Product Subgroup Update

10th March 2017

Goal

Deliver Minimum Viable Product for PMS by mid 2019 to realise intended Pharmacovigilance value underpinning IDMP standards

Objectives

Deliver Pharmacovigilance use cases and create additional stakeholder value through Type 1A variations data only submissions, Veterinary Products integration and robust validation mechanism for Competent Authorities

Strategy

Focus on creating and implementing a fit for purpose Target Operating Model serving EMA, NCAs and Industry

Tactics

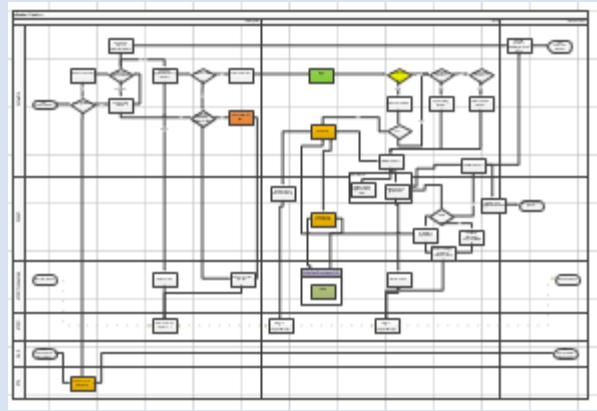
Develop a High level Business Process for Mid-2019 (with ROG)	Define Iteration 1 Data Elements to meet business cases	Create EU Implementation Guide suitable for all stakeholders	Identify, Assess and determine resolution for any technology gaps relating to Mid-2019 TOM	Design a migration plan for users, data and technology to be executed by mid-2019

High Level Business Process

Main Discussion Points

1. What is the mechanism for MAH to submit Iteration 1 Data Elements (including messaging standard)?
2. When are IDs generated, by whom and how?
3. How will PMS integrate into the Regulatory Activities e.g. Competent Authorities validating the information?

Note: High Level Business Process is based on output from Regulatory Optimisation Group (ROG)



Options to Submit Information

Option 1	Option 2	Option 3	Option 4
• Amend Application Data Set (created by CESSP) to capture all Iteration 1 data fields • data for NtAs extracted and displayed • data for XEVMPD extracted	• XEVMPD to capture all Iteration 1 Data Fields • Extract for NtA use Consensus on Ruling this option out as not viable	• Both Application Data Set (created by CESSP) and PMS files to be included in Dossier submission e.g. eCTD for Human Medicines	• PMS submission generating MPID • CESSP (with eAF included) allows for entry of MPID and data is retrieved from PMS where possible user fills in the rest

Notes:

- Technical Messaging Standards including XEVPRM, SPL R8 and the DES for eAF were also evaluated
- Options need to consider different contexts for Veterinary and Human Medicines

Iteration 1 Data Elements

- Iteration 1 Data Elements were discussed in context of overall goal and “minimum viable product” approach

- ROG identified Type 1A variations with highest volume to be addressed in Iteration 1

- 79 Fields of Iteration 1 Data Elements accepted and consensus agreed
- 4 additional Fields are in scope pending Type IA Variation agreement
- 12 additional Fields to realise full e-prescription implementation

- The following are agreed, but pending further analysis:

    - Package Description needs urgent impact analysis and deeper evaluation
      (e.g. text description vs data field to realize Phg use case and Article 57 migration)

EU Implementation Guide

Draft EU Implementation Guide First Review Round Completed

- 10 Respondents : All feedback was high quality and insightful

Overall Summary: Structure is generally fine, content is a strong start, some practical suggestions for improvement:

- Process and Procedural Related
- Linking to other Materials
- Readability and System Comments

Next steps

- Business Case for EMA Gate 2 approval to be determined against future options by 1st May
- Small scale Proof of Concept for Structured Product Labeling Feasibility Analysis for mid 2019 implementation based on High Level Business Process (Industry, NCAs, EMA) after EMA Gate 2
- Migration Plan for Users, Data and Technology to be defined as a priority
- Finalise Target Operating Model and High Level Business Process based on assumptions by 1st May
  - including Competent Authority Validation Approach integrated in Regulatory processes
  - Including eAF vs Iteration 1 Evaluation
  - Validating Type 1A Variation Approach for Regulatory process simplification (via ROG)
- PMS Implementation Plan
- Update EU Implementation Guide based on above outcomes