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'DOING NOTHING IS SIMPLY NOT AN OPTION'.

THE RESULTS OF THE TRAC SERVICES IDMP SURVEY

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Why do we need IDMP?

The main purpose of IDMP is to standardise the way the pharmaceutical industry refers to medicinal products, providing a universal identification for drugs that can be referenced in individual case safety reports (ICSRs). Currently each country has different identifiers for ICSRs, which complicates the tracking and analysis of patient safety alerts. Under IDMP every product will be identified in the same way. Devised by the International Organization for Standardisation (ISO), the IDMP is comprised of five information management standards on the use, consumption and packaging of drugs. The standards will 'specify definitions in terms for all data elements required to uniquely and with certainty identify medical products for human use.'

IDMP SURVEY DISCUSSION

Following TRAC's recent survey to understand the top issues companies are facing with regards to the upcoming Identification of Medicinal Products (IDMP) standard, Lisa Pascoe takes a look at the results from an EU perspective.

The survey respondents consisted of representatives of small to medium-sized Pharmaceutical, Biotech and Medtech companies and results show that almost 90% will be impacted immediately by IDMP when it comes into force.

We asked people to share with us their concerns around IDMP. **This identified five common issues companies are facing:**

- The implementation deadline
- Lack of management buy in about the need to address IDMP
- Time and resource needed to be ready for compliance
- Lack of awareness of what the EMA will actually require
- Current internal data control – data standardisation and harmonization

The following update provides advice and guidance on how best to address these issues given what is already known about implementation of the IDMP standard.

THE DEADLINE

As mandated by EU legislation, IDMP will be implemented on 1st July 2016. Therefore, doing nothing is simply not an option. Taking action now is essential if companies are to meet this deadline.

LACK OF MANAGEMENT BUY-IN

One of the biggest challenges facing the survey respondents, which is of real concern, is lack of management buy-in and awareness. No project can hope to succeed without this and therefore this issue needs to be addressed quickly. This document will help you with that process.

Building a sound business case and raising awareness needs to be a priority. It is crucial that companies face up to the realities of IDMP and start preparing to meet the 1st July 2016 deadline.

IDMP compliance will be mandatory in the EU for all companies who have marketing authorisation licences. 'Opting out' is not possible so management need to understand the issues being faced very quickly. Companies found to be out of compliance with the new regulations in the EU will risk "financial penalties for infringement of certain obligations in connection with marketing authorisations". This could mean fines of up to 5% of your daily or annual turnover in the European region. In the extreme, should a company be found to be repeatedly out of compliance, they could have their licences revoked until a time they can demonstrate satisfactory IDMP practises.

Aside from the ever approaching deadline, which is now just over a year away, IDMP brings several issues with cost implications; getting current data management under control, the purchasing of software and the time and expertise needed to implement solutions. Without support from the highest levels of the company, your IDMP implementation plan is going to quickly run into problems.

For those who don't understand the details of IDMP it is easy to assume that, as it is replacing XEVMPD, the systems and knowledge are already more or less in place to satisfy the requirements. However, whereas XEVMPD is mainly a pharmacovigilance led initiative with regulatory input, IDMP's scope is much wider and is going to require input from several departments, depending on how your company is structured.

To summarise, the business case you develop needs to cover the following:

1. Compliance is compulsory
2. Consequences of non-compliance
3. Timescales needed to comply – clearly indicating that action is needed now
4. Potential resources needed to achieve compliance:
    a. People – impact will be across multiple teams
    b. Costs – software, additional support (internal or external)
5. High level project plan outlining how compliance will be achieved:
    a. Indication of what functions/departments are involved
    b. Key activities that need to be undertaken and any dependencies within these
    c. Risks associated with the implementation of the plan
6. Specific request that IDMP compliance is made an organisational priority for the reasons outlined in the business case

TIME AND RESOURCE NEEDED

Our survey shows that people within the industry are starting to recognise the scale of the task they face to implement IDMP. The relative short timeline for doing so means that, for most companies, significant resources will be needed (people and budget). This makes gaining management buy-in essential (see above).

At this stage project planning is key:

- Raise awareness in your organisation - The level of complexity is such that from an organisation perspective, multiple departments will have a responsibility to help deliver the project objectives. Details for IDMP implementation will need to come not only from regulatory, but potentially also manufacturing, packaging, R&D and clinical teams. Although IDMP has been on the regulatory radar for some time, other departments are unlikely to understand what it means for them. This is where management input, to ensure collaboration between often quite separately run business areas, can be vital.
- Information storage - Assess where and how (i.e. electronic or paper) the information required is currently stored. A key area of this project will be to establish a facility to bring this information into a single repository. The information will have to be complete, conform to the controlled vocabularies and be in the correct format. Harmonizing existing data across the company (e.g. substance terminology) early will allow a far smoother transition into the IDMP terminology as the new terms can be mapped according to the established internal standard.
- Tools - Software solutions will be required to not only bring the information from different sources together but also to allow this to be maintained and submitted as part of ongoing business activity. The choice of software will be key a decision to ensure it works in partnership with existing internal regulatory information management (RIM) systems where possible.
- Roles and responsibilities – The IDMP compliance strategy should identify key business areas and personnel responsible for delivery. As discussed, this will not simply be just a regulatory responsibility. Clearly defined roles and responsibilities will need to be established across the organisation not only for IDMP compliance preparation but also for ownership and the ongoing maintenance of the information. For information that is duplicated across business areas, a clear owner should be identified to ensure consistency.
- Training – IDMP is not a case of establishing a snap shot of how information is stored now but, going forward, should be a standard to be adhered to for all involved business areas. Roles and responsibilities of individual departments and personnel will have to be integrated into working practices along with the processes required for IDMP maintenance. This will require new training programmes, standard operating procedures and best practise guidance documents. Due to the timelines it is essential that each business unit is ready to deliver at implementation.
- Implementation – Successful planning will lead to successful implementation. Achieving IDMP compliance may not be achievable using only in-house resource and expertise, so remember; where external support is utilised, the strategy will have to define how this is managed going forward also.

LACK OF AWARENESS OF EMA REQUIREMENTS

We recognise that at this point in time no one knows exactly what the standards will consist of. However, there is enough information already available to enable significant preparation. This lack of specific detail cannot be a reason for inactivity given the tight deadline and the potential scale of the task as already discussed.

The following websites provide further information and updates:

European Medicines Agency Information Page:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000594.jsp&

ISO IDMP international standard:

http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=55034

Transition to ISO IDMP implementation is required by Article 25 and 26 of Commission Implementing Regulation (EU) No 520/2012:

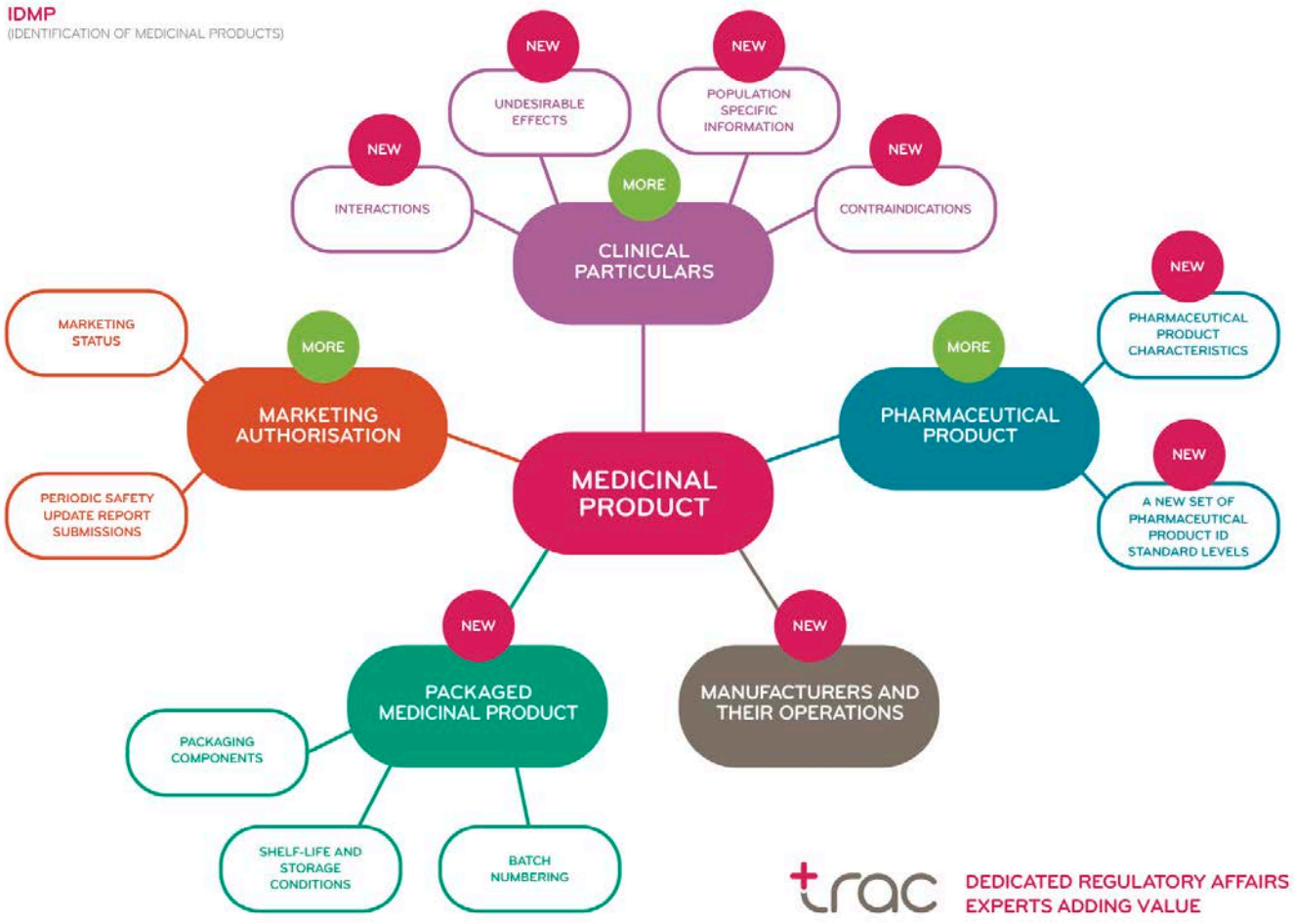
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:159:0005:0025:EN:PDF

CURRENT INTERNAL DATA CONTROL

In most companies, there is likely to be cross-over of ownership between departments of certain information, and with numerous versions comes the high possibility of discrepancies. There could also be numerous formats and/or systems that the data is stored in. Where there is more than one source, data will need to be analysed to establish who 'owns the truth'.

As IDMP will specify definitions, multiple sources will not be feasible going forward and so a clear owner will need to be identified for each aspect. This could be a painful exercise initially with departments, and systems, needing to work in partnership more than ever before. However it will also bring real efficiencies and aid with compliance once a structure is in place.

The infographic below outlines the key differences between IDMP and XEVMPD.



The issue of internal data control raises a number of questions you need to consider:

1. What do these differences mean for your organisation?
2. Where and how the information that is required is currently stored?
3. How many 'versions of the truth' exist across your teams?

CONCLUSION AND NEXT STEPS

With just over 12 months to go until the compliance deadline in the EU, taking action now to prepare for IDMP is essential. Based on the results of our survey it is clear that in many cases sufficient work isn't being done and as a result meeting the EMA requirements will be a significant challenge.

This is the first in a series of resources TRAC will be producing to help companies achieve compliance. Watch out for our next regulatory news update in your inbox for further details and visit our website for ongoing updates.

If you would like to discuss your IDMP compliance plans with one of TRAC's dedicated regulatory affairs experts please get in touch via email, hello@tracservices.co.uk or call our office +44(0)1209 612650.