



24 February 2016
EMA/155769/2016
Information Management

Minutes of EU ISO IDMP Task Force meeting

19 February 2016, 09:00-17:00, co-chaired by Ilaria Del Seppia (EMA), Joris Kampmeijer (Netherlands), John Kiser (EFPIA)

Role	Name
Present	EUNDB: Jeffrey Martin (Sweden), Ly Rootslane (Estonia), Antonio Blazquez (Spain), Kevin Horan (Ireland), Aziz Diop (FR), Giovanni Ferretti (Italy), Georg Neuwirther (Austria), Hans-Joachim Bigalke (EDQM) NCAs Experts: Louise Petré-Linder (Sweden), Dubravka Sudić (Croatia), Triin Maesalu (Estonia), Philippe Durr (France), Jose Manuel Simarro (Spain), Fabio Macchiagodena (Italy) Swissmedic: Philipp Weyermann FDA: Vada Perkins EDQM: Christopher Jarvis AESGP: Andrew Thornley, Andreas Franken EGA: Remco Munnik, Kelly Hnat, Nora Weitbrecht, Vito Strasberger EFPIA: Neil Newman, Dave Wilson, Paul Mills, Joerg Stueben, John Kiser, Frits Stulp, Patrick Middag EuropaBio: Laurent Desqueper Vaccines Europe: Edouard Michoud, David Scanlon, Eveline Wyss EUCOPE: Megann Looker EBE: Gordon Topping, Herve Rique, Lobna Lyngby ECI-EEIG: Eeva Ryky Vendors/software providers: Andrew Marr, Christof Gessner, Gary Saner, Joel Finkle,



Role	Name
	Markus Pfahlert, Rune Ringsholm Bergendorff, Susan Metz, Ursula Tschorn, Wim Cypers EMA: Francisco Penaranda, Paolo Alcini, Ilaria Del Seppia, Agnieszka Laka, Isabel Chicharo, Kepa Amutxastegi, Panagiotis Telonis
Minutes	Malgorzata Durka-Grabowska

1. Welcome & announcements

The meeting was opened and participants were welcomed.

Task Force members greeted two new participants who joined the group: Georg Neuwirther, representing Austria, and Philipp Weyermann, who joined as an observer from Switzerland. It is also expected that veterinary NCA experts will join Task Force from next face-to-face meeting and following nomination at the EUTMB.

Adoption of draft agenda

Draft Agenda was adopted with one amendment: update on new Telematics governance model was removed as the proposed model is still subject pending HMA approval.

Francisco Penaranda informed that, due to the inclusion of veterinary area in the Task Force operations, the name of the group needs to be revised to reflect the change and will be converted to SPOR Task Force. It was also noted that the Terms of Reference document will require an adequate update.

Update from HMA meeting

Francisco briefed the Task Force about the discussion which took place at the HMA meeting in the Netherlands. He confirmed that implementation of SPOR was recognised as an important foundation for other programmes and as a key driver for this year. Significant dependencies between projects running in parallel were acknowledged (e.g. with Falsified Medicines). Special emphasis in 2016 will be placed on the implementation of R and O. The need to strengthen and improve the communication was also emphasised during HMA meeting and it was agreed that a contact person should be appointed per NCA as channel into and out of SPOR. Francisco invited NCAs and industry colleagues to collaborate and contribute to the communication plan prepared by the Agency regarding SPOR to ensure it reaches all concerned stakeholders.

John Kiser informed the group about industry and vendors meeting held on 18 February 2016 and confirmed that communication was also discussed as a topic of a high importance. Comprehensive information on SPOR implementation must reach all pharmaceutical industry, particularly those not participating directly in the Task Force meetings. The idea of creating and publishing industry briefing or concept paper, directly on or linked to the Agency's ISO IDMP webpage, was introduced. The aim is to simplify access to related information and documents, produced by different sources, by making it available via one central point.

ACTIONS:

- To investigate the possibility of linking industry briefing paper and other related documentation on ISO IDMP implementation to the Agency's ISO IDMP dedicated webpage.

Action owner: Agnieszka Laka

Re-confirmation of Task Force sub-groups composition

Low attendance and low contribution concerns in O and R sub-groups activities and teleconferences were reported. Taking into account significant importance of these two projects in 2016, the level of involvement in sub-group activities is expected to be very high to accommodate extensive workload. Therefore, the composition of each sub-group needs to be revisited to ensure that the group is composed by individuals with required skills and ability to actively contribute.

2. Referentials sub-group

Status update and next steps

Isabel Chicharo presented to the Task Force current status update on behalf of R sub-group and following extensive discussions at EUNDB level. Task Force was briefed about activities undertaken since last face-to-face meeting and, also, about upcoming actions, e.g. UAT and webinars dedicated for IT directors. It was also stated that the process of setting up and formalising the relationships with other business providers (WHO, MSSO) had started. Projects risks and difficulties, such as ongoing technical issues, limited resources, were noted. One particular project dependency was identified – with the Identity and Access Management (IAM) project (IAM project covers the area of registration and authorisation of users). Isabel stressed the importance of R sub-group monthly teleconferences. Taking into account wide range of actions and time constrains, active participation, immediate feedback and contribution is essentials to implement necessary requirements in timely manner. Task Force members were invited to take the lead on some R sub-group activities to be able to clearly express their vision, requirements and identify next actions. Isabel presented the outlines of high-level roll-out plan including the timelines, listing other projects with some interactions identified in Telematics Road Map. List of recommended actions for NCAs and Industry was also provided.

The importance of publishing agreed and endorsed information regarding implementation of next steps for RMS on the Agency's ISO IDMP webpage was highlighted by industry. Published communication needs to clearly indicate roles, responsibilities, and timelines. Specific need to provide guidance for the transition period where both systems, XEVMPD and RMS, will co-exist was highlighted. It was also stressed that communications designed for non-technical people should be prepared to ensure common understanding of new processes.

Isabel informed that for planned UAT it is intended to use focal points to collect feedback from participating testers. Focal points will communicate collated and consolidated comments to EMA. This pragmatic approach was decided to avoid delays in project implementation. Set of actions needs to be commenced to ensure smooth UAT process; including: preparation of testing methodology, testing plan and testing scripts. It was noted that testing period and testing strategy is very similar for O and R and will be open to as many testing parties as needed to assure best possible results covering all aspects. Based on the experience with Art.57 3rd acknowledgment testing, it is recommended for 20-25 vendors to perform UAT. Testing is open to vendors which are not part of the Task Force as long as comments are

submitted via nominated focal points. The importance of appropriate testing preparation was stressed. It was stated that introductory training is considered as necessary element before the testing starts for participants to understand the process.

Isabel presented the conclusions of the previous day for the Task Force. With regards to the data management process related to legacy terms, it was proposed that terms should be considered legacy if they were once used in a valid/approved medicinal product. If the terms are no longer deemed suitable for use they should be marked as non-current and the process should be consistent in all lists (EDQM/Bfarm owned). This is not currently the process in place with EDQM and EMA-EDQM need to reach an agreement on how to implement this and ensure that official Standard (ISO) Terms are not confused with these terms.

Regarding identifiers to be used in PMS several options were discussed and it was decided that S&P sub-group will continue the discussion and come back to the Task Force with feedback.

The proposals on the globally unique identifiers (OIDs) were contested such that RMS should not use a simple OID to the entire system and that the placing of the lists in the hierarchy was incorrect. It was agreed to schedule a dedicated TC to further discuss this and come back with a revised proposal.

ACTIONS:

- To share with R sub-group the data model to be applied by industry to consume R data.
Action owner: Neil Newman
- To provide Isabel with any projects which might be missing in R high level roll out plan and could be related to R implementation.
Action owner: All
- To engage EMA colleagues representing other projects led by the Agency where possible interlinking with RMS was identified.
Action owner: Isabel Chicharo
- To share backwards compatibility analyses outcome for the transition period (from Dec 2016 onwards) regarding registration of new term with Art.57 IWG.
Action owner: Ilaria Del Sepia & Isabel Chicharo
- To schedule joint R and O teleconference to prepare UAT testing; to explain approach, plan and methodology, prepare and review UAT scripts, agree on necessary training needed to understand testing process.
Action owner: Isabel Chicharo & Kepa Amutxastegi
- To coordinate nomination of focal points on behalf of industry associations with the option of appointing one focal point per each association represented at the Task Force by end of February 2016.
Action owner: John Kiser
- To coordinate nomination of two focal points on behalf of vendors represented at the Task Force by end of February 2016.
Action owner: Andrew Marr
- R data models to be shared with Task Force.
Action owner: Isabel Chicharo

- To lead discussion on the list of identifiers and OIDs in cooperation with Vada Perkins, Panagiotis Telonis and Nick Halsey and to lead topic oriented teleconference for all Task Force.
Action owner: John Kiser
- To consider strategy to move from free text (such as packaging) to CVs and report back to R sub-group.
Action owner: John Kiser and Andrew Maar on behalf of Industry/Vendors
- To reflect on integration of new lists which are currently not in XEVMPD (such as target species) and report back to R sub-group.
Action owner: Industry/Vendors
- To provide thoughts to R sub-group about management of R in the context of regulatory processes.
Action owner: John Kiser on behalf of Industry
- R sub-group to check GiNAS and OMS lists.
Action owner: R sub-group

R sub-group membership review

In order to rationalise future discussions with full Task Force regarding R related subjects, the membership of R sub-group requires to be reviewed so more topics can be closed at the sub-group level. There is a necessity to identify colleagues who wish to take the lead on some subjects and actively contribute to the work in sub-group to bring in industry perspective and requirements. NCAs, industry and vendors were invited to nominate additional experts. It was confirmed that sub-group specialists can be appointed even though they are not (and will not be) member of the Task Force thus will not participate in Task Force meetings.

ACTIONS:

- To briefly outline and share with Task Force the profile of experts to be recruited for R sub-group.
Action owner: Isabel Chicharo
- To coordinate the nomination of additional experts for R sub-group from industry and vendors by 2nd March 2016.
Action owner: John Kiser
- To transfer R sub-group membership from Jennifer Lynch to Kevin Horan.
Action owner: Isabel Chicharo

3. Organisations sub-group

Status update and next steps

Kepa Amutxastegi presented Organisation status update and roll-out plan. Task Force was informed about activities undertaken since last face to face meeting and about upcoming actions. Kepa confirmed that the dictionary with initial content (all Marketing Authorisation Holders for nationally and centrally authorised products) will be available for stakeholders in November along with functioning service desk to deal with received registration requests. The data placed in the dictionary will not be confidential and will be

available publicly as it will contain minimum information on specific organisations. Duplicate detection activity will be processed by standard data management tool. Organisations hierarchical structure and relationships will not be managed in the initial phase; however, operating model and technical solution allows implementing this at the later stage. Regarding creation and records update, it was confirmed that all registered and authorised users for specific organisation can initiate such request. Dictionary content will be expanded incrementally as part of maintenance.

The Phase I operating model was supported by Task Force and, according to Telematics Governance, will be next presented to the IT Directors for adoption.

It was also stated that XEVMPD will be used as data source for O in the initial phase therefore it is important to ensure that all entries are complete. A mapping of own data against xEVMPD to identify missing products will allow us to have more complete xEVMPD and accordingly more complete dictionary by the time we go live in November. The detailed process to ensure MAHs/NCAs have access to xEVMPD data and missing products are submitted to Art.57 will be discussed and decided within the sub-group. David Scanlon updated the group on the UAT approach and areas to test for OMS. The aim of testing is to robustly and fully examine the system. It was noted that selected method is similar to RMS UAT process. Test plan and methodology will be further discussed and shaped at joint R and O teleconference. It was noted that testing period falls during summer, however, the duration was extended (July and August) to ensure availability of testing parties. Appointment of official testers or contacts for the UATs was proposed. They will act as the coordinators to ensure additional testers appointed within their own stakeholder groups are appropriately trained on the UAT process, and all UAT feedback is collated and provided to EMA as one report. Feedback reports are envisaged to be created in Excel format.

ACTIONS:

- To coordinate the nomination of focal points and testers for UAT applying the same approach as for RMS.
Action owner: David Scanlon and Remco Munnik

O Sub-group membership review

To strengthen the collaboration and ensure timely progress with all scheduled activities for OMS implementation following colleagues will join O sub-group:

- Paul Mills
- Aziz Diop
- Andrea Johnson
- Birgitta Lohschelder-Käfer (expert nominated by Thomas Balzer)

4. Substance and Products sub-group

Status update and next steps

Gordon Topping presented, on behalf of the S&P, an update on the latest developments of the work progress on the EU Implementation Guide (EU IG) framework creation. It was noted that starting point for EU IG creation was the review of Art.57 guidance content, user guide and training materials. As the

outcome of these analyses, it was stated that EU IG should be created as a modular set of components (documents) to simplify the navigation and browsing. Process on how the future versions of the EU IG will be managed still needs to be established. It was recommended that EU IG should cover all SPOR components in a modular consistent format. Consequently, EU IG creation will require input from all sub-teams for completeness and accuracy. It is planned to build EU IG with two parts. A first part should be process oriented with the targeted audience being the business users. A second should be a detailed, technical specification for IT audience. It was stated that business process details, needed as necessary input into the guidance content, still need to be defined. Presented IDMP process impact diagram is the outcome of initial discussions and is considered to be a working draft.

Andrew Marr informed the meeting about an analyses aimed at identifying which sections of the ISO Medicinal Product standards are mature to commence the drafting of the EU IG relevant part for PMS Iteration 1 (i.e. so-called stability analysis). All Iteration 1 data elements were analysed based on the comments received by the ISO ballot and classified according to sections that are less stable (i.e. defined *at risk* of being changed in the next released version of the document) and sections safe to progress with further work. It was noted that the number of potential issues will be reduced with time due to upcoming ISO teleconferences and standards re-drafting.

Next step for the S&P sub-group is to further develop the EU IG. This action requires progress in two main aspects: 1. data content and format consolidation; 2. identification and definition of submission processes for entire SPOR.

ACTIONS:

- To discuss with Telematics office the need to escalate potential IDMP process impacts on different programmes and projects which are going beyond remit of Task Force.
Action owner: Francisco Penaranda
- To commence drafting R and O parts of EU IG based on the requirements provided by R and O sub-groups.
Action owner: S&P sub-group

PMS Iteration 1 scope

Ilaria Del Seppia reported to Task Force the outcome of data categorisation exercise. This exercise involved some NCAs represented at EUNDB and EMA. 92 data elements, proposed for Iteration 1, were mapped in terms of value and effort. The results from NCAs were averaged in a single value per data element and compared with EMA results. The outcome of these analyses suggested to amend the number of elements for PMS Iteration 1: i.e. around 20 data elements were removed/streamlined/re-modelled and 5 data elements were included to cover additional business cases. Total of 79 data elements in PMS Iteration 1 was recommended by EUNDB. After the discussion, the Task Force supported the implementation of this amended data model with 79 elements but it was noted that more information and analysis are required to be defined to ensure comprehensive understanding and to clarify which of these data elements are going to be mandatory and under which conditions. All these aspects, as well as related business rules will be described in the EU Implementation Guides.

It was also clarified that the full timelines for the implementation of PMS Iteration 1 and 2 will be soon released and updated in the EMA ISO IDMP webpage and that PMS iteration 2 (investigational products)

has been shifted and will not be implemented at the same time of PMS iteration 1.

ACTIONS:

- To share with Task Force detailed analyses from the data categorisation exercise.
Action owner: Ilaria Del Seppia
- To investigate possible relationships with lists created within epSOS and Expand projects.
Action owner: Paolo Alcini
- To include updated graph on high level SPOR implementation plan in TF meeting minutes.
Action owner: Agnieszka Laka (see end of this document)

5. Communication strategy

Agnieszka Laka presented current SPOR communication plan to Task Force. The proposal was built taking into account feedback from external and internal stakeholders. Communication schedule is aligned with SPOR phased approach and, consequently, majority of communication and change management activities in 2016 will be focused on R and O. Task Force was informed about steps already taken by communication team, e.g. preparation of high level plan and production of initial stakeholder list. In order to better deliver communication, industry and NCAs colleagues were requested to appoint primary contact points. This proposal was presented to HMA and it was decided that each NCA will assign one person to serve as primary contact point for the Agency. Task Force industry representatives decided to appoint David Scanlon as single communication contact point with a possibility to nominate additional person as a back-up.

It was also noted that the plan is to use different communication channels to enable stakeholders to prepare for the change more effectively. EMA public website will be used more often for SPOR updates and publication of additional documents. Moreover, the use of additional communication channels is being currently explored. Next steps for the Communication team are to finalise the details of the communication plan and communication materials.

ACTIONS:

- To check EMA policy on external publications/communications and media co-operation and investigate if these channels could be used as additional source of communication.
Action owner: Ilaria Del Seppia

6. Falsified Medicines status update

Paul Mills updated Task Force on Falsified Medicines Directive and European Medicines Verification System (EMVS). Delegated Regulation was published on the Official Journal on 9 February 2016. Consequently, for those involved with medicines verification, it means the clock started ticking the three year time implementation period. Paul highlighted responsibilities of different stakeholders with regards to Falsified Medicines (industry, pharmacists, wholesale and NCAs) and gave update on current status of EMVS. It was recommended to integrate EMVS with IDMP in particular with master product data and organisational data.

ACTIONS:

- To lead further discussion on FMD via dedicated teleconference.
Action owner: Paul Mills/Paolo Alcini
- To coordinate nomination of additional industry colleagues who wishes to join the FMD discussion
Action owner: John Kiser

7. Report on International Activities

SPL update from US

Vada Perkins briefed the group about HL7 SPL(R7) publication and Common Product Model. He also informed about the outcome of mapping exercise: IDMP data elements which will be implemented in the EU where mapped against FDA data for O and R. It was noted that all multinational companies, located in the US, already submit structured information on organisation, usually on annual basis. It was confirmed that majority of the 79 data elements identified for PMS Iteration 1 are already structured in SPL. FDA aims to utilise the same terminology with regards to SPOR to ensure global harmonisation.

International activities status update HL7/ ISO

Report on international activities progress within HL7 and ISO was postponed. Panagiotis Telonis presented a demo on technical specification and modelling which are currently being prepared following HL7 and ISO discussions and decisions. This solution was considered a key set of documents to constitute the second part of the EU IG (i.e. the more technical IT oriented).

ACTIONS:

- In the context of S&P sub-group, to explore possible synergies between models being prepared by industry and EMA in order to avoid duplication of efforts.
Action owner: Panagiotis Telonis

8. Wrap up of the meeting

Review of actions log

It was decided that actions log will be reviewed and updated during monthly co-chair teleconference. Updated file will subsequently be circulated to Task Force members.

ACTIONS:

- To review and update actions log.
Action owner: EU ISO IDMP TF co-chairs

9. A.O.B.

2016 meetings: duration and schedule

Provisional EUNDB and Task Force meeting schedule for 2016 is:

- 30 June, 1 July
- 12, 13, 14 December

It is expected that duration of the Task Force meetings will be extended. The length of each meeting will be confirmed closer to the date depending on the agenda.

Dates previously announced for November are no longer valid due to clash with ISO Plenary.

ACTIONS:

- To review the governance of Task Force including membership and remote participation.
Action owner: EU ISO IDMP TF co-chairs

Post meeting note

As per action recorded under agenda point 4, graph on high level SPOR implementation plan is attached below.

Overall high level plan for SPOR

