAFT state |
| Basic UDI-DI (EUDAMED-DI) /UDI-DI (EUDAMED-ID) Version | N | DELETE if in a state of DRAFT or SUBMITTED |

We will analyze your proposal to see how to improve DD and BR. DD must remain simple enough and complemented by BR for special conditions.

1. **Release notes**

* We appreciate the efforts to implement release notes in the playground to be able to follow the updates to the testing platform. Thank you for keeping up this practice both for the testing and for the production platforms. Release notes are necessary to understand which functionalities and which features have been / will be added to the new version of the playground comparted to the previous one. E.g. list of implemented changes, list of known bugs, list of planned updates. The FDA page serving similar purpose: <https://www.fda.gov/medical-devices/global-unique-device-identification-database-gudid/gudid-enhancements-and-fixes>

Normally we have it in EUDAMED. We will consider your comment to make it right for future releases.

1. **Continuous EUDAMED playground environment (UI and M2M)**

* We appreciate the continuous access provided to the playground environment. Thank you also for ensuring that the playground is updated before the production site is updated with new features to keep them aligned and to allow testing features before they go live.

New features and significant improvements should go first in PG. Bug fix or small improvements could go directly in PROD (and in PG).

* To be able to detect bugs more efficiently we appreciate if the playground feedback period could be prolonged to 6 weeks (from 4 weeks). To ensure a fast development, we need to be fast in collecting feedback.
* The advantages of a continuous test environment (throughout the development of EUDAMED and also post go-live):
  + the industry can test before going into production.
  + help visualize possibilities and check necessary data elements and their value requirements.
  + facilitates the training of potential new users as it gives an overview to the transfer data process (especially in UI).

1. **Expected documents:**

* We list here documents that the Commission’s EUDAMED team is expected to release which contain valuable information for implementation projects. Thank you for indicating an expected date for their release:
* document describing the notification email messages per module (expected) – will be available by production release
* document describing the acknowledgements (expected) – Work in progress
* document describing the possible error messages (expected) – Work in progress
* updated UDID data dictionary Excel with embedded, UDI-DI triggers – DD v7 available since 26/05 – more to come, not to be considered as a UDI trigger catalogue
* document including the list of values (enumerations) – Work in progress (some already provided)
* updated UDID Business Rules (expected) – Work in progress
* updated XSDs (expected to be updated) – available since 26/05
* updated DTX Service definition (expected to be updated) – available since 26/05
* updated Functional Specifications doc (expected) – Will be reviewed whenever necessary and when new major release will be deployed in production.

1. **Helpdesk**

* We appreciate to be able to address inquiries to two helpdesks with UDI and EUDAMED related questions. For a comprehensive support all types of questions will need to be answered: Technical (IT related), Quality & Regulatory concerns and Policy related questions. How can a user decide which question could be addresses to which help desk?

The EUDAMED helpdesk offers assistance on technical EUDAMED-related questions (e.g. concerning the use of the modules).

The UDI Helpdesk offers assistance as regards Regulatory and technical questions on the UDI system, as well as the EMDN and the UDI module of EUDAMED.

* Will there be a connection between the two ensured (one channel to ensure appropriate oversight)?

Yes, the two helpdesks have a channel of communication, and in case one receives an inquiry that should have been addressed to the other, they will directly exchange information for an easier follow-up.

**Thank you in advance for your reaction on the above suggestions/questions.**  K**ey features listed above are not foreseen for first release, but it is critical they are going to be implemented in the upcoming releases.**