LSCP Life Sciences Consulting Partners

***Our current thinking*:**
IDMP Status Reflections update

Introduction:

ISO IDMP is coming – proposed now as an EMA *phased approach* – but we are not there yet, with EC to approve: Worth reading!

When we listen at conferences or webinars to participants, the discussion is mostly around the regulatory burden rather than *elaborating on the many business opportunity* these standards will enable. Talk to us, without any commitment to learn more by sending an email to the address at the end of this document. Thanks!

IDMP timing for Implementation in the EU still not confirmed, *but*

- The EMA Task Force submitted a phased implementation
- Suggestions approved by the Authority on the EU level
- NCAs to review and comment this week
- EMA submitted proposal to the European Commission (EC)
- EC, if time permits (Greece complexity!) will review and comment this month

LSCP considers the news a long await and if the EU Legislation approves a phased approach to implementation, the information below may be a real relief!

While looking on what to do, your will find further down **recommended steps** (please see page 4). We strongly suggest to look at IDMP (and ICSR[R3]) not only from an EU perspective, but include the US approach (SPL) in this context as well!

(Sources: EMA Information Day of June 24; eRA Munich presentation on July 1, 2015, mainly Dr. Andrew Marr)

Here is, what we consider selected, relevant information:

- A single implementation of the ISO IDMP standards on the July 2016 legal deadline is regarded as unrealistic due to dependencies on
  - Availability of the ISO Implementation Guides
  - Required technology changes and other external factors such as CVs
  - Interfaces with databases

- A phased implementation of ISO IDMP would mean:
  - More effective Change Management

- Result in better adoption of the new operating model
- Achieve a sustained higher quality of data
- Allow for the necessary resources to be forecasted appropriately

4 Phases are proposed (excl. veterinary – tbd)

Data elements for each phase (for AMPs) are to be defined during July 2015

#	Scope	Guidance Date	Start Implemn.	Enforce Implemn.
1	Content currently available in the Article 57 format and minimum required elements to assign and maintain identifiers for authorized medicinal products and support product life cycle management (MPIDs, PCIDs and PhPIDs) In support of PV, Regulatory Submissions (pre and post-authorization), GMP/Inspections (specifically PV inspections), e-prescriptions (specifically cross-border identification of medicinal products in the (EU)	**Q1 2016**	**Q1 2017 XEVMPD supported**	**Q4 2017 XEVMPD no longer supported**
2	Additional data elements and ISO IDMP 11615 content to support the assignment and maintenance of the Investigational Medicinal Product IDs (i.e. development products) In support of CT and pre-authorization regulatory activities (e.g. excluding scientific advice, orphan and paediatrics application) and regulatory submission support (e.g. including CT Application)	**Q4 2016**	**Q4 2017**	**Q2 2018**
3	Remaining EU requirements for the Clinical Particulars section In support of PV and e-prescription	**To be confirmed in 2016**		
4	Batch Identifiers and remaining EU ISO 11615 and ISO TS 20443 compliance In support of GMP/Inspections (e.g. full traceability of medicinal products), scientific advice, orphan and paediatric applications, e-prescription, anti-falsified medicines	**To be confirmed in 2016**		

Controlled Vocabularies (VC) with EMA acting as a broker for global activities (please see also dates in the table above for dependencies)

#	Scope	Implementation Date
1	Global vocabularies for ISO11239 (dose form, route of administration, unit of presentation and packaging) and ISO11240 (unit of measurement)	**By end Q1 2016**
2	Some vocabularies required to support first two iterations of Products and for Substances	**By end Q2 2016**
3	Remaining vocabularies required to support first two iterations of Products and for Substances	**By end Q4 2016**
4+	Implementation of additional vocabularies in support of subsequent iterations for Products and Substances	**From Q4 2016**

Organizational Level

- EMA to act as Maintenance Organization
- 3rd Party Identification to be required (GS1, Dun & Bradstreet etc.)
- May utilize an EU Organization ID in addition
- Pre-registration of Organizations to be required (if legally possible)

#	Scope	Implementation Date
1	MA holders and unique MA contact persons	**By end Q1 2016**
2	MA Applicants and regulatory authorities	**By end Q2 2016**
3	Sponsor and contacts	**By end Q4 2016**
4	Manufacturers (Supporting CAPs and NAPs)	**By end Q4 2017**
5	CROs and CT sites and Data submitters on behalf of MAH/Sponsor/MA Applicant (to be confirmed)	**By end Q4 2018**

Andrew Marr's Key Points

- ISO Standards and Guidance establishes a framework
- EU guidance will provide the specifics of what is required, under what circumstances
- EU IDMP Roadmap will define the timescales, phasing etc. of the implementation
- Guidance will align with phasing

if EC accepts the phased approach …

LSCP Recommendations

Typical Preparatory Steps

- Initiate a 'Pre-Project'
- Create Awareness on C-Level (What is it?)
- Identify Steering Committee (SC) and Program Management Teams

  Get Executive Level endorsement I
- Vision and Strategy (V&S, include SPL)

  What is it that you want to do and how?
- Current/near-future state assessment (Inventory)

  Gap analysis
- Assess Data (and Sources) & Quality, report findings (Analyze)

  Recommendations, including suggested prioritization
- Design, execute Proof-of-Concept with a selection of typical products & representative information re-use mapping exercise (Reality Check)
- Identify, consider Business Model – Process Options (Future Business Operations)
- Consider technical solutions (Technical Options)

  Recommendations
- Make Business Case (long term, phased BC for investment)

  Get Executive/SC Level endorsement II
- Monitor guidance/regulator's plans
- Initiate implementation

Products to be assessed (EU relevant)

- Representative products with a number of variables which represent different scenarios e.g.
  - MRP/DCP vs National
  - Older vs Newer
  - Simple vs more complex
  - In-house vs contract manufacture
  - Language: English vs local
  - Rx or OTC
  - etc.

Potential Source Systems

- RIMS (and related systems)
  - Name
  - Auth. Number
  - Status
  - Procedure
  - …
- XEVMPD data sources
- Safety
  - Indications
  - Undesirable effects
- EDMS/Labeling
  - SmPC/PIL
  - Other Authorization Documents
- ERP
  - BM
  - IDs – Batch/Data Carrier

Suggested Source Documents

- SmPC
- EURD List

- Dossier (paper and electronic)
- CMC Conformance Documents (dependent upon how companies manage these)
- Partner or Vendor sources
- Webpages
- Emerging ones out of Alliances (consider the global approach!)

So, make your Enterprise Information Assets become actionable! For more details, please contact **LSCP** or read our last posts of June 12 and February 2015 about our current thinking.

For further information, please contact: **ruedi.blattmann@lsconsultingpartners.com**