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Data Complexities with the EU UDI Regime

As the US ploughs ahead with its UDI regime, the EU's launch of Medical Device Regulation (MDR) draft documents last year helped progress industry understanding. However, a lot of uncertainty remains regarding the European UDI landscape. On average, a selection of experts have highlighted one key hurdle the market should brace for: data management with the EU UDI regime. Due to this area being expected to differ from the FDA's GUDID process quite sharply in some places.

With the MDR due to come into effect in a few years time, Pharma IQ gains insight on the forecasted data complexities attached to the EU's UDI gameplan.
State Of Play

The Line up

- State Of Play
- UDI at a Glance
- Considerations for the database
- Approaching the EU UDI data complexities.
- Final remarks
- Reserve Your Place Today - UDI & Traceability Forum
- Resources

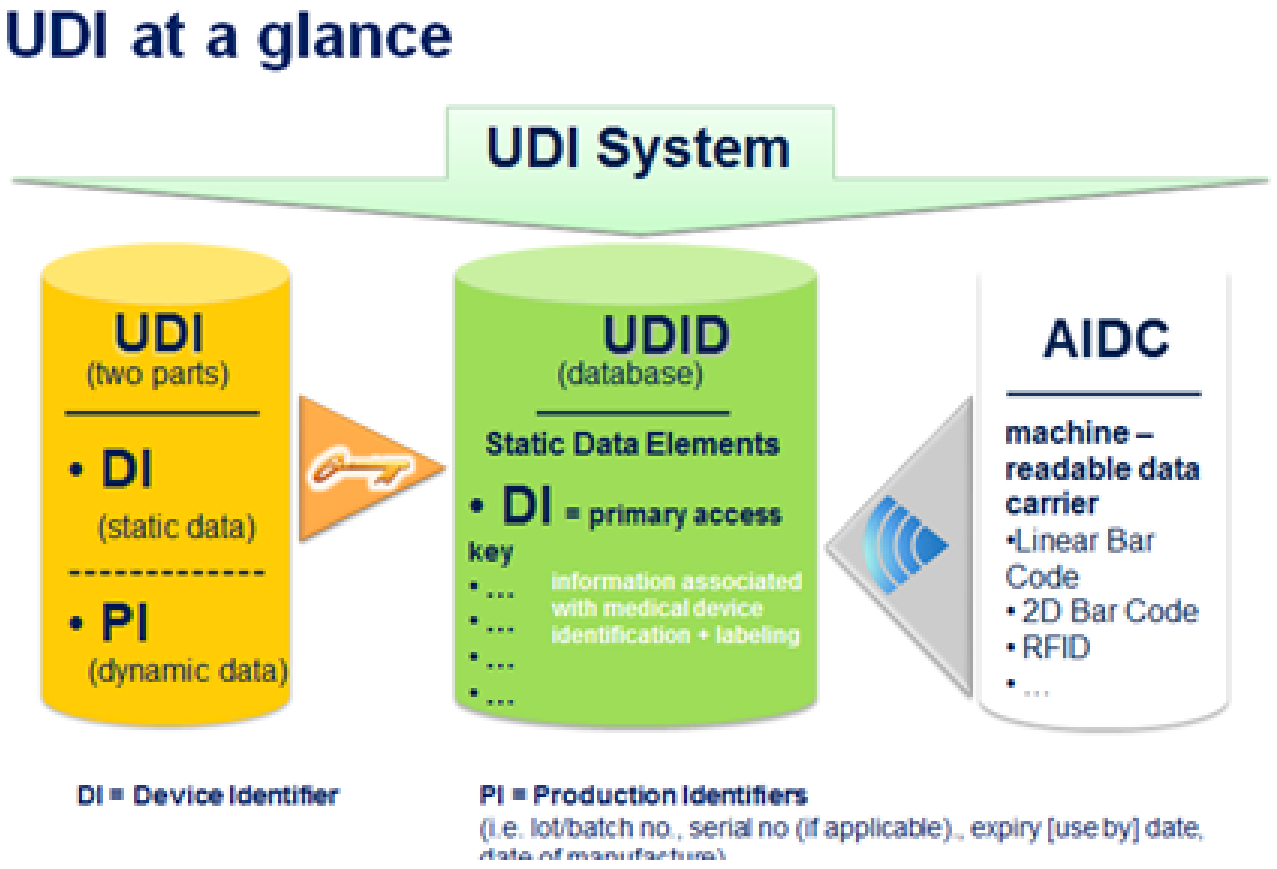
The State of Play

Proposed new legislation in the EU will cause the initial landscape to change as follows:

- Medical Devices Directive
- In-Vitro Diagnostic Devices Directive

- Medical Devices Regulations
- in-Vitro Diagnostic Devices Regulations

The UDI initiative stands as one small element of the refresh of the European Medical Device and IVD regulation.



From Andy Crosbie Medicines and Healthcare Products Regulatory Agency (MHRA) (2016) UDI – What's in the legislation? Presentation to UDIs & Traceability for Medical Devices Forum - 25-26 May 2016 - Munich

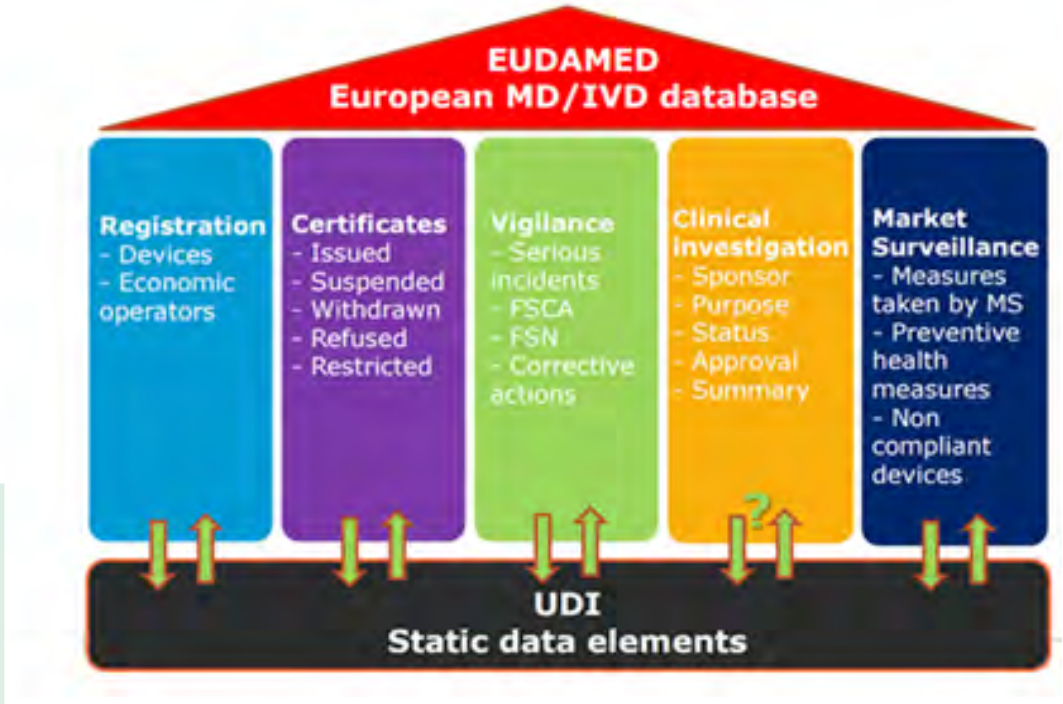
The UDI database requires the Commission to set up and manage an electronic UDI database (UDID). The UDID is also going to be publically accessible.

Annex V– Part B outlines 23 items about the device and the manufacturer that must be included in the European UDID. Only Device Identifier (static information) is required. Information for each device includes:

- Description of the device
- Information about the manufacturer
- The UDI-DI
- The Global Medical Device Nomenclature (GMDN)
- Single use?
- Sterile?
- Contains latex or DEHP?

In an article for the 2016 UDI and traceability conference Andrew Rutter, Senior Regulatory Affairs Associate, EDMA UDI Task Force, Ortho-Clinical Diagnostics noted that in comparing the intended purpose of the EU database with the US system, the only operators who access the US GUDID in terms of data transfer are manufacturers and the FDA. There is a public access element, which is hosted, but that is limited information.

The UDID will be part of the European DAtabank (EUDAMED III)



From Andy Crosbie Medicines and Healthcare Products Regulatory Agency (MHRA) (2016) UDI – What's in the legislation? Presentation to UDIs & Traceability for Medical Devices Forum - 25-26 May 2016 - Munich

He continued: "However, the scope of EUDAMED in Europe is going to be much greater. I believe it's going to be based on a series of modules, because it's going to involve registration right through to traceability. So, it's also going to be used for the registration of devices, the registration of certificates by notified bodies. It's going to be used for the repository for data for clinical investigations and performance studies of medical devices and IVD medical devices, and then also it's going to be used by the relevant stakeholders for vigilance and also for market surveillance.

"So, it's a much more multipurpose database with the requirement to have access from a greater number of stakeholders or actors in the medical device framework in Europe."

Typical challenges in the synchronisation of product master data include data models differing, interfaces not existing, are insufficient or require compensation by human interfaces.

Considerations for the database: as noted by Andy Crosbie of the Medicines

Approaching the EU UDI Data Complexities

and Healthcare Products Regulatory Agency (MHRA) in his presentation to UDIs & Traceability for Medical Devices Forum in 2016.

- The protection of personal data
- The legitimate interest in protecting commercially sensitive information,
- The convergence of UDI systems developed at international level

Hajo Reissmann and Melissa Berlich of the University Medical Center Schleswig-Holstein, Lübeck & Kiel noted in their presentation at the 2016 event that it's not only regulation that's got healthcare providers going master data mad. Rising demands, limited resources, services having to be provided with increasing efficiency are all reasons why good product master data is a must. They added that good product master data is vital for patient safety in regards to identification, registers, recalls and locating product characteristics. Also, supply chain management with procurement, terms and conditions, tracking and stock surveillance. Clinical processes, revenue, analytics & science all benefit from good product master data.

There are many challenges with master data communication with one being that many-to-many communication between vendors and customers can be labor intensive for all parties.

More clarity of intent is needed, this may come as EUDAMED and its architecture including communication protocols and data attribute mapping become better defined or understood.

We spoke to a couple of UDI experts to hear their thoughts on approaching the EU UDI data complexities.

Stay Active in the Industry

Work on the details that have been confirmed within the regulation. Try to keep an ear to the ground: maintain your contacts, read industry journals and industry bulletins.

Dawn Fowler, Program Manager - UDI, Masimo : "Participating with others within the industry such as the UDI and Traceability Conference is very very important. I think it's a great exchange of information and that's where the experts will be to answer questions to the best of their knowledge with what information they are allowed to give. You can make those contacts so that as the legislation moves forward throughout the European Union you can be kept up to date with what's going on. This will help you to understand how you can prepare for it and what may impact your organization."

Look at your situation now so you can map your trajectory

Identify existing classes of products and if possible any process gaps – some manufacturers have found existing compliance issues in the audits for their UDI projects.

In regards to preparing for your EU UDI programme Melissa Finocchio Director, Product Labeling and Documentation bioMérieux says: "There is a big volume challenge here so it's really important to start early - even if it's not 100% clear - so that manufacturers at least understand where they are [at the current time]. Take the time to prepare the lists of products and look at the data you have, [locate] where the data is, do an audit of the labelling, the packaging, the supply chains, so that you really understand your as-is situation.

"If you don't know where you are now, it's hard to map where you need to be, because you can't plan appropriately for gaps that you don't know you have."

Don't underestimate the task of data capture

For those firms that don't have a system in place or have a system that doesn't host all of its data - this is an urgent area to address. This will involve locating and electronically synchronising data which may only exist in hard copies in

folders.

Melissa Finocchio noted: "If you have a high volume of product, which is the case for some manufacturers, trying to find that data, collate it and put it into a system that you will be able to eventually synchronise, is quite a challenge. The data is important and it takes a certain level of expertise to find that data, clean it and make sure that it's in a format that can synchronise."

She gave the example of entries regarding temperature, the format entered into systems may not be consistent which could cause problems.

She added: "We don't know what EUDAMED will look like. We don't know exactly what that interface will look like yet, so [manufacturers] can't design that interface yet, that's for sure. But they shouldn't let that stop them from beginning to organise their data."

Final remarks

Looking at the market as it stands in regards to the EU regime, Dawn Fowler said: "I think everyone has a high anticipation rate for this next conference to learn exactly what's going to be required from us from the European Union. As well as, what are we going to have to do as manufacturers to be able to comply, because right now it seems to be a very grey area, without a lot of details out there. We are all chomping at the bit because we have learned a lot from the FDA regulation and now we want to get started on the European ones so that we can be compliant as quickly as possible." However , she adds it is important that the approach taken is methodical and based on evidence rather than guesswork as to avoid wasting resources on implementing the wrong plan.

Want more clarification on your EU UDI data strategy, reserve your place today.

UDIs & Traceability for Medical Devices

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Join us at the Medical UDI & Traceability Forum to ensure that your company is maximising it's efforts for improving compliance, whilst maintaining your competitive edge!

4 Reasons to Attend:

- Through **regulatory discussions,** panels, roundtables and practical case studies, this forum is tailored and uniquely positioned to highlight the state of urgency in the industry, **address implementation challenges** - plus **maximise the ROI of your UDI implementation** in the future, ensuring it continues to drive business value.

- Excellent networking - build connections with others to leverage their experience.

- Hear from peers that have completed US UDI on lessons learned.

- Hear from the experts in the European community on what is expected form the EU UDI.

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