EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

ISO IDMP status Update & EU Implementation Guide

EU ISO IDMP Task Force meeting - 31 March 2015

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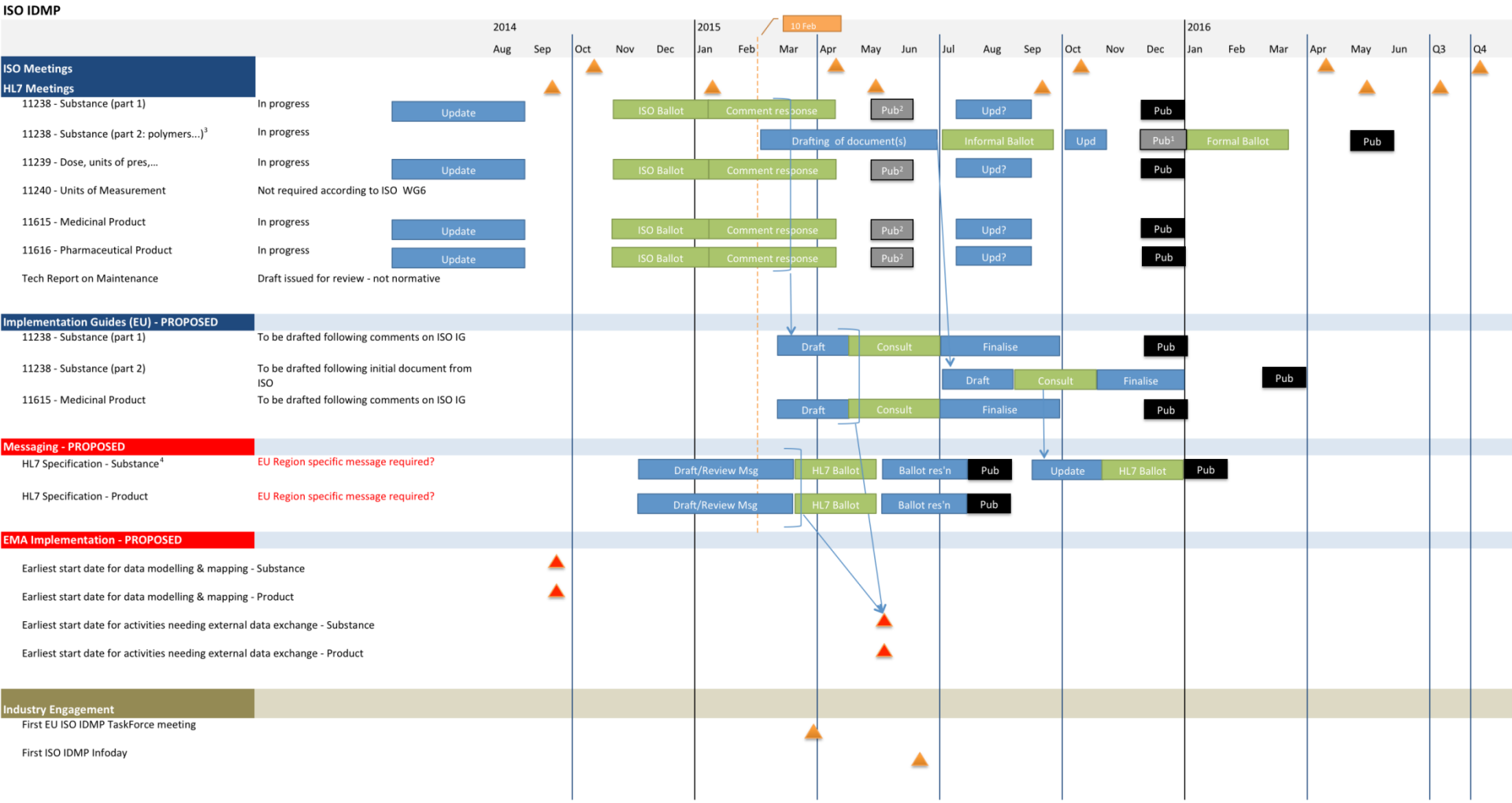
ISO IDMP Activities



Notes

1 The final list and source of data for substance CVs will only be defined at the conclusion of the Substance Part 2 implementation guide drafting
2 ISO Implementation guides may be available in Q2 2015 or at least in a stable form to allow EU implementation planning. There is the risk that this is delayed until some time in Q4 if a further ISO ballot/vote is required.
3 The implementation guides for substances are progressing in 2 phases.
4 The HL7 message may need to be revised following completion of the ISO Implementation Guide covering the remaining substance classes

Considerations on Substance (11238)

- EMA will make use of the software developed by NCATs/FDA (i.e. G-SIS) to exchange substance data in the ISO 11238 format
- The EMA will be the Maintenance Organisation for EU Substance and Specified Substance IDs

Considerations on Medicinal Product (11615)

- The Product Management System (PMS) will be based on the ISO 11615 standard
- PMS will be implemented in phases and iterations
  - **Iteration I**: focused on current Article 57 data and the minimum required elements which will ensure assignment and maintenance of the Medicinal Product IDs
  - **Iterations II, III, n**: to extend PMS to support additional business cases
- Milestones and scope of each iterations will be defined based on gap analysis and legislative requirements

EU Implementation Roadmap

To cover the following aspects:

- EU Operating models for PMS
- Article 57/ISO IDMP Gap Analysis and Business Processes
- Migration strategy
- Timelines

Current estimated start date April 2015 in close cooperation with EU ISO IDMP Task Force

EU Implementation Guide

- ISO IDMP EU Implementation Guides will be drafted based on robust and mature version of the ISO IDMP Technical Specifications
- Outlining the EU conformance and rules (e.g. define further what ISO describe as ‘conditional’)

Dependencies:

- Availability of the EU Operating models
- Availability of Article 57 /ISO IDMP Gap Analysis and Business process optimisation
- International activities deliverables
- The Business Cases to be supported by each iterations are defined

Current estimated start date June 2015

Thank you

Question?