

Industry Points

SPOR Task Force

22 June 2018

Iteration 1 preparation for Industry

- In order for Industry to start data preparation what's needed is:
 - Final List of Iteration 1 fields
 - Confirmation of fields needed for Type 1A variations
 - Impact of Type 1A optimization on TOM
 - Business rules/requirements/validation rules for each field
 - Source to be used for each field – for example:
 - Module 3/part 2:
 - Substance and Substance Strength fields (Active, Adjuvant, Excipients)
 - SmPC
 - Full Product Name and Product Name Parts, indication text
 - MedDRA/SNOMED
 - Confirm source to be used for additional coded indication fields

Recommendation to support design of Legacy Data Cleansing and TOM Requirements

- Working through real-world scenarios will be very useful to ensure the models and processes which are being designed are robust
- Recommendation to hold a series of workshop meetings with a small group of industry, NCA and EMA participants to run a series of scenarios designed to test processes as designed and identify weaknesses, improvements, etc
- Data cleansing process
 - Need to understand how the data migration, enrichment, data resubmission, legacy data cleansing will all work together to make sure they don't overwrite each other, etc.
- TOM
 - Different procedures, types of changes to data, submission types, etc
 - How will this work through the TOM? 'Conference room pilot' style walkthroughs of scenarios

OMS use as master data in other processes

- Industry is continuing to have fundamental concerns with OMS that we think it is important to discuss
- We appreciate the formation of the OMS key user group and believe this will be a good forum to raise and address these
- Could EMA provide a brief status of its formation? When do you plan to share the ToR with this group?
- If the formation of the group is going to be delayed could we please have an opportunity to raise the critical items sooner