Referentials

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Topics

1. Project status
2. Referentials Roll-out plan
3. RMS User Acceptance Testing (UAT)
4. Referentials topics
   - List Identifiers and OIDs
   - Term Identifiers: what to use in PMS
   - Data management & concepts: legacy terms

Status update

Project Status

Amber

Key achievements since last EUNDB/Taskforce reporting (September 2015)

1.Detailed Use case discussions with EDQM and Bfarm
2.Involving veterinary stakeholders in the SPOR activities (via EUNDB, ISO IDMP TF)
3.Work started to sett up the Referentials Service Desk

Key risks & issues (R/I):

1.Lack of resources and limited network support for the project (I)
2.Ongoing technical issues with solution and integration with IAM (I)
3.Limited availability of operational resources after go-live dictates strict adherence to the roll-out plan (R)

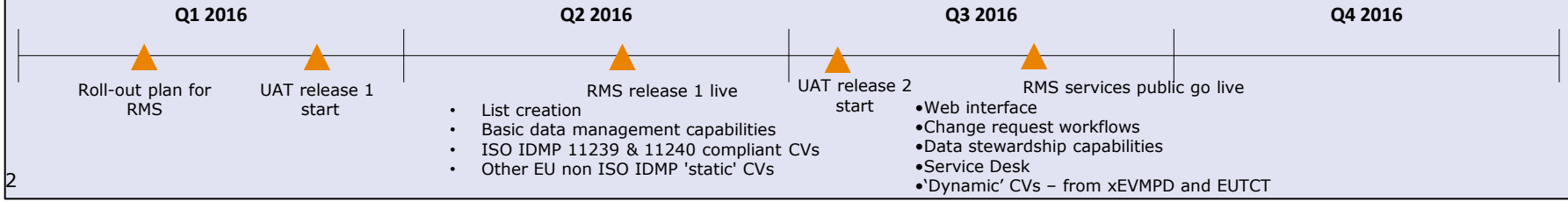
Activities since last f2f EUNDB / Taskforce (September 2015)

1.RMS release 1: completed development, SIT started
2.RMS release 2: completing A&D; started development
3.Roll-out plan for NCAs / Industry prepared with the EUNDB
4.TCs on translations and change requests
5.Setting up relationship with other business providers such as WHO, Kew Gardens and MSSO

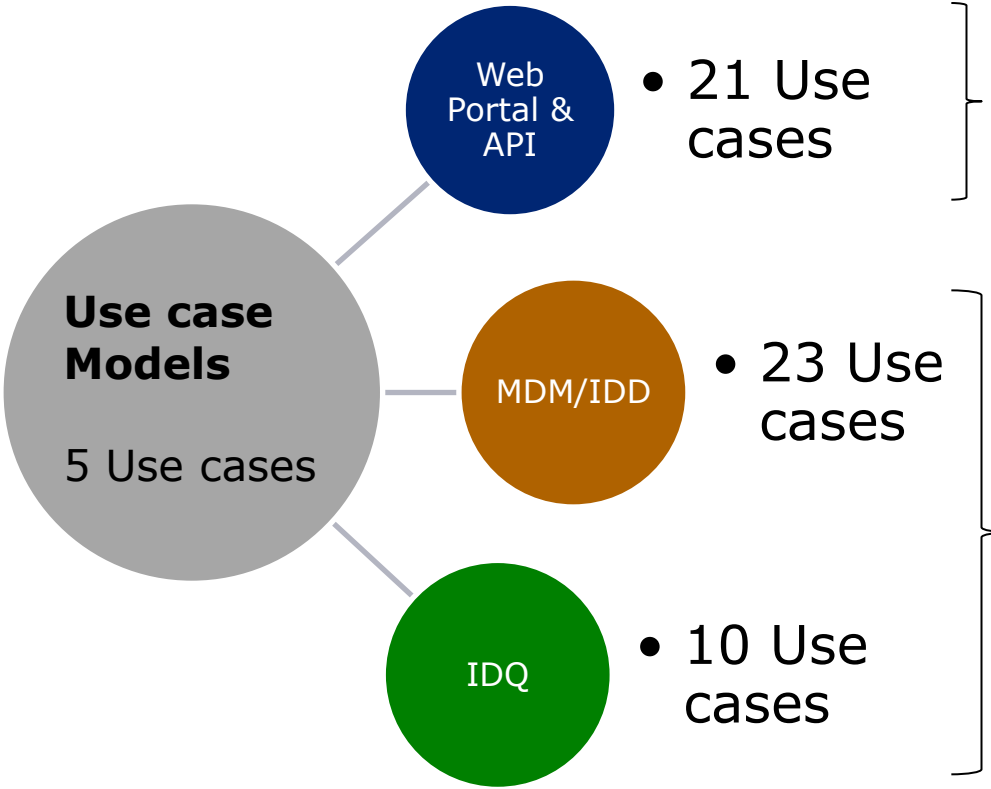
Upcoming activities

1.Internal UAT for RMS release 1 in Mar / April 2016
2.UAT for RMS release 2 planned for July / August; go-live for end August/September
3.Presentation of the RMS Roll-out plan at the HMA in February
4.Dedicated webinars to be delivered to IT Directors February / March to present the RMS roll-out plan and discuss mapping considerations
5.First set of requests on RoAdm & Dosage Forms expected from September-November

Future milestones (until end 2016)



Status update – System Use Cases



Impacting EMA, NCAs and industry
- view/search lists or terms
- Change requests
- Translations
- User preferences: Tags, subscriptions
- Documents
- API

Impacting only EMA

Risks & Issues

Need network support from:

- **RMS SG:** Discuss CVs for Products, Organisations and Substances,
  - PMS SG: Identify P scope (92 elements?) > PMS SG: answer questions> RMS SG: see answers and prepare CV content > RMS project: implement
  - PMS SG: Identify S scope & CVs> RMS SG: analysis GinAS CVs & map to EU needs> RMS SG: questions> PMS SG: answers> RMS SG: see answers and prepare CV content > RMS project: implement
  - RMS & PMS SG: discuss differences found between EUTCT-EV & way forward
- **EDQM/Bfarm:** process details & SLAs > RMS SG: advice on issues > EUNDB: recommendation
- **Invited experts (ISO IDMP TF + EUTCT NCAs):** participate in topic TC & provide input to processes & system functionality
- **Nominated UAT testers:** UAT system (web portal & API)
- **All:** spread the message about RMS; implement Roll-out plan = start mappings

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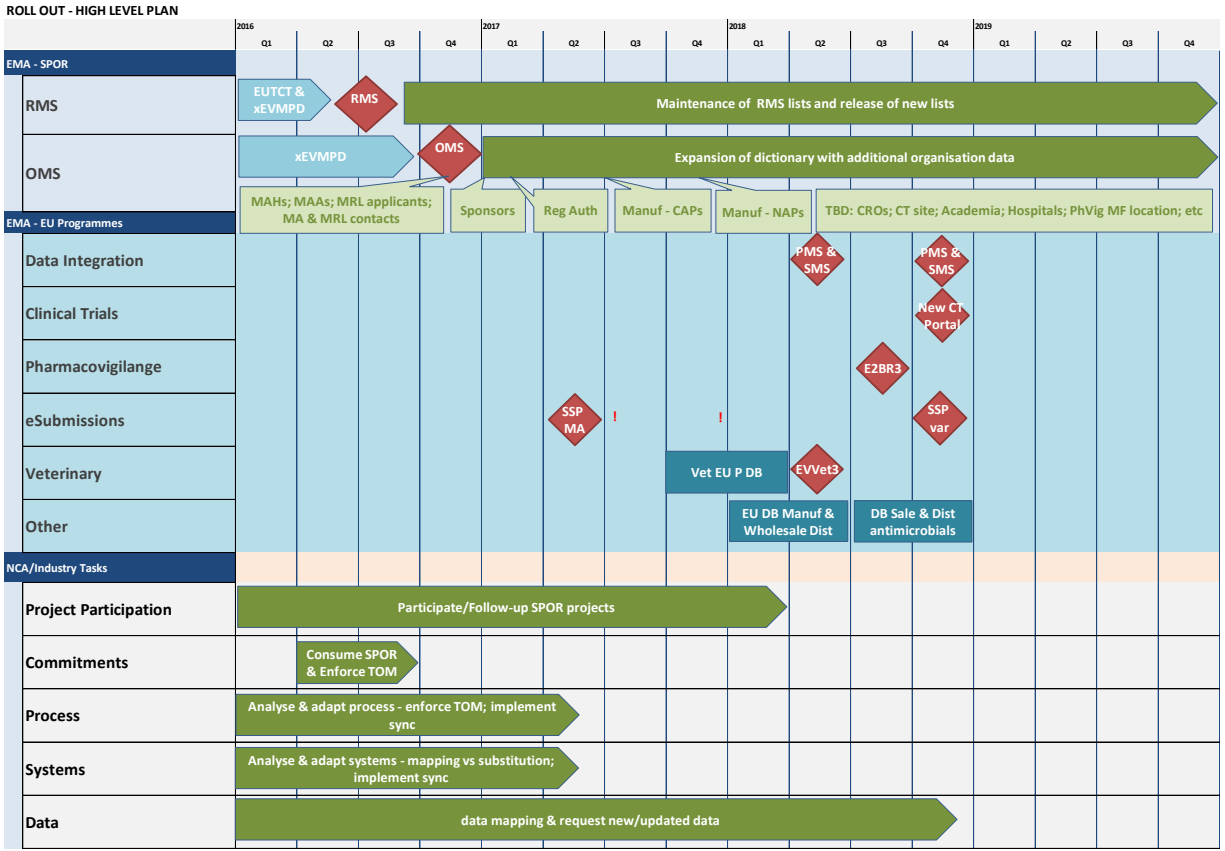
Referentials Roll-Out Plan

High Level Roll-out Plan



Referential Data Roll-out Plan

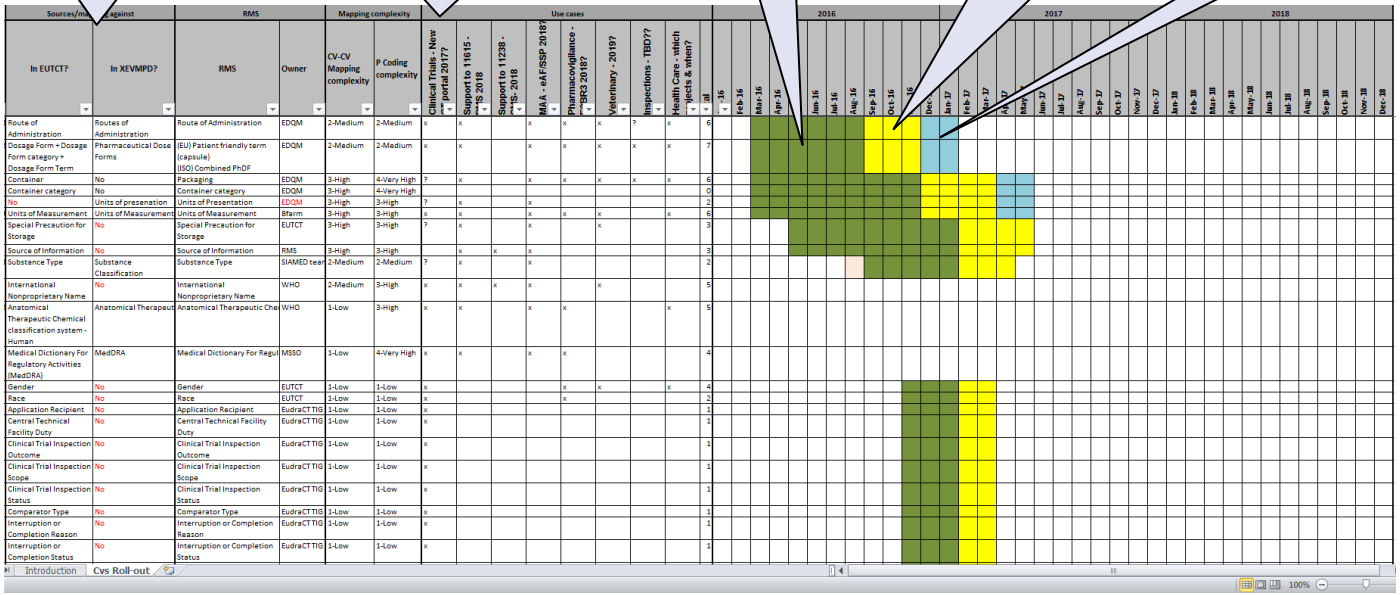
What lists to map against

The use cases i.e. drivers for the mapping

When to map

When to request new/updated terms

Approval period



Sources/mapping against		RMS		Mapping complexity		Use cases										2016												2017												2018											
In EUTCT?	In XEVMPD?	RMS	Owner	CV-CV Mapping complexity	P Coding complexity	Clinical Trials - New portal 2017?	Support to 11615 - IS 2018	Support to 11238 - IS- 2018	MAA - eAFSSP 2018?	Pharmacovigilance - PBR3 2018?	Veterinary - 2019?	Inspections - TBD??	Health Care - which ojects & when?	tal	16	Feb-16	Mar-16	Apr-16	Jan-16	Jul-16	Aug-16	Sep-16	Oct-16	Dec-16	Jan-17	Feb-17	Mar-17	Apr-17	May-17	Jun-17	Jul-17	Aug-17	Sep-17	Oct-17	Nov-17	Dec-17	Jan-18	Feb-18	Mar-18	Apr-18	May-18	Jun-18	Jul-18	Aug-18	Sep-18	Oct-18	Nov-18	Dec-18
Route of Administration	Routes of Administration	Route of Administration	EDQM	2-Medium	2-Medium	x	x		x	x	x	?	x	6																																			
Dosage Form + Dosage Form category + Dosage Form Term	Pharmaceutical Dose Forms	(EU) Patient friendly term (capsule) (ISO) Combined PhDF	EDQM	2-Medium	2-Medium	x	x		x	x	x	x	x	7																																			
Container	No	Packaging	EDQM	3-High	4-Very High	?	x		x	x	x	x	x	6																																			
Container category	No	Container category	EDQM	3-High	4-Very High									0																																			
No	Units of presenation	Units of Presentation	EDQM	3-High	3-High	?	x		x					2																																			
Units of Measurement	Units of Measurement	Units of Measurement	Bfarm	3-High	3-High	x	x		x	x	x		x	6																																			
Special Precaution for Storage	No	Special Precaution for Storage	EUTCT	3-High	3-High	?	x		x		x			3																																			
Source of Information	No	Source of Information	RMS	3-High	3-High		x	x	x					3																																			
Substance Type	Substance Classification	Substance Type	SIAMED team	2-Medium	2-Medium	?	x		x					2																																			
International Nonproprietary Name	No	International Nonproprietary Name	WHO	2-Medium	3-High	x	x	x	x		x			5																																			
Anatomical Therapeutic Chemical classification system - Human	Anatomical Therapeutic	Anatomical Therapeutic Che	WHO	1-Low	3-High	x	x		x	x			x	5																																			
Medical Dictionary For Regulatory Activities (MedDRA)	MedDRA	Medical Dictionary For Regul	MSSO	1-Low	4-Very High	x	x		x	x				4																																			
Gender	No	Gender	EUTCT	1-Low	1-Low	x				x	x		x	4																																			
Race	No	Race	EUTCT	1-Low	1-Low	x				x				2																																			
Application Recipient	No	Application Recipient	EudraCT TIG	1-Low	1-Low	x								1																																			
Central Technical Facility Duty	No	Central Technical Facility Duty	EudraCT TIG	1-Low	1-Low	x								1																																			
Clinical Trial Inspection Outcome	No	Clinical Trial Inspection Outcome	EudraCT TIG	1-Low	1-Low	x								1																																			
Clinical Trial Inspection Scope	No	Clinical Trial Inspection Scope	EudraCT TIG	1-Low	1-Low	x								1																																			
Clinical Trial Inspection Status	No	Clinical Trial Inspection Status	EudraCT TIG	1-Low	1-Low	x								1																																			
Comparator Type	No	Comparator Type	EudraCT TIG	1-Low	1-Low	x								1																																			
Interruption or Completion Reason	No	Interruption or Completion Reason	EudraCT TIG	1-Low	1-Low	x								1																																			
Interruption or Completion Status	No	Interruption or Completion Status	EudraCT TIG	1-Low	1-Low	x								1																																			

Introduction | Cvs Roll-out

- Mapping can start ASAP either against EUTCT (NCAs) *or xEVMPD (Industry)*
- Mapping of new lists can start in Sep 2016 against RMS
- Requests can only start in Sep 2016
- Mapping/requests need to complete ideally 3 months before implementation of intended Use case
- All major programmes have deliveries before 2019 -> to map all lists work needs to start ASAP

Referentials Roll-out plan in the Short term

What	When	Details
• Participate/Follow-up RMS projects	• Throughout 2016	

• NCA Commitments
  • Consume SPOR & Enforce TOM
  • Contact Points
	• By end February	• **Each NCA to nominate a contact point for SPOR (to be provided to IT Directors in preparation of the Telematics Forum)**

• Adapt systems & processes	• From 2016	• Analyse impact on existing processes to support:
		  • Implementation of **target operating models (TOMs) including pre-registration of referential data**
		  • Transformation / enrichment / mapping of data locally
		  • Data consumption / synchronisation with RMS
		• Choose implementation approach: continuous mapping between own system & SPOR vs substitution of own data by new SPOR references

• Map data	• Start ASAP vs EUTCT (NCAs) or xEVMPD (Industry)	• From **now until September 2016** map:
		  • Routes of administration (from EDQM) in EUTCT
		  • Dosage Forms (from EDQM) in EUTCT
		  • Target Species in EUTCT
		• From **now until November 2016** map:
		  • Containers (from EDQM) in EUTCT
		  • Units of measurement (from Bfarm) in EUTCT

• Request new/updates data	• From September 2016	• **No requests before September!**
		• From **September to November 2016** request terms for:
		  • Routes of administration (from EDQM) in RMS
		  • Dosage Forms (from EDQM) in RMS
		  • Target Species in EUTCT
		• From **December to March 2017** request terms for:
		  • Containers (from EDQM) in RMS
		  • Units of measurement (from Bfarm) in RMS

• Keep data in sync	• From September 2016	

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RMS UAT

RMS UAT

Phase	Objective	Who	Dates
UAT nominations **(focal points!)**	• NCAs = 5 H + 3 V (across L/M/S NCAs) • Industry = 4-6 H + 2 V • Software vendors = 2 • Data suppliers = EDQM + Bfarm+ WHO + MSSO • EMA = 2	**All**	**February 2016**

UAT Preparation	Test cases for:
	•*User registration*
	•API interface – EUTCT compatible & New RMS API
	•Web interface
	  • Viewing & searching for lists/terms
	  • Change requests
	  • Translations
	•MDM data stewardship
	Data Preparation
		RMS SG	**February– May 2016**

Review	• Review Test Cases and Data	RMS SG & UAT testers	May - June 2016
Kick-off & Perform UAT – Cycle 1	• Kick-off & Training • Execution of UAT Test scripts, report any feedback	UAT testers	26 July – 1 August
Perform UAT – Cycle 2	• *Execution of UAT Test scripts, report any feedback*	UAT testers	2 – 18 August 2016
UAT fixes & completion report	• Ensure the UAT feedback has appropriately been taken into account • Draft and review of the report	EMA	26 July – 6 September 2016

Nominations:
NCAs through IT Directors
Industry & others thrugh ISO IDMP TF – mdms@ema.europa.eu

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Referentials Topics

LIST
ID
OID
Name
Owner
Etc

TERM
ID
Name & translations
Shornames & translations
Othernames & translations
Descr
Status
Etc
Mappings
- Source of information: EDQM-ISO — source terms ID: ISO code
- Source of information: xEVMPD — source term ID: EV code
- Source of information: EDQM-mapping — source term ID: not ISO code

Current ID

Data management & concepts: Legacy terms

- If a term was **historically widely used in EU** but not in the Maintenance Organisation list
  - RMS would accept the request and create a provisional term
  - EDQM (e.g. topical use):
    - Would reject the request
    - Would not publish the term as deprecated (with ISO code) but could publish as mapped term (no ISO code)
      - For EDQM a term is deprecated/non-current only if it was ever a Standard Term (even if it was widely used in EU).
    - RMS would **reject the change request and set the term status to nullified**
    - **RMS should review the process to always treat them as non-current**
    - **RMS-EDQM need to agree the details on how to distinguish EDQM non-current which were once approved vs these non-current**
  - Bfarm (e.g. ppm):
    - Would approve the request
    - Would publish the term as deprecated/non-current (and also as a non-unit in some cases)
      - For Bfarm a term is deprecated/non-current if it was widely used in EU
    - RMS would **approve the change request and set the term status to non-current**

- Open issues:
  - How to define historically widely used in EU? Used in a valid/approved product
  - Is it ok to have different practices across lists? No, the semantics of the status needs to be the same
  - If not what is the practice EU wants to adopt? If used in a product the status should reflect non-current

Term Identifiers: what to use in PMS?

- **PMS expected to use:**
  - ISO IDMP (EDQM) codes (as per ISO 11239)
  - UCUM codes (as per ISO 11240)
    - *but codes not always shortly available*

- **Issue:**
  - *RMS can issue (provisional) RMS IDs that never change*
  - *RMS cannot issue (provisional) ISO IDMP (EDQM) codes*
  - *EDQM only issues ISO IDMP (EDQM) codes at approval which is not immediate*
  - *RMS could store proposed UCUM codes but these could change*
  - *Bfarm only issues UCUM codes at approval which is not immediate*

  - **Options:**

    1. PMS only uses approved ISO IDMP (EDQM) codes
       - *Not applicable in some use cases*
    2. No provisional codes used and short SLA for EDQM approval – 2 days
       - *Short SLAs not always possible, realistically we are talking about 6-8 weeks*
    3. Use RMS ID if provisional term and ISO IDMP (EDQM) codes once approved
       - *Requires PMS/ all users capability to translate codes & update records*
       - *Preferred option, likely that the ID used will change depending on the business use case*
    4. Always use RMS ID (unchangeable, mandatory)
       - *Difficulties in global harmonisation*
    5. Include a technical validation at point of request to ensure provisional UCUM codes at least adhere to the UCUM semantic rules
       - *Not planned by Bfarm and not EMA responsibility/scope*

List Identifiers and OIDs - Introduction

- To support IDMP / HL7 based implementation of PMS the RMS needs to provide globally unique identifiers (OIDs) for lists
- OID uses hierarchical notation with numbers and dots; they are paths in a tree structure and each OID is created by a Registration Authority. Registered OID numbers can be browsed e.g. here http://www.oid-info.com/
- EMA has a number of OIDs assigned under Individual International Conference on Harmonisation (ICH) node for members to identify regionally (EU) required objects
  - joint-iso-itu-t(2) country(16) us(840) organization(1) hl7(113883) externalUseRoots(3) ich-estri(989) regional-specialised(5) sub-reg(1) eu(1)
  - 2.16.840.1.113883.3.989.5.1.1
- This EU node contains:
- crossDomain(1) - Code systems that may be used across several domains. No children nodes
- productInformation(2) - Code systems related to medicinal product information. No children nodes
- procedureManagement(3) - Code systems related to the European Union regulatory network procedure management. No children nodes
- clinicalTrials(4) - Code systems related to clinical trial activities. No children nodes
- **pharmacovigilance(5)** Code systems relating to pharmaco-vigilance activities. Children nodes:
  - eu-icsr-msg-type(1) European Union (EU) Individual Case Safety Report (ICSR) message type
  - eu-method-assessment(2) Method of assessment
  - eu-result-assessment(3) Result of assessment
  - eu-source-assessment(4) Source of assessment
- compliance-and-inspections(6) - Code systems relating to compliance and inspection activities. No children nodes
- veterinarySpecific(7) - Code systems specific to veterinary medicinal products and their regulatory activities. No children nodes

List Identifiers and OIDs – Proposals/Discussion

- EMA would register OIDs only for lists maintained by EMA.
- EMA should register one OID for the whole RMS. This works well as the Term Ids are unique in the system and independent of list
- If RMS is registered, consequently all lists are registered not just HL7/IDMP lists.
- Lists required for HL7/IDMP should be registered under a new node - HL7 > IDMP> Global vs EU
  - Use similar hierarchy as other EU node (cross domain, CT, PhV, vet, etc.)?
  - If we are registering RMS does it all fit under the same node?
- MSSO, UCUM, Bfarm, EDQM would have to register their own OIDs if necessary.
- RMS acting as a broker for vocabularies will be able to expose both EMA and other providers OIDs
  - Which OIDs will be mandated for PMS, e.g. EDQM OIDs vs RMS OIDs? Suggestion, implement OID in the mapping at level of source of information so depending on the coding system being used a different OID goes with it
  - If EMA creates provisional terms in a given list and the provider does not have such terms which OID should be referred to? EMA lists will have RMS OID, the provider OIDs will be only in the mappings
  - Should EMA register similar lists as sub-codes of the list owner?

For further investigation:

- Cost and process, particularly if the cost is for registration only or there is a cost for maintenance of OIDs

Thank you