Referentials:
Report from subgroups

EU ISO IDMP Task Force meeting
25 September 2015

Referentials - content

1. Progress report on ISO IDMP TF Referentials Subgroup
   - Main discussions/conclusions
   - ISO 11239 (routes of administration, pharmaceutical forms, packaging)
   - ISO 11240 (Units of Measurement)
   - Technical discussions

2. Outstanding discussions

Progress report on ISO IDMP TF R Subgroup

- Two additional TCs held since last update (15 July & 18 August)
- Main discussions/conclusions:
  - Phased implementation for referentials
    - endorsed by HMA as proposed
  - ISO 11239 (routes of administration, pharmaceutical forms, packaging)
    - EDQM presentation of high-level plan
    - Ongoing discussions with regards to mappings, processes and details on content
  - ISO 11240 (Units of Measurement)
    - Bfarm proposal to be MO for 11239
    - TC with FDA & RI (UCUM)
  - Technical discussions
    - Conceptual & Logical data model + snippets circulated to subgroup in July for comments
      - *Messaging data model still to be discussed*
    - Ongoing discussions on Term and Change Request confidentiality
    - Ongoing discussions on Mapping strategy

Progress report on ISO IDMP TF R Subgroup

- ISO 11239 (routes of administration, pharmaceutical forms, packaging)

  - EDQM proposed timelines

What	When	Who
Provide APIs to get the TEST data from the StandardTerms database	As from 20/07/2015	EDQM
Test API and provide feedback	Until 31/08/2015	EMA (other interested users)
Adapt database model to include « mapping »	31/08/2015	EDQM
Provide adapted APIs including mapping	10/2015	EDQM
Provide Feedback on adapted APIs (including mapping)	Until 30/11/2015	EMA (other interested users)
Provide « final » APIs (REAL data)	Q1/2016	EDQM
Contractual agreement (including SLAs)	Q1/2016 (signature!); negotiations to be started ASAP	EDQM/EMA
Agree on all relevant processes and define them.	Q1/2016-Q4/2016 (reflections should start earlier)	EDQM/EMA
Adapt to further needs (global implementation)	2016/2017 and beyond	EDQM/all

Progress report on ISO IDMP TF R Subgroup

- ISO 11239 (routes of administration, pharmaceutical forms, packaging):
  - EDQM/EMA data model alignment complete
  - APIs for EDQM standard terms circulated by EDQM in July. Adapted and final APIs expected in the coming months
  - Ongoing discussions with regards to mapping strategy
  - Ongoing discussions with regards to processes particularly
    - EDQM & process for CT terms
    - EDQM/broker & process for translations
  - **Outstanding:**
    - *discussions on content particularly on Containers, closures & packaging details*
      - *How to deal with IDMP "granularity"*
      - *Principles & examples*
    - *Agreements required on contractual agreements, SLAs, business processes and rules, messaging format, etc.*

Progress report on ISO IDMP TF - R Subgroup

- ISO 11240 (Units of Measurement):
  - Clarifying concepts:
    - **UCUM** - building blocks and a **grammar** for constructing any UoM
    - **UoM CV** - a finite, controlled list of UoM's that are acceptable for use within a single application or community
  - TC with FDA & RI (UCUM) in August
    - RI perspective:
      - RI is responsible to manage **UCUM** as in the **grammar** for constructing any UoM
      - RI will focus on governance (e.g., how to construct UoM) instead of products (e.g., the what or the controlled list itself). RI may provide oversight
      - **RI does not see itself maintaining a UoM CV**
      - RI could consider to add value to UCUM, by turning the algorithm used to build unit codes into a transportable format (JSON, RDF, XML if you must), so that a service could dynamically build and return the _definition_ of a UoM, in response to a request formulated using the UCUM code

Progress report on ISO IDMP TF - R Subgroup

- ISO 11240 (Units of Measurement):
  - FDA/RI Proposed approach
    - Outline a charter document where RI/UCUM responsibilities are clearly delineated and all other activities are owned by external groups
    - Additional conversation will be needed on scope definition, resources/funding, and copyright information.
  - Bfarm proposal
    - Bfarm came forward proposing to be the MO for the UoM CV for 11240
    - Bfarm should prepare an official proposal which will have to be accepted by the EUTMB and organise teleconferences to explore the details/prepare the plan
  - **Outstanding:**
    - *Maintenance organisation (MO) to be decided.*

Progress report on ISO IDMP TF - R Subgroup

- Ongoing discussion on Term vs Change Request (CR) confidentiality
  - CRs will be visible to the industry user who requested them
  - CRs will be visible across industry users that belong to the same organisation
  - Terms will be visible to all as soon as they are validated/become provisional
  - "generic" terms may be considered in certain circumstances
    - Assumptions:
      - The context on how the term is used is explained in the CR but not in the term itself.
      - Approach already followed by several EMA systems e.g. EudraCT displays all terms, eAF displays all substances even development ones.

Progress report on ISO IDMP TF R Subgroup

- Data model
  - Conceptual & Logical data model + snippets circulated to subgroup in July for comments
  - **Outstanding:** *Messaging data model*
    - *EUTCT old rest services*
      - *Unauthenticated*
      - *EUTCT common schema*
      - *EUTCT list schemas with extensions e.g. county, variation classification, target species, etc*
    - *New RMS API*
      - *Options available:*
        - *generic extension to existing EUTCT schema vs Genericode vs CTS*
      - *RMS option – to be discussed:*
        - *Authenticated*
        - *RMS common schema – similar to EUTCT common but extended & generic (list extensibility)*
        - *RMS specific list schemas?? **TBC**: MedDRA, VedDRA, ATC*

Outstanding discussions

Open issue	Next steps
ISO 11239: • data model, APIs & messaging format for EDQM standard term • business processes and rules • discussions on Containers, closures & packaging details • contractual agreements , SLAs, etc	• Follow strategy and timelines proposed by EDQM to address all pending issues.
ISO 11240: • Appoint Maintenance Organisation for Units of Measure (ISO 11240)	• Analyse Bfarm proposal to become MO for UoM • See if timelines fit with implementation plan - EMA may need to temporarily maintain this data?
New RMS API: • Available options: generic extension to existing EUTCT schema vs Genericode vs CTS • RMS common schema vs any RMS specific list schemas	• Discuss available options • Discuss and agree final schema