Heads-up: *IWG group meeting on ISO IDMP at EMA*

The European Commission (EC) and Heads of Medicines Agency (HMA) have agreed with the *phased* wise implementation of ISO IDMP

After another delay of three months (EC level), there is some news here letting us to believe that there is substantial progress as to how IDMP will be implemented in steps (as proposed), but still some important information is not (yet) available:

The following has been agreed in the last days of September 2015

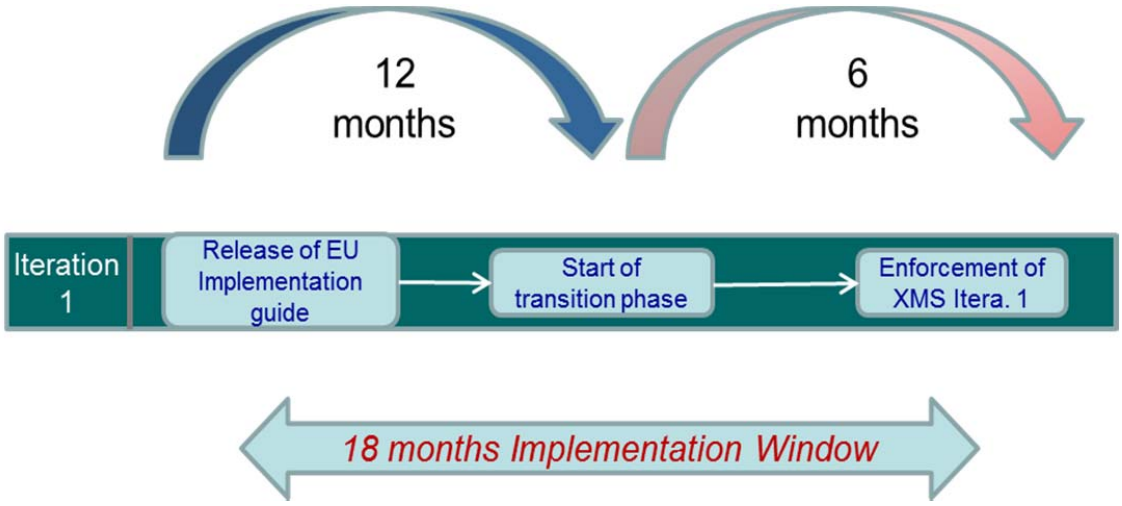
- Implementation will start in July 2016, with an update of current Controlled Vocabularies (CVs) to ISO IDMP, release of Regional ISO implementation guide, etc.

  LSCP comment:

  Between the release of the EMA Implementation Guide for Iteration 1 and the effective introduction there will be a time window of 9 - 12 months

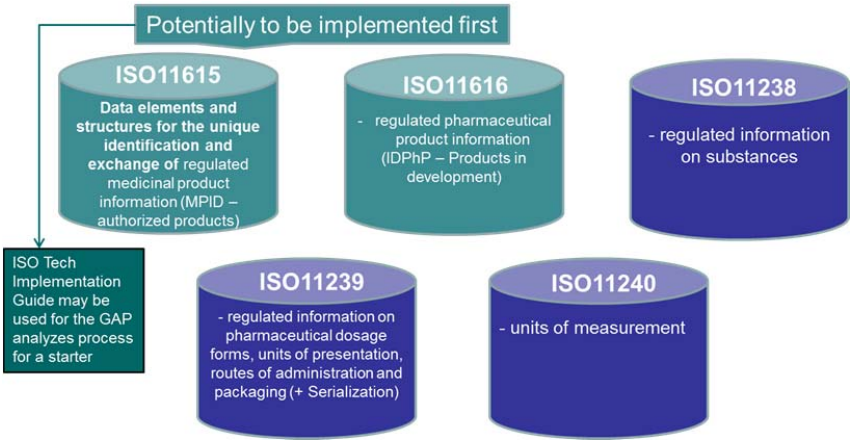
  From such check point it will take another 6 – 9 months until the implementation guidance will become *mandatory*, now anticipated *end of 2017* as illustrated below

  In other words there will be most likely an Implementation Window of 18 months «granted» (Still to be confirmed by EMA, but at least an indicator we suggest to work with!):



- The first phase is Iteration 1,

  LSCP visual:



  in which additional data for the product has to be submitted. The exact data fields still to be defined. For now these are *33 additional fields* for ISO IDMP vs. XEVMPD.

  3 other iterations will follow until IDMP will be fully implemented, plus 1 for the adaption in the veterinary domain (Further information for the planning stream available).

- EMA will update the information on their website about the deadline and phased wise approach. **LSCP** considers that EMA will adopt the process recommended to the EC in June 2015

- Industry is requested to provide real life examples of the issues for the implementation of ISO IDMP. **LSCP** is currently working on relevant examples, based on current information available, but if you have any issue that you would like to mutually clarify, please contact: ruedi.blattmann@lsconsultingpartners.com

AND

Our recommendation is, that to re-visit your ***Enterprise Ambition*** about what you want to achieve while implementing all the ISO *IDMP AND ICSR* Standards: How important is Information and it's management to you? Let's discuss and document this BEFORE you start your planning process … it is worth the effort!

Reminder:
ISO IDMP is, though the EU is legally in the driver's seat a *global initiative* which includes ICSRs – 18 months to mandatory implementation from mid 2016 – *don't underestimate*!