International activities and IDMP

2nd EU ISO IDMP Task Force Meeting, 12 June 2016

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Data Standardisation and Analytics

The European Medicines Agency is an agency of the European Union

Outline

Activities in ISO/TC215 WG6

- –Work in Progress, Next Steps & Timelines

Activities in HL7

- –Work in Progress, Next Steps & Timelines

Other International Activities

- –GInAS next workshop in brief
- –OpenMedicine Project in brief
- –Joint ISO-HL7-IHE meeting in brief

Activities in ISO TC/215 WG6 (pharmacy and medicines business)

ISO/TC215 activities (Resolutions)

- Last ISO/TC 215 WG6 meeting: 21–23 April 2015, San Francisco, USA
- *"prEN ISO/DTS 20440, Health Informatics, IDMP, IG for EN ISO 11239 Data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging"*:
- Resolution Submission for DTS Ballot

Dates:

- provision of the text of prEN ISO/DTS 20440 and NP ballot reconciliation to the WG6 secretary by 15 June 2015 and to TC215 secretary by 22 June 2015
- TC 215 secretary to launch a 2-month DTS ballot by 30 June 2015 and CEN/TC251 launch a parallel 2-month DTS ballot

✓ Publication is expected in Q1 2016

ISO/TC215 activities (Resolutions cont.)

- "*prEN ISO/DTS 19844, Health informatics, IDMP, IG for EN ISO 11238 Data elements and structures for the unique identification and exchange of regulated Information on substances*". Resolution: submission for publication

(*Iteration 1: first 4 annexes/substance classes*]

Dates:

- Provision of the updated text and the final disposition of comments to the WG6 secretary by 31 July 2015, to the TC215 secretary by 7 August 2015 and to ISO/CS by 15 August 2015.
- Publication expected in August (prEN ISO/TS 19844:2015) AND:

ISO/TC215 activities (Resolutions cont.)

- *"prEN ISO/TS:2015 19844, on EN ISO 11238 Data elements and structures for the unique identification and exchange of regulated Information on Substances"*:

Resolution: revision of EN ISO/TS 19844:2015 & submission an ISO/PWI for the revision

Dates:

- Provision of the ISO-PWI for the revision of EN ISO 19844:2015 to the WG6 secretary by 15 June 2015, to the TC215 secretary by 22 June 2015 and to ISO/CS for a 2-months ballot by 30 June 2015
- CEN/TC 251 to launch a parallel 2-months CEN/PWI ballot

ISO/TC215 activities (Resolutions cont.)

- *"prEN ISO/DTS 20451", IDMP, IG for EN ISO 11616 and,*
- *"prEN ISO/DTS 20443" IDMP IG for EN ISO 11615*:
- Resolution: Submission for DTS ballot

Dates:

- Provision of the text prEN ISO/DTS 20451 and NP ballot reconciliation to the WG6 secretary by 15 June 2015 and to the TC215 secretary by 22 June 2015;
- TC 215 secretary to launch a 2-month DTS ballot by 30 June 2015 and CEN/TC251 launch a parallel 2-month DTS ballot

ISO/TC215 activities (Resolutions cont.)

- *"revision of EN ISO 11238:2012, EN ISO 11615:2012 and EN ISO 11616:2012":*
- Resolution: revision of the standards above and submission for each an ISO/PWI

Dates

- Provision the ISO/PWI for the revision of EN ISO 11238:2012, EN ISO 11615:2012 and EN ISO 11616: 2012 to the WG6 secretary by 15 June 2015, to the TC215 secretary by 22 June 2015
- TC215 secretary to submit these items to ISO/CS 2-months ballots by 30 June 2015 and CEN/TC 251 to launch parallel 2-months CEN/PWI ballots

Other ISO TC/215 WG6 activities

Other ISO/TC215 resolution activities

- prEN ISO/DIS 17523 Health informatics- Requirements for Electronic Prescriptions:

Resolution: submission for FDIS ballot

- prEN ISO/DTS 19256, Health informatics – Medicinal Product Dictionary (MPD) systems for health care:

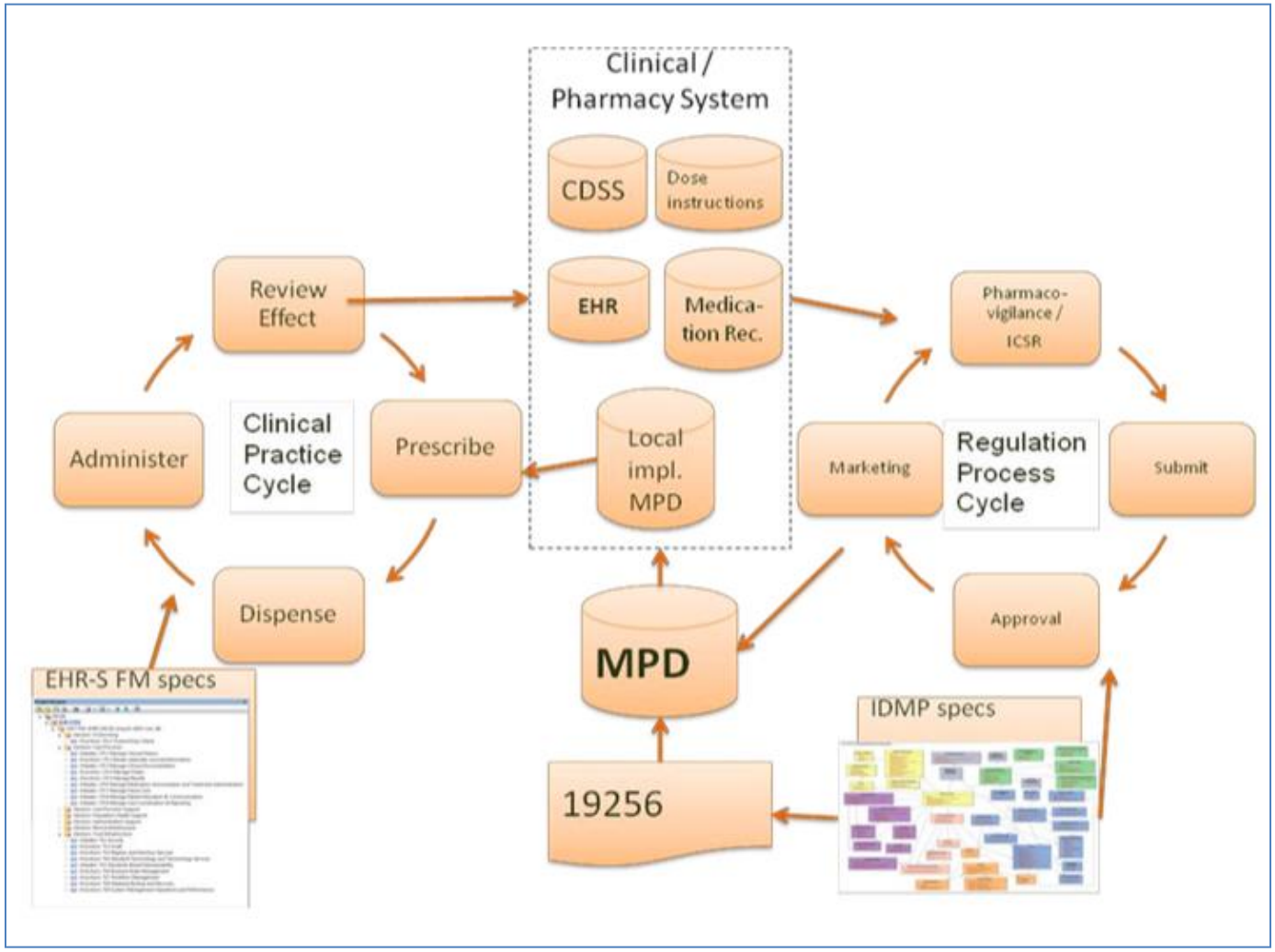
Resolution: submission for 2nd DTS ballot

- prEN ISO/TR/NP, Health informatics - Medication management concepts and definitions:

Resolution: submission for NP/DTR ballot

The MPD-system does not exist on its own. It is a component of a larger clinical and/or pharmacy information system

(*slide presented by Jean-Francois FORGET, Joint ISO/HL7/IHE meeting, May 2015*)



Next ISO TC215 Meetings

- ❑ 2-6 November 2015 Bern, Switzerland
- ❑ 2-6 May 2016 Amsterdam, the Netherlands
- 17-21 October 2016 Kuala Lumpur, Malaysia
- April or May 2017 in China
- October or November 2017 in Korea

HL7 WG activities

Report on HL7 activities

- Last HL7 International WG Meeting: May 10-15 Paris, France
- As per IDMP-CPM-SPL Project Scope Statement (PSS) and following the working activities within the HL7 O&O (Orders and Observations) and the HL7 RCRIM (Regulated Clinical Research Information Management) WGs, the out-of-cycle ballot for the following HL7 candidate standards will start in June 2015 as planned:
- HL7 Version 3 Standard: Common Product Model (CPM) CMETs, Release 3.
- HL7 Version 3 Standard: Structured Product Labeling (SPL) Release 7.

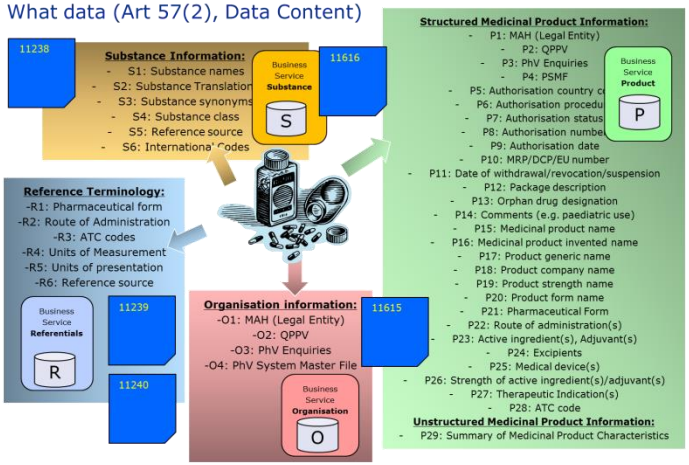
HL7 Ballot Dates

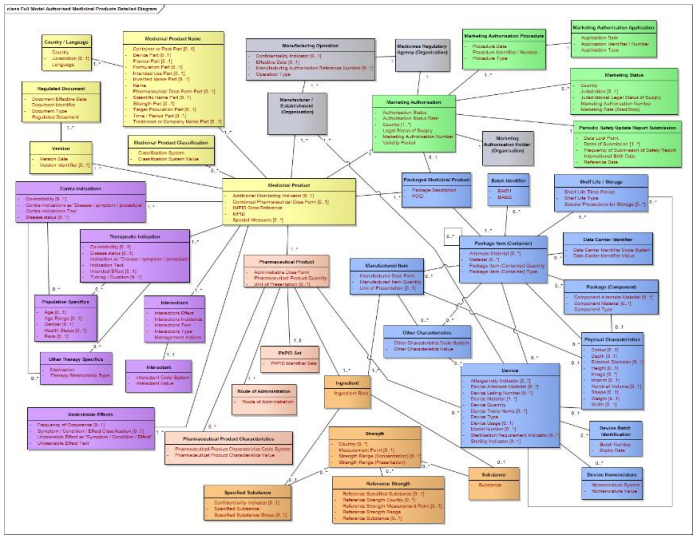
- Signup Open Day: Monday, May 18, 2015
- Signup Close Date: Jun 18, 2015
- Ballot Open Date: Friday Jun 19, 2015
- Ballot Close Date: Monday Jul 20, 2015
- The ballot activities are expected prior to the next HL7's September 2015 Working Group Meeting. Comments received from consensus group members will be addressed at Work Group conference calls leading up to the Plenary & Working Group Meeting Oct 4-9, 2015 in Atlanta.

What this means practically

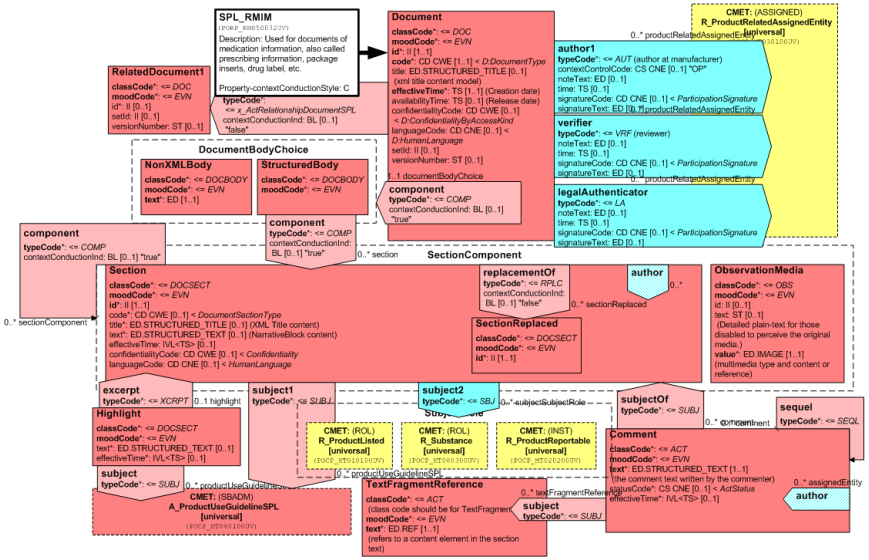
- The scope of the project is to describe the use of SPL R7 as the data exchange format to support the ISO IDMP Technical Specifications.
- The ISO IDMP Technical Specifications are describing data exchange considering the content requirements for the five ISO IDMP International Standards.
- The new HL7 SPL R7 will now include all the ISO IDMP elements plus the specific EU/EMA data fields. Therefore, if approved, it will replace the current Art 57 format use for the current product and substance submissions to the EMA.

Work in Progress

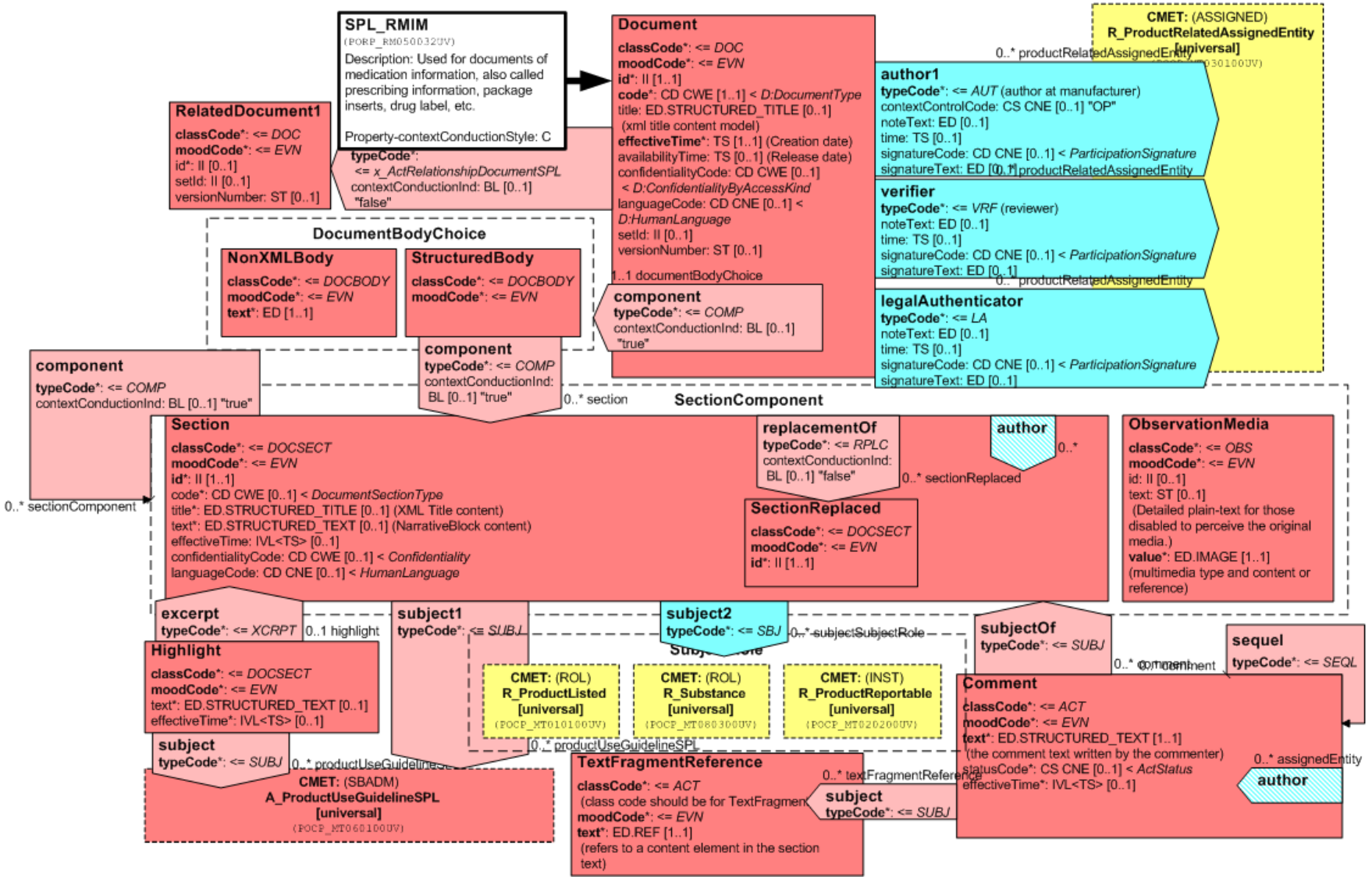




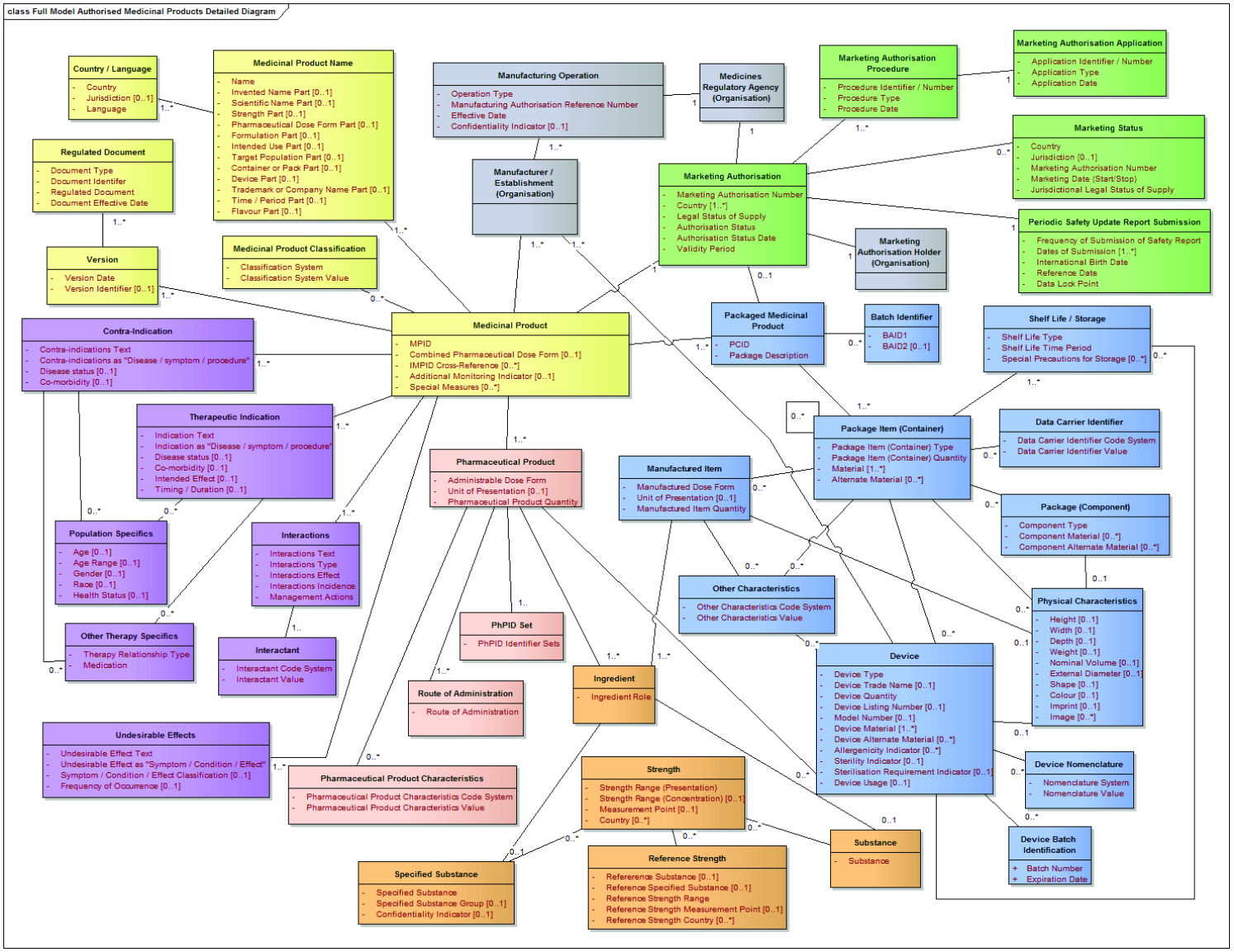
Where to put my data?



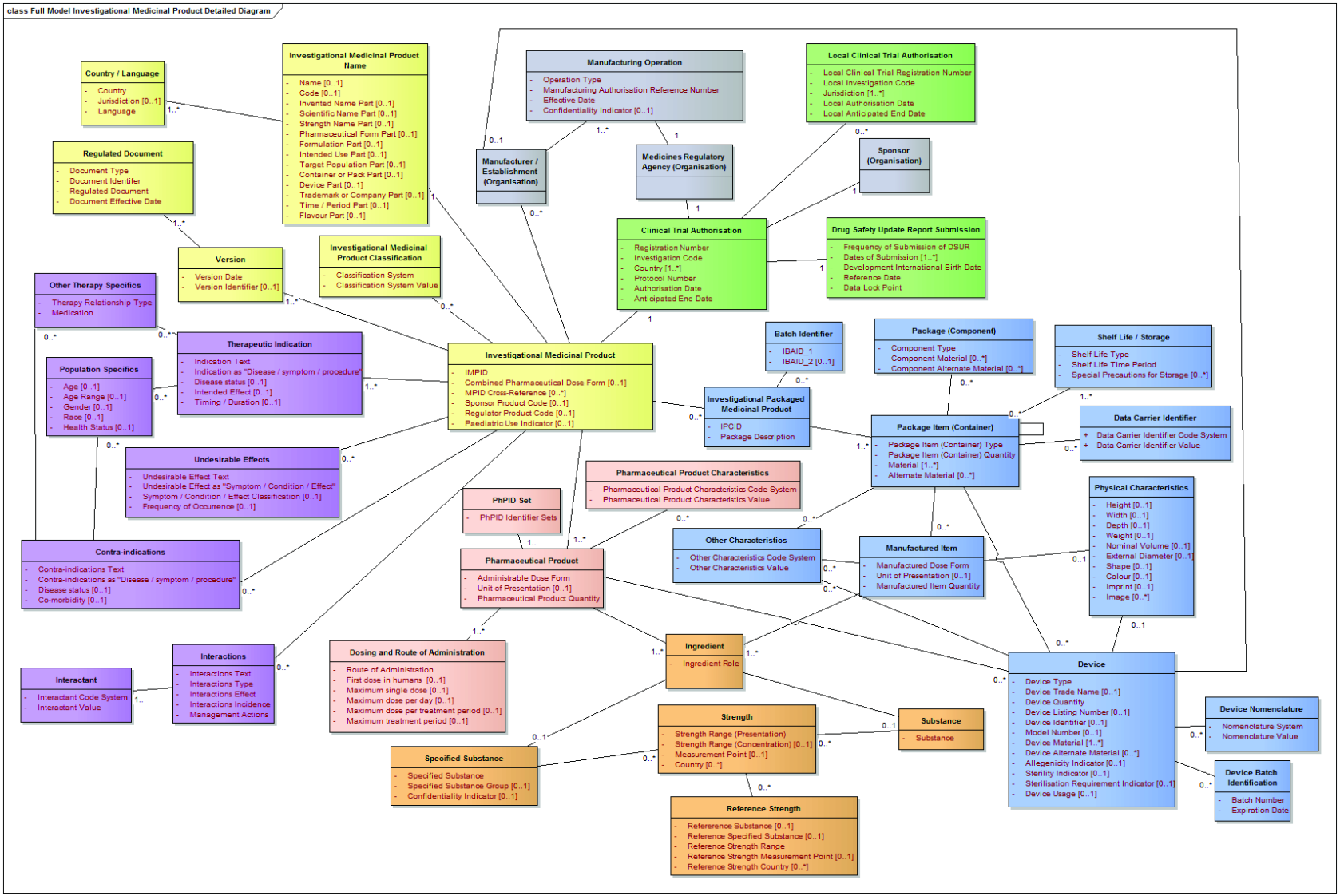
SPL R.6 Quick Overview – the Header



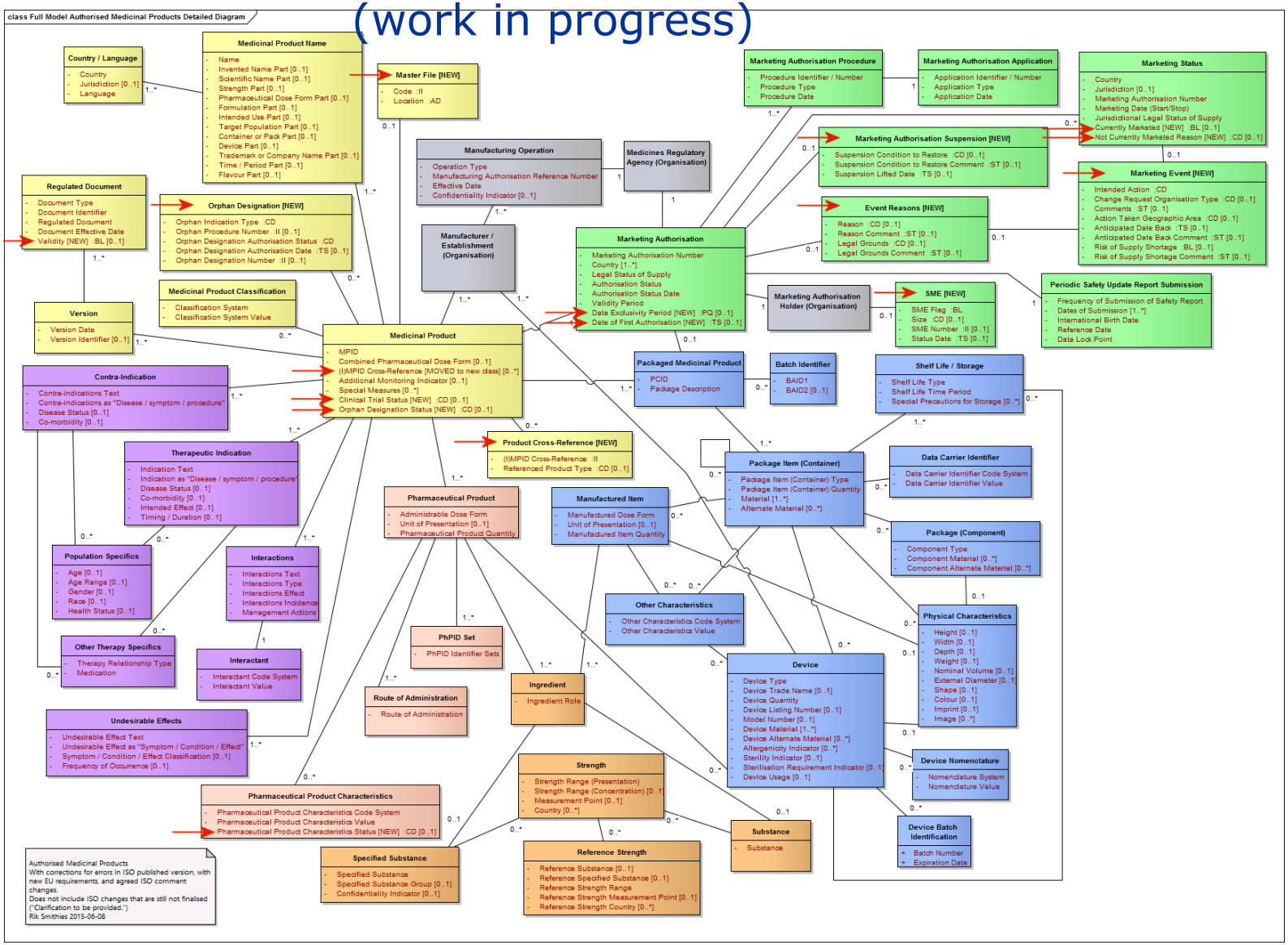
IDMP 11615: Authorised Medicinal Product



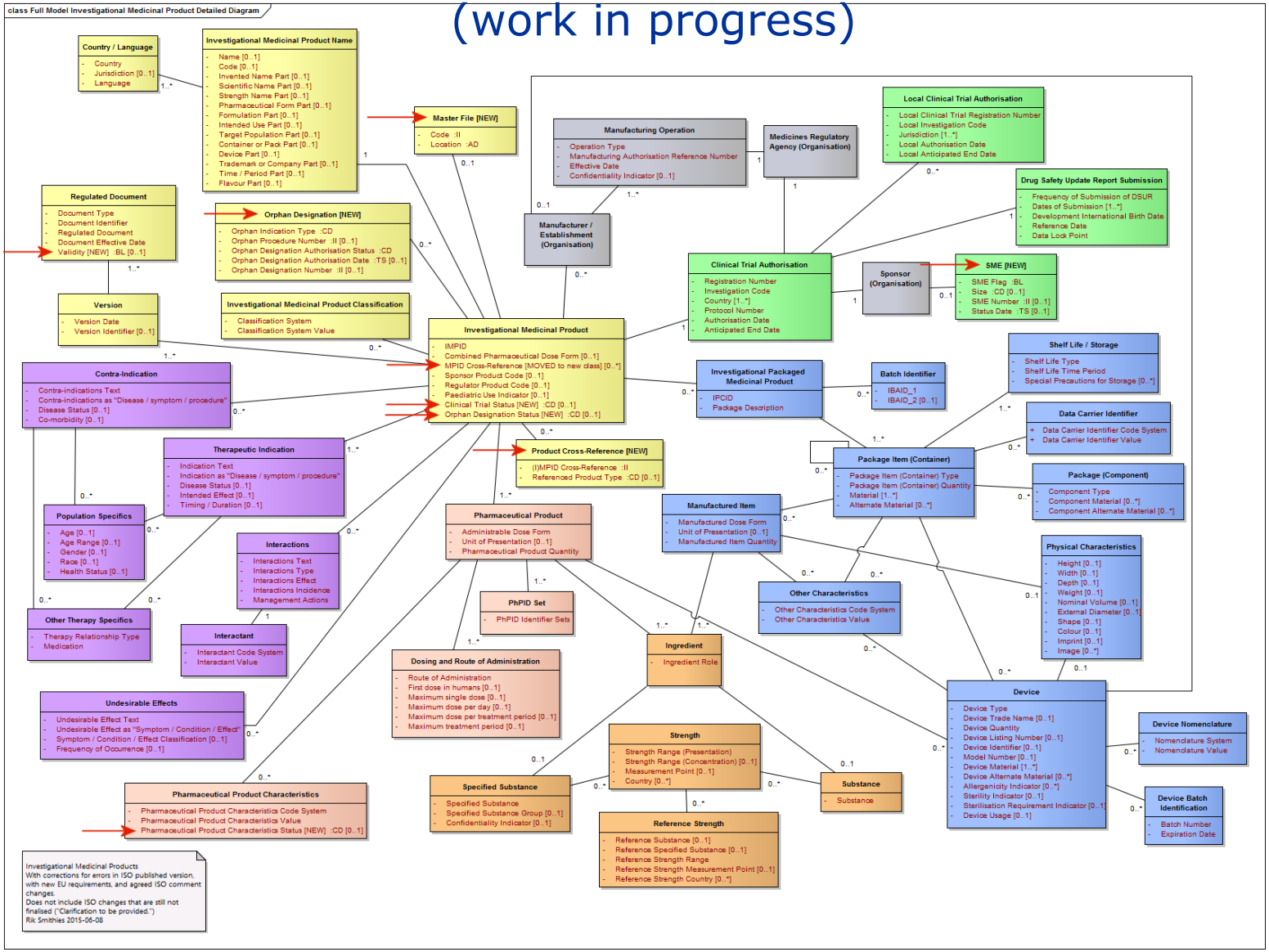
IDMP 11615: Investigational Medicinal Product



An Authorised Medicinal Product DAM (work in progress)



Investigational Medicinal Product DAM (work in progress)



ISO Extensions are coming from:

comments, EMA/EU req., Art. 57/IDMP gap analysis, etc. (work in progress)

D24 | Marketing Authorisation withdrawal/revocation legal grounds comment

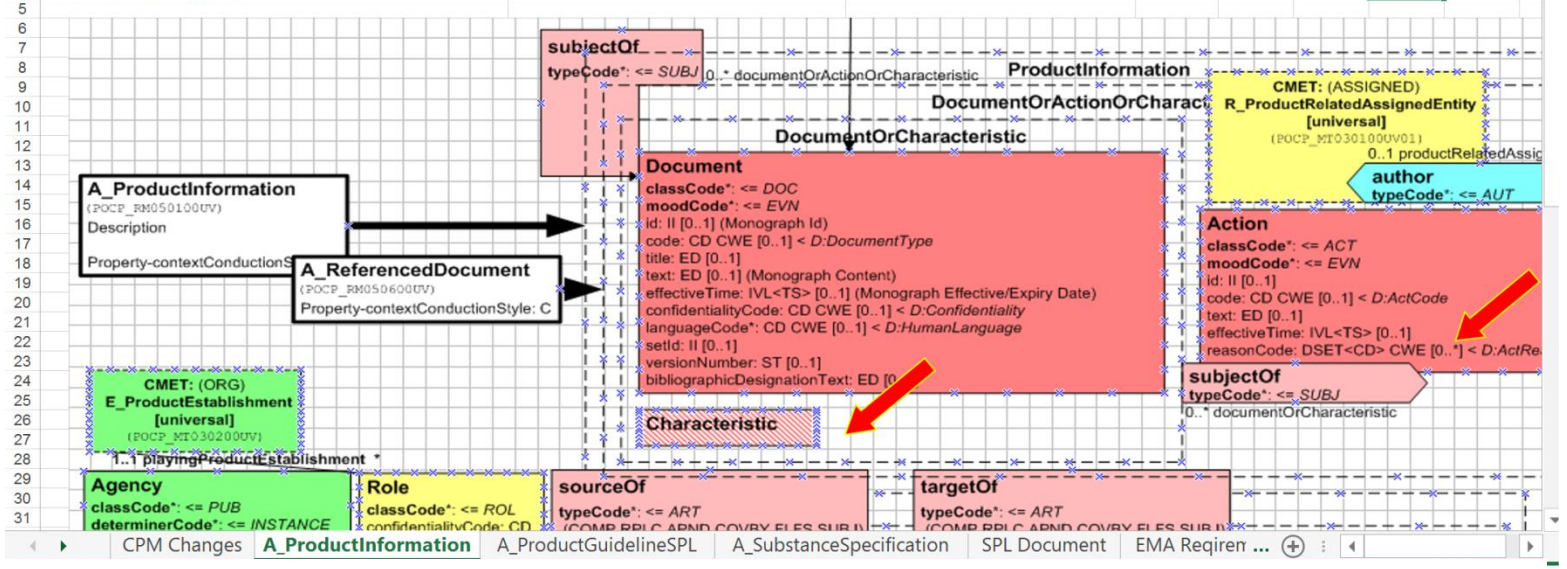
	A	B	C	D	E	F
1	Category	New requirement	Description/Justification (original)	Specific data items request (extracted from text at left which in some cases covers must be fulfilled by several data items). Note that these may already exist in some form in the model, this just lists the request)	New cardinality	New data (see Key s
19		**Marketing Authorisation withdrawal/revocation date** in each MS and/or third country (by strength, pharmaceutical form, route of administration if applicable) together with the reasons and legal grounds Note for reasons: need for a structured field	(as in Articles referenced above)			
20		listing grounds laid down in Articles 116 and 117 of the Directive, or "commercial", "industrial" or "other" and another field allowing the MAH to include more details on the reasons for action	(as in Articles referenced above)	Marketing Authorisation withdrawal/revocation date (this and all below are per MS, by strength, pharmaceutical form, route of administration) **[Clarifying note: the "per member state" requirement will be covered by having different products (meaning dfferent MPIDs). This means that the Marketing Authorisation class is suitable here, and it doesn't require use of the Marketing Status class to represent country/jurisdition specfic authorisations or events]**	n/a	n/a
21		*nb. No "date back on market", unlike above*	(as in Articles referenced above)	Marketing Authorisation withdrawal/revocation reason	n/a	n/a
22			(as in Articles referenced above)	Marketing Authorisation withdrawal/revocation reason comments	n/a	n/a
23		*nb. No "risk of supply shortage", unlike above*	(as in Articles referenced above)	Marketing Authorisation withdrawal/revocation legal grounds	n/a	n/a
24			(as in Articles referenced above)	Marketing Authorisation withdrawal/revocation legal grounds comment	n/a	n/a
25		**Marketing Authorisation suspension date** in each MS and/or third country (by strength, pharmaceutical form, route of administration if applicable) together with the reasons and legal				
26			(as in Articles referenced above)	Marketing Authorisation suspension (this and all below are per MS, by strength, pharmaceutical form, route of administration)	n/a	n/a
27			(as in Articles referenced above)	Marketing Authorisation withdrawal/revocation reason	n/a	n/a

Reqs | Datatypes key | Change log

IT 017				te	Product withdrawals in each MS and/or third country by strength, pharmaceutical form, route of administration together with the reasons, legal grounds, anticipated dates as to when the medicinal product is no longer available on the market of each MS Note for reasons: need for a structured field listing grounds laid down in Articles 116 and 117 of the Directive, or "commercial", "industrial" or "other" and another field allowing the MAH to include more details on the reasons for action	Include a new field in the ISO TS addressing the need and update the ISO 11615 standard accordingly retrospectively.	Persuasive with modificatior Some items can be addressed in the ISO TS an standards and other items identified are business rules to be implemented regionally. Clarification on what is an ISO item and regional item to be identifiec for appropriate disposition.

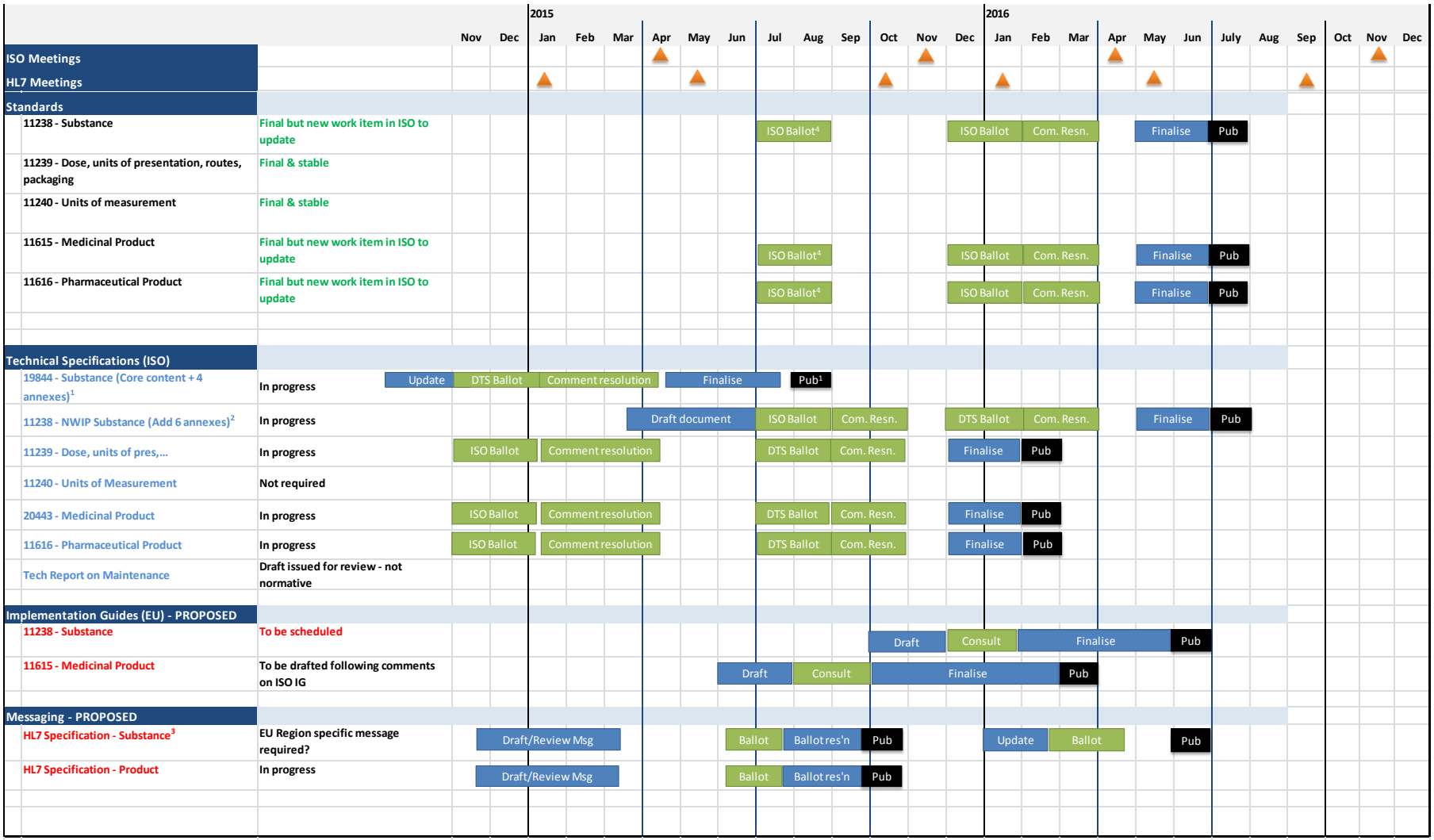
and go to the HL7 Ballot (June-July):

	A	B	C	D
2	**Requirement**	**Addressed By**	**Area**	**Done?**
3	MarketingAct and Approval reason and legal grounds.	Action.reasonCode (multiple codes possible)	A_ProductInformation (Approvals, Actions)	done
4	Indicate a risk of supply shortage for marketing cessation, SME size standard, action needed to restore, possibly legal grounds, possibly the specific slotted comments, etc.	Add Characteristics to annotate Approval, Actions, etc.	A_ProductInformation (Approvals, Actions)	done



	C	E	F	J	L	M
1	**ISO Reference**	**Data Element Name**	**Class**	**Datatype**	**Cardinality**	**HL7 Mapping**
41	7.3.2.1	Marketing Authorisation			1	[R_ProductListed]/ManufacturedProduct/manufacturedProduct
42	7.3.2.1.1	Marketing Authorisation Number	Marketing Authorisation	II	1	[R_ProductListed]/ManufacturedProduct/manufacturedProduct/asIdentifiedEntity/subjectOf/approval/id
43	7.3.2.1.2	Country	Marketing Authorisation	CD	1..*	[R_ProductListed]/ManufacturedProduct/manufacturedProduct/asIdentifiedEntity/subjectOf/approval/author/territorialAuthority/territory/code
44	7.3.2.1.3	Legal Status of Supply	Marketing Authorisation	CD	1	[R_ProductListed]/ManufacturedProduct/manufacturedProduct/asIdentifiedEntity/subjectOf/approval/pertinentInformation/policy/code

High level Project Plan (update in progress)



Notes

1. The TS for 11238 includes the following annexes: chemicals, nucleic acids, proteins and herbals
2. The TS for 11238 (2nd part) will include the following annexes: polmers (started), homeopathics (started), allergens, vaccines, biologics and advanced therapies
3. The HL7 message may need to be revised following completion of the ISO Implementation Guide covering the remaining substance classes
4. The ballot on the existing standards is initially just to agree to re-opening the standards to align then with the Technical Specifciations (New Work Item Proposal NWIP)

Other activities

GInAS workshop & G-SRS

- Next GInAS Workshop: September 7-8 2015, Uppsala, Sweden
- Presentations by stakeholders will provide regulatory and practical perspectives on the description and use of substance information.
- Case studies, demonstrations of the Global Substance Registration System (G-SRS) software, and status updates of the ISO IDMP implementation process and deployment of the software at FDA will also be presented.
- The meeting will conclude with discussion of use of GInAS for generating global substance identifiers and refining a roadmap for the further development of the GInAS project.
- You can register here: http://tripod.nih.gov/ginas/register.html

- Vision in high level: To better enable cross-border healthcare delivery, particularly the exchange of ePrescriptions and safe dispensation of prescribed medicinal products
  - A common data model based on and extending standards in use for prescribed medications
  - an unambiguous vocabulary for the description and identification of medicinal and pharmaceutical products
  - robust rules to account for and gradually harmonize concepts and practices of therapeutic and economic substitution
  - an actionable global roadmap to advance post-project implementation realising interoperable and safe eHealth services across local, state, and international borders
  - coordination of practical solutions and policy recommendations of OpenMedicine with the policy recommendations of the EU/US roadmap process for eHealth cooperation.

openMedicine (cont)

- The project builds on the results of the epSOS project and includes use cases such as substitution.
- The project will proved guidance / use cases that can be used for ISO/DTS 19293 - Requirements for the record of dispense medicinal products (on hold till the end of the project, early 2017).
- Collaboration and guidance from EMA/participating NCAs/Stakeholders so that IDMP could be fully leveraged..
- URL: http://http://www.open-medicine.eu/openmed/
- Expert Council meeting: June 25, 2015 at the European Medicines Agency in London, UK.

Other Activities (cont)

IHE-HL7-ISO Joint Meeting, May 15, Paris, France

- Update of IHE Pharmacy & HL7 Pharmacy work items
- Presentation of the current status of IDMP and discussions on the impact of IDMP in the ongoing activities on MPD, eP, eD

- *IHE: Integrating the Healthcare Enterprise. IHE is an initiative by healthcare professionals and industry to improve the way computer systems in healthcare share information*

Thank you!