2 October 2015
EMA/645750/2015
Information Management

Minutes of EU ISO IDMP Task Force meeting

25 September 2015, 10:00-16:00, co-chaired by Ilaria Del Seppia (EMA), Joris Kampmeijer (Netherlands), John Kiser (EFPIA)

Role	Name
Present	EUNDB: Joris Kampmeijer (Netherlands), Thomas Balzer (Germany), Jeffrey Martin (Sweden), Ly Rootslane (Estonia), Antonio Blazquez (Spain), Kevin Horan (Ireland) NCAs Experts: Anja van Haren (Netherlands), Louise Petré-Linder (Sweden), Dubravka Sudić (Croatia), Giovanni Ferretti (Italy), Triin Maesalu (Estonia), Philippe Durr (France), Jose Manuel Simarro (Spain), Catherine Russell (UK) EDQM: Christopher Jarivs AESGP: Christoph Kox, Andrew Thornley, Andreas Franken EGA: Remco Munnik, Kelly Hnat, Anjana Pindoria, Vito Strasberger EFPIA: John Kiser, Neil Newman, Paul Mills EuropaBio: Claus Lyng Nielsen, Amy Williams, Laurent Desqueper Vaccines Europe: Edouard Michoud, David Scanlon, Eveline Wyss EUCOPE: Matthias Wilken, Maren von Fritschen, Dot Bruce EBE: Gordon Topping, Herve Rique ECI-EEIG: Eeva Ryky Vendors/software providers: Andrew Marr, Barry Hammond, Christof Gessner, Markus Pfahlert, Rune Ringsholm Bergendorff, Susan Metz, Ursula Tschorn, Wim Cypers, Malin Jakobsson EMA: Alexis Nolte, Francisco Penaranda, Paolo Alcini, Ilaria Del Seppia, Isabel Chicharo, Kepa Amutxastegi, Panagiotis Telonis, Herman Diederik, Mihaela Savastre,

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Role	Name
	David Livolsi
Joined via TC	Marta Terron Cuadrado (EC) Christine Haas (Germany) Lobna Lyngby (EBE) Vendors/software providers: Catherine Kessler on behalf of Joel Finkle, Gary Saner, Bob Allkin
Minutes	Malgorzata Durka-Grabowska

1. Welcome & announcements

The meeting was opened and participants were welcomed.

Adoption of draft agenda

Draft Agenda was adopted without amendment.

Update from EMA

Alexis Nolte, Head of Information Management at EMA, joined the Task Force meeting to present the general, high level plan for SPOR implementation prepared by the Agency. Alexis emphasised the importance of the ISO IDMP project for the harmonised implementation of the standards across the EU and acknowledged the challenging milestones, still to be achieved, including the legal deadline. The overall plan for SPOR implementation was prepared reflecting the phased approach that consists of a preparation phase, a transition phase and a maintenance phase.
The need for clear and regular communication was stressed by John Kiser as an essential factor to help all industry, specifically those who are not present at the Task Force, so that they can keep track of the project's plan and progress. Alexis confirmed that all communication will continue via existing channels. He also referred to the Telematics Road Map. This document lists all Agency's programmes and provides clear overview to the interested stakeholders.


Agenda item 1 EMA Update.pdf

Update from Industry

John Kiser presented an industry perspective to the Task Force. The dependencies between ISO IDMP and overall EU Telematics strategy/programmes were analysed by industry and they have identified some potential gaps. As an example, lack of knowledge about IDMP requirements driven by E2B(R3) was mentioned, along with Falsified Medicine and the need to link iteration 3 with eLabeling activities. It was

also stated that it will be highly beneficial if a clear roadmap across EU Telematics strategy including IDMP beyond 2017 was jointly developed. John confirmed that industry is willing to actively participate in all stages of planning, testing and implementation of SPOR, to clearly understand projects and budget dependencies and to establish well-defined process for the submission and maintenance of common data. Ilaria Del Seppia re-confirmed that industry is welcome to contribute to progressing the work via sub-groups and, if needed, the sub-groups membership can be further supplemented. Members will be nominated from the Task Force and preferably, those with knowledge of existing Art.57 requirements will be selected to ensure improvements/optimisation from the current practices. It is important that the sub-groups work efficiently so that they can progress quickly with the assigned tasks to achieve the project milestones. Therefore, taking into account time constraints and the workload, only colleagues who can actively participate and contribute towards the work should consider this assignment. The size of the sub-group was also noted as significant factor; these are the operational groups and the size should be limited.

Ilaria also informed the task force about the data pilot of 92 data elements proposed to be falling within the PMS iteration 1 scope. The data pilot aims for testing data and scenarios with an active participation from industry. Furthermore, during the consultation period of the EU ISO IDMP Implementation Guide (EU ISO IDMP IG), engagement from the whole of the regulatory network is considered as a critical and valuable factor. The first draft of the EU ISO IDMP IG is to be prepared by the S&P sub-group and is expected to be ready for public consultation by Q1 2016. The broader Task Force group will be involved in the final review of the document to make sure all stakeholders are in agreement/alignment. The dependencies between the above document and the ISO Implementation Guides (ISO IGs) were acknowledged. It was noted that the ISO IGs could be a subject of further delay as numerous comments were received on the draft documents and some voting countries rejected the guides in full. It was decided to continue working on the EU ISO IDMP IG for iteration 1 and to then assess the implications from the outcome of the next ISO plenary meeting in November at a later stage.

Agenda item 1
Industry update.pdf

ACTIONS:

- Concerns raised by industry will be addressed by the EU ISO IDMP co-chairs after consulting the EUNDB.
  Action owner: EU ISO IDMP co-chairs
- Request for industry's input into Telematics strategy going beyond 2017 will be raised at the next EU TMB.
  Action owner: EU ISO IDMP co-chairs
- Members of the EU ISO IDMP Task Force that are also contributing to the work within the ISO WG6, to come up with possible options on how to resolve the comments in the ISO arena ensuring high quality documents agreed upon in a timely manner with the EU ISO IDMP Task Force planning in mind.
  Action owner: All

- EU IDMP IG work to commence, plan to be drafted with the proviso that it may need modification based on the outcome from ISO.
  Action owner: S&P sub-group
- Plan for the migration of Art.57 data into IDMP iteration 1 to be developed including the required steps to be outlined.
  Action owner: S&P sub-group
- Workshop on the standard to be held before the next ISO meeting to review the 92 data elements and to ensure that comments are addressed or way forward on how to address them is defined.
  Action owner: S&P sub-group/Ilaria Del Seppia

2. Report on International activities

HL7/ISO

The update on international projects of HL7 and ISO was presented by Panagiotis Telonis and Paolo Alcini. The timelines and the status of each project were reported to the group. The group noted that HL7 implications to the ISO format are important in order to identify and ensure harmonisation of process between all the regions. Panagiotis informed the group that the ISO IDMP Technical Specifications are describing data exchange considering the content requirements while the work in HL7 describes the use of the HL7 Common Product Model and HL7 SPL as the data exchange format to support the ISO IDMP Technical Specifications. He also stated that HL7 processes are more agile and flexible and the HL7 models (and the subsequent published schemas) allow for adoption of the ISO standards and their adaptation to jurisdictional implementations. Training and knowledge sharing is also expected as there is not enough expertise in this area.
It was noted that the next HL7 WG meeting will be held in October 2015 in Atlanta. Particularly for IDMP and, as a follow up of the last out-of-cycle ballot that took place during June-July 2015, it is expected that all typos/editorial comments and small model corrections will be addressed as per ballot resolution calls during HL7 RCRIM & O&O WG teleconferences. Finally, the next step is to have all material corrected and ready for the next ballot and for publication of the HL7 messaging specification.
Limited knowledge and lack of experience with HL7 and SPL across NCAs and industry along with the need to develop it was acknowledged. The requirement of training to bring everyone to the same level of understanding was highlighted and it was stated that EMA is aiming to provide such training.


Agenda item 2
Update on Internatio

GInAS meeting

Paolo Alcini briefed the Task Force about the last GInAS meeting held in September 2015. During the meeting it was re-confirmed that EMA is fully committed to use G-SRS software[1]. Paolo gave also update

[1] The Global Substance Registration System (G-SRS) concept is related to: a) the development and distribution of a single, unique identifier for every substance in medicinal products and clinical trials between the regions, b) freely distribute an information system (open source software) capable of supporting the implementation of a global public repository for

on GInAS data model and data migration. It was stated that the aim of GInAS operating model is to have one common model, shared across the EU and US. Paolo identified as future challenges the need to incorporate additional EU requirements and the need to have FDA requirements fully documented. It was also noted that in order to allocate the necessary budget and human resources, a joint software maintenance and governance model between EU and US is necessary.
Global substance identification was also discussed as one of the areas of key importance. Joris reminded the group that the approach on substances was agreed during Task Force meeting in June 2015 and one set of identifiers, one software and one common model were agreed. Joris suggested that EMA should consider splitting the S&P sub-group into two smaller groups. Colleagues involved in S&P sub-group noted many dependencies within S and P projects and suggested to keep the management of both groups centrally.

ACTIONS:

- S&P to explore the possibility of re-organising the sub-group into two separate workstreams managed by Ilaria.
  Action owner: S&P sub-group
- Industry and NCAs are requested to provide additional S and P experts to advance the work of the S and P workstreams.
  Action owner: All
- Connection between IDMP and the FMD (EU Falsified Medicines) requirements to be explored and recommendations to be explored.
  Action owner: John Kiser/Industry
- Workshop/information to be provided on HL7 to both industry and regulators.
  Action owner: EMA

Agenda item 2 GInAS Highlights.pdf

3. Substance & Products

Report from sub-group

Amy Williams presented S&P report on behalf of the sub-group. The major focus of the sub-group is currently on PMS iteration 1 in order to determine the mandatory and optional data elements falling into the scope of iteration 1. Sub-group is also managing the risk and issue log to capture all concerns raised during its work. Proposed data scope of PMS iteration 1 containing 92 data elements was presented to the group. It was also stated that the S&P sub-group has planned to perform data pilot for testing products and scenarios against PMS iteration 1. The importance of this testing was emphasised; examples used for the testing should cover a wide range of possible scenarios.
Amy also noted that it is intended to consult the EUNDB on the implementation of the target operating

definitional, regulatory and scientific information on substances and content as applicable, c) facilitate harmonization registration that is compliant with ISO 11238 and regional practices. Not to be confused with the GInAS consortium.

model.
It was stated that minimum set of data fields for indications will be a part of iteration 1. The coding system will be MedDRA, as required by the legislation.

ACTIONS:

- Proposed 92 data elements for PMS iteration 1 to be shared to the Task Force.
  Action owner: Ilaria Del Seppia
- Determine the best way to share the documents outside of the EMA file sharing solution.
  Action owner: Thomas Balzer
- Proposed data scope slide of PMS iteration 1 to be amended with PhPID and MAH fields.
  Action owner: S&P sub-group


Agenda item 3
S&P_Reports from su

4. Referentials

Report from sub-group

Isabel Chicharo and Christopher Jarvis presented a report on behalf of the Referentials sub-group. The Task Force was briefed on work progress and on discussions held within the sub-group. Main workstream was focused on planning the phased implementation for R, also on the routes of administration, pharmaceutical forms, packaging and on units of measurement.
It was noted that BfArM proposed to become maintaining organisation (see next section) for the UCUM list (ISO 11240). This proposal needs to be further analysed and decision on appointing the maintenance organisation needs to be taken.
Specifically challenging was a discussion on term and change request confidentiality. It was also noted that some lists could be classified as more sensitive than others.
Conceptual and logical data model was also discussed within sub-group; however, the messaging data model is still to be discussed. Another item with an ongoing discussion is the mapping guidance. Clear direction on terms selection for mapping, and also on the process for mapping the local terms versus reference terms is required.
Isabel reflected on the dependencies of the work of other sub-groups. The S&P sub-group identified 92 elements for products but needs to clarify which of those are CVs and, if so, what CVs are required and whether it is already in EUTCT. She also pointed out that some of the 92 data elements may have been implemented in the past as free text and will now become CVs e.g. the packaging details.

With regards to substances, the sub-group still needs to identify the data elements and consequently their CVs. An earlier presentation pointed out that the G-SRS system contained 58 CVs but analysis is still required to find out which ones are already in use in the EU.

ACTIONS:

- Representatives of software suppliers to join R sub-group.
  Action owner: Andrew Marr
- Set up an action plan for rollout of Referentials (systems, NCA, industry).
  Action owner: R sub-group
- RMS implementing process to be described and shared.
  Action owner: R sub-group
- S&P data pilot to report to R sub-group of any findings as regard confidentiality of certain CVs and their terms as well as the CV for packing details.
  Action owner: S&P sub-group

Agenda item 4
R_Reports from subg

UCUM

Thomas Balzer briefed the Task Force on the proposal for BfArM to act as the maintenance organisation for Unified Code for Units of Measure within Europe. This would be provided as a service through RMS. The scope of this activity is related to the implementation, maintenance, and application of the UCUM ISO IDMP standards. It was noted that this proposal requires further, detailed definition and would need to be endorsed by the EU TMB.

ACTIONS:

- Service level agreement and process to be defined and agreed.
  Action owner: Isabel Chicharo/Thomas Balzer

Agenda item 4
UCUM.pdf

5. Organisations

Report from sub-group

Kepa Amutxastegi and David Scanlon presented the report from Organisations sub-group. Kepa thanked all sub-group members for intense and fruitful discussions during last 6 weeks. It was highlighted, that despite difficulties, progress is being made and the agreement on major principles has been achieved. Many of the discussions have already produced outcomes which have been transformed into requirements for the Organisations project. The Task Force was informed about the development work for the logical data model. As a part of this data model, support for multi-level organisation classification was discussed.

The sub-group agreed with supporting organisation data in 'English' only; however, the address will be accepted and stored in local language too. It was stated that, in principle, only Latin characters should be used for the terminology but additional language characters used in the EU languages will also be supported with the exception of Cyrillic and Greek characters.
The need across the network to have unique EU ORG ID was re-confirmed and the O sub-group is currently working to establish business rules and criteria on the following processes: issuing new EU ORG IDs and updating existing EU ORG IDs as new versions. The Task Force enquired about the approach towards organisations which are placed in multi-lingual countries and, consequently, have got multi-lingual names. Kepa ensured that specific matching rules will be defined and tested to guarantee that this scenario, along with all other business scenarios, is covered.
The Task Force was also briefed about the user management and the plan to introduce the Super/Administrative User role. Super User will be validated by EMA and will assign access for other users associated to the same organisation to send requests to register/update organisations data.


Agenda item 5
O_Reports from subg

6. Plan for next activities

Communication strategy

David Livolsi (EMA) presented the Communications Strategy for the SPOR programme. Communication channels include a quarterly newsletter, supplemented by targeted communications relating to key activities and milestones across the programme. A communication plan will be developed and distributed to the stakeholders in line with the overall programme plan. Sub-group members would be involved in producing the content for these.
The ISO IDMP webpage will be used to make stakeholders aware of planned communications events, as well as to publish content. Industry representatives raised the issue that not all industry stakeholders would be looking at this page, so it was agreed to also ask NCAs to use their own websites to inform their own stakeholders about the EMA page. Industry representatives also emphasised the importance of communications for the success of the programme. It was agreed that members of the wider Task Force should be used to review communications content.
It was confirmed that the EC acknowledged the explanations provided by EMA and supported the plan of a phased implementation proposed by the EU ISO IDMP Task Force. It was agreed to communicate this information on the EMA website.

ACTIONS:

- Develop a milestone plan with the critical path and present to EU TMB. EUNDB and EU ISO IDMP Task Force to be consulted.
  Action owner: EMA
- Publish the communication plan on the EMA website.
  Action owner: EMA

- NCAs to investigate if the link to the EU ISO IDMP webpage could be placed on their websites to assure wider communication.
  Action owner: NCAs represented at EUNDB
- Update the EU ISO IDMP webpage and to announce separate news item to inform all stakeholders about the agreement of EMA, NCAs in EUDNB and EC on the phased implementation of ISO IDMP and SPOR with a start from July 2016 onwards.
  Action owner: EMA


Agenda item 6
Communications Strat

7. Review of actions log

Actions log was reviewed and table was updated accordingly.


EU ISO IDMP TF
Actions Log.pdf

8. A.O.B.

EU ISO IDMP Task Force - Meeting frequency

It was suggested that, in order to progress with effective and pragmatic discussions, main focus should be placed on sub-groups meetings and activities. It was therefore recommended to reduce number of the EU ISO IDMP Task Force face to face meetings from 2016 on and to progress with two meetings per year only. John Kiser commented that meeting up together as whole group is highly beneficial and he suggested looking at the timelines and deliverables for 2016 to determine when it would be most appropriate and effective to have the entire group meet. However, in light of the fact that the timelines are not available at this point, three meetings for next year were advised. It allows better, wider communication and ensures regular status report and material sharing with entire Task Force. Industry also commented that, with reduced face to face meetings, communication within the EMA Task Force needs to be improved in between these meetings, in particular to those Task Force members not included in the sub-groups. Also, communication across the sub-groups needs to be very effective to ensure alignment; this was partially accomplished via the face to face meetings. Industry representatives suggested to EMA sharing meeting preparation efforts between all Task Force members and offered the possibility to host some of the future meetings. Moreover, possibility of organising additional Task Force meetings as teleconferences was proposed.

ACTIONS:

- To further discuss frequency of the face to face meetings and to communicate the outcome to the group.
  Action owner: EU ISO IDMP Task Force co-chairs

EU ISO IDMP Task Force – participation via teleconference

The Task Force co-chairs agreed between them that the option of participation via phone in the face to face meetings should be closed. This is to ensure that only authorised and nominated participants have got access to the meeting. It was also noticed that all meeting documents and meeting outcome recorded in minutes are published at the Agency's ISO IDMP dedicated webpage. As some concerns were raised by industry and vendors, co-chairs decided to take this subject for off-line discussion and communicate definite outcome to the group in due course. Industry commented that on-line webinar option allows the meeting organiser to see who has dialled in and to "reject" participants if needed. This technology could be used to organise future teleconferences for the Task Force group.

ACTIONS:

- To follow up on discussion about the closure of participation via teleconference at face to face meetings and communicate the decision to all members.
  Action owner: EU ISO IDMP Task Force co-chairs

Next meeting date

The question was raised about next Task Force face to face meeting. EMA representatives informed that the meeting is currently scheduled on 27 November 2015 (subject to further confirmation).

POST MEETING NOTE:

During the Task Force meeting in June 2015, 24 November was communicated as a potential meeting date. As stated in the previous meeting minutes, all meetings dates are subject to further confirmation, usually send via email.