Substances & Products: Reports from subgroup

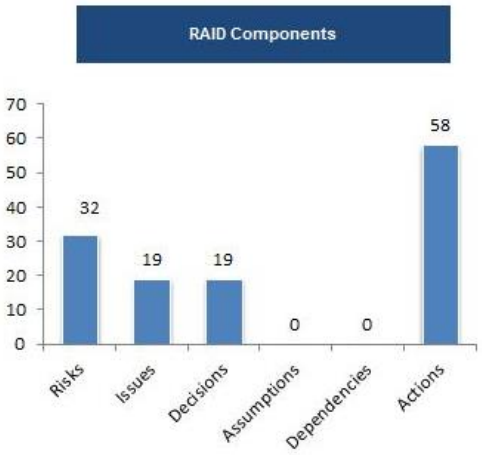
EU ISO IDMP Task Force meeting
25 September 2015

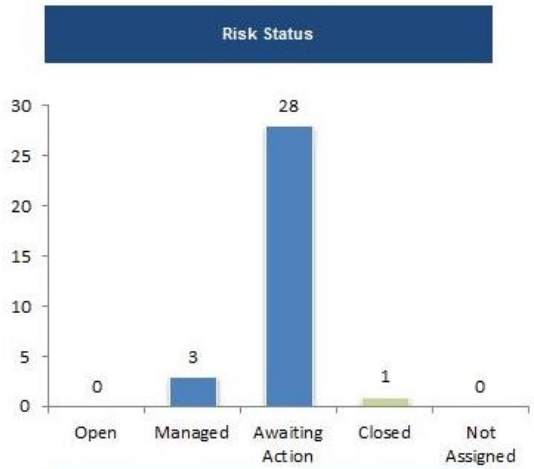
Products & Substances - content

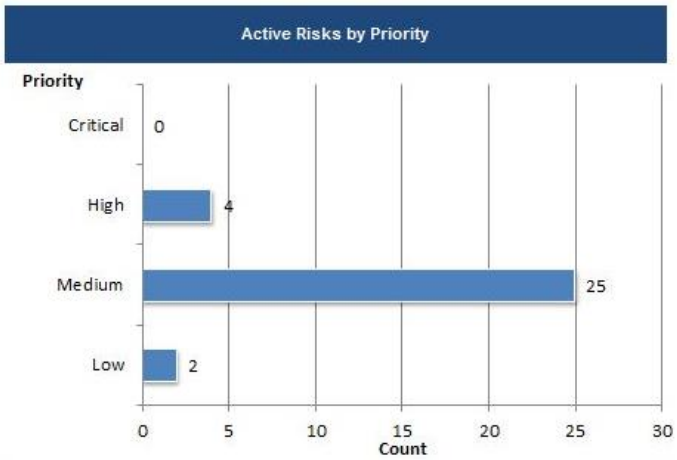
1. S&P subgroup report
2. Focus & Achievement
3. Next activities

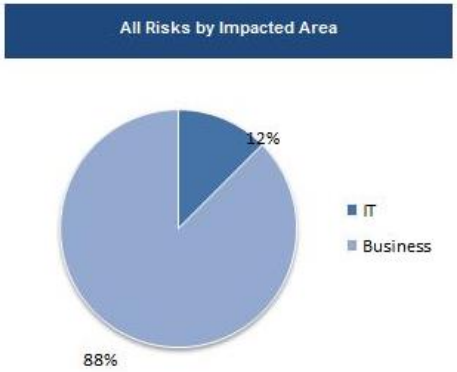
S&P subgroup report

1. 4 TCs since June









S&P – Focus on PMS

Iteration #	Scope	Business case
1	Content currently available in the **Article57** format and minimum required elements **to assign and maintain identifiers** for authorised medicinal products and support product **life cycle management** (MPIDs, PCIDs and PhPIDs)	• **Pharmacovigilance iteration 1** (i.e. to power the activities currently supported by Article 57) • **Regulatory submission Iteration 1** (i.e. MAA and post-authorisation submission) • GMP/Inspections Iteration 1 (current processes as supported by Article 57 database e.g. PhV inspections) • e-Prescription Iteration 1 (e.g. cross border identification of medicinal product in EU)
2	Additional data elements and ISO IDMP 11615 content to support the assignment and maintenance of the **Investigational Medicinal Product** IDs (i.e. development products)	• **Clinical Trial** and pre-authorisation regulatory activities iteration 1 (e.g. excluding scientific advice, orphan and paediatrics application) • Regulatory submission support Iteration 2 (e.g. include the Clinical Trial application)
3	Remaining EU requirements for the **Clinical Particulars** section	• **Pharmacovigilance iteration 2** • e-Prescription iteration 2
4	**Batch Identifiers** and remaining EU ISO 11615 and ISO TS 20443 compliant	• **GMP/Inspections** Iteration 2 (e.g. full traceability of medicinal products) • Scientific advice orphan/ paediatrics application • e-Prescription Iteration 2 • **Anti-falsified medicines**
5	Additional standards (TBC) to support **Veterinary** medicinal product	• **Veterinary products**

Draft of the data elements falling into the scope of PMS Iteration 1

Criteria to determine Iteration 1 scope:

- Any data elements (either mandatory or optional) that is part of Article 57 format
- Any data elements required to:
  - Initial assignment and maintenance of the MPIDs, PCIDs and PhPIDs
  - Support Product Lifecycle management

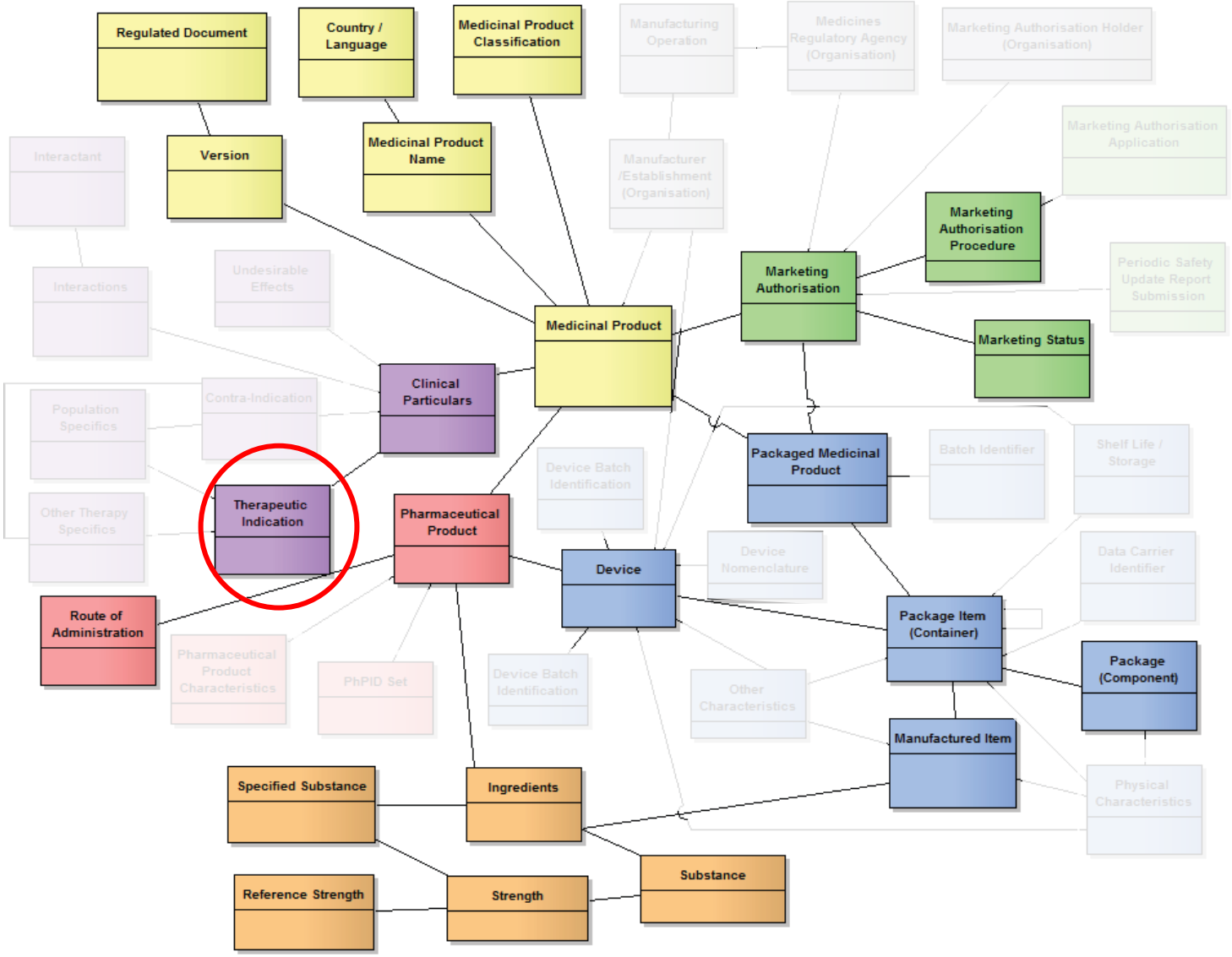
Proposed data scope of PMS Iteration 1

Number of data elements in Article 57	Number of data elements in PMS it. 1	Δ
59	92	**+33***

* these include:

- 3 data elements that are still under discussion (i.e. on indication)
- 9 data elements potentially managed by OMS [TBC]
- Some elements in Article 57 that have become multiple elements in PMS (e.g. package description)

Proposed data scope of PMS Iteration 1



Data scope for PMS Iteration 1

Key clarifications discussed within the subgroup:

- EMA will make available the current Article 57 data in an IDMP compatible format for industry to confirm the migrated data and enrich with the additional required information
- Transition to the target operating model will occur in a phased manner
  - Details to be discussed including pilots to be run with Industry to define the best way to achieve this
- The implementation of the target operating model will be planned in coordination with the EUNDB

S&P - Next activities

1. Draft the **business case** that will be supported by each data element within PMS Iteration 1 scope
2. Plan and perform **Data Pilot** for testing products and scenarios within the PMS Iteration 1 scope
3. Define the data elements falling into **PMS Iteration 2 scope**
4. Kick off activities on substance to progress on the **SMS iteration 1***
5. Provide inputs in the overall **SPOR programme plan, communication strategy** and **change management**
   - Drafting EU IGs for PMS Iteration 1 with detailed specifications and business rules
   - Definition of the Art.57 data migration strategy and plan
   - Analysis and planning of the business process change (i.e. target operating model)
   - Contribute to the development of the EU Roadmap for the ISO IDMP implementation

*SMS iteration 1 to cover all EU minimum required mandatory elements as defined in ISO TS 19844 to assign and maintain global Substance and Specified Substance Identifiers

Thank you