15 June 2015
EMA/236653/2015
Information Management

Minutes of EU ISO IDMP Task Force meeting

31 March 2015, 09:30-17:30, chaired by Francisco Penaranda

Present	EUNDB: Thomas Balzer (Germany), Fabio Macchiagodena (Italy), Joris Kampmeijer (Netherlands), Kevin Horan (Ireland), Darko Krnić (Croatia), Ly Rootslane (Estonia), Marta Terron Cuadrado (European Commission) NCAs experts: Herman Diederik (Netherlands), Anna Eriksson (Sweden), Dubravka Sudić (Croatia), Giovanni Ferretti (Italy), Triin Maesalu (Estonia), Jennifer Lynch (Ireland) AESGP: Christoph Kox, Andrew Thornley EGA: Remco Munnik, Kelly Hnat , Anjana Pindoria, Vito Strasberger EFPIA: Neil Newman, John Kiser, Paul Mills EuropaBio: Amy Williams, Laurent Desqueper ECI-EEIG: Eeva Ryky Vaccines Europe: Edouard Michoud, David Scanlon, Eveline Wyss EUCOPE: David Huggins EBE: Lobna Lyngby, Herve Rique, Gordon Topping Vendors/software providers: Andrew Marr EMA: Francisco Penaranda, Paolo Alcini, Ilaria Del Seppia, Isabel Chicharo, Kepa Amutxastegi, Marek Lehmann, Adam Stiling, Panagiotis Telonis, Rik Smithies
Joined via TC	EDQM: Hans-Joachim Bigalke EuropaBio: Claus Lyng Nielsen EGA: Katarina Nedog Vendors/software providers: Barry Hammond, Patrick Revelle, Wim Cypers, Ursula Tschorn, Gary Saner, Katja Koesterke-Wagner on behalf of Joel Finkle, Susan Metz, Rune Ringsholm Bergendorff
Minutes	Malgorzata Durka-Grabowska

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1. Welcome and adoption of draft agenda

The meeting was opened and participants were welcomed by Francisco Penaranda, Head of Business Data & Analytics department. Francisco highlighted the great importance of this Task Force group for harmonised implementation of the ISO IDMP standards across the EU. He also explained that the new nomination system applied within this group is to ensure transparency and to involve a wide range of interested stakeholders. Francisco commented on the size of the group c60 participants noting the intention that smaller, topic focussed working groups would be formed.

The draft agenda was adopted without amendments.

2. EU ISO IDMP Task Force: Terms of reference

The terms of reference document for the Task Force for implementation of International Standards on Identification of Medicinal Products in the EU (i.e. EU ISO IDMP Task Force) was circulated prior to the meeting and was also extensively revised during the discussion. Francisco stressed that the role of the Task Force is to provide recommendations and advice.

It was agreed that decisions will be taken by consensus, no voting is foreseen. Different opinions, if any, will be reflected in the meeting minutes.

The following changes will be applied:

- Section 2 – Membership: number of EUNDB experts will change from 8 to 10.
- Section 2 – Membership: number of additional EU Regulatory Network participants will change from 20 to 22.
- Section 2 – Membership: up to 24 places are allocated to representatives of industry associations with a maximum of 3 experts per association. A note will be added to clarify that "Should the available 3 places not be taken by the individual associations, the remaining places can be re-allocated to other associations. However the maximum number of representatives nominated by Industry Association is fixed to 24 members".
- Section 3 – Modus Operandi: will be supplemented with the following paragraph relating to formation of sub-groups. "In order to ensure efficient progress in specific topic areas, smaller working groups comprising dedicated topic experts will be created. These sub-groups will present findings/recommendations back to the full group for review".
- Section 4 – Mandate: the EU ISO IDMP Task Force objectives:
  - point 1 will be amended as follows: "Recommendation on the best practice on the EU operating model and EU data governance for the registration and maintenance of substance and medicinal product information in the EU";
  - point 3.1 will be amended as follows: "Contribution to and endorsement of the gap analysis of Article 57 format (i.e. xEVPRM) vs ISO IDMP";
  - point 3.2 will be amended as follows: "Contribution to and endorsement of the data submission and maintenance business processes based on the agreed EU operating model and data governance";

  - point 3.3 will be amended as follows: "Contribution to and endorsement of the business processes to enrich the additionally required data."
  - point 6 will be amended to reflect the importance of communication with regulators outside of the EU.

- Section 4.1 - Governance Model will be adapted to include all five Agency programmes to present the wider governance framework. Groups included in the governance model should also be supplemented with the links to the corresponding webpages to help with full understanding of their roles and responsibilities. This will also facilitate alignment of related business processes and models.

Key points in discussions on this topic:

- It was requested that deliverable dates be added to the ToR activities:
  Dates are included in the EMA Road Map and will be included in the EU ISO IDMP Road Map, the ToR should be focused on the Modus Operandi of this Task Force and not an implementation schedule.
- The importance of collaboration with regulators outside of the EU was stated by multiple participants and was requested to be included in the ToR:
  The ToR will be updated to reflect this. Francisco also advised the group of the on-going FDA-EMA bi-lateral discussions relating to the IDMP standards and informed the group that the FDA may also participate in some specific discussions held within this group to facilitate harmonisation.
- The relationship between the Data Integration programme and other Agency programmes (such as Pharmacovigilance) was questioned – especially in relation to the governance model. How will decisions taken by the Task Force influence these other programmes to ensure a coordinated approach is taken to the adoption of IDMP:
  Ilaria overviewed the projects within the Pharmacovigilance programme and Francisco advised that within the EMA there is coordination across the programmes both directly between each programme's projects and through the broader governance structures that are in place. The Road Map for master data within the Agency has been developed in consultation with the other programmes (Pharmacovigilance, Clinical Trials, E-Collaboration and On-line).
- A decision was taken that the ISO IDMP Task Force agrees on proposal by consensus. The recommendations delivered by this group have to be finally adopted by the EU Telematics management board (EUTMB).
- The definition of the precise scope of what "IDMP compliance" means was raised (specifically in respect of NCAs):
  It was generally agreed that IDMP compliance will be beneficial but that clarification on exactly what this means is required (see actions).

Actions:

- Task Force members to send additional comments on ToR within 2 weeks. It is planned to formally endorse the document at the next Task Force face to face meeting in June. Subsequently, the ToR will be submitted to the EUTMB for adoption.
- Task Force members to provide EMA with suggestions on how to re-phrase Section 4 point 6 (Mandate) to highlight the importance of global harmonisation.

- EMA to revise the governance model image to reflect the dual nature of the Task Force operating in both strategic and operational capacities.

- EC to respond/investigate the rational and extent of compliance required by the EMA and NCAs regarding IDMP implementation by July 2016 and consequences should this not be achievable.

EU ISO IDMP Task Force: Nomination of co-chairs

The co-chairmanship was decided as follows:

- EMA co-chair: Ilaria Del Seppia
- NCA co-chair: Joris Kampmeijer
- Industry co-chair: John Kiser

Francisco stressed that the co-chairs would have to cooperate to prepare meeting documents in a timely manner (supporting documents should be ready 4 weeks prior to the meeting where possible), to agree the draft agenda and meetings schedule. The minutes and presentations of the ISO IDMP Task Force will be published on the EMA corporate website to ensure full transparency. Also, the names of the EU ISO IDMP Task Force members will be included in the meeting minutes. Secretarial support to this meeting will be provided by the Agency, including meeting schedule communication, logistical arrangements, agenda and supporting documents circulation, recording of actions and minutes. The group agreed with the above approach.

3. Industry perspective - business case for ISO IDMP, expectations, concerns

Joint view from EFPIA, EBE, Vaccines Europe, EGA, AESGP and EuropaBio was presented by John Kiser, Neil Newman, Eveline Wyss and Amy Williams.

Item 3 EFPIA_EU IDMP Task Force.pdf

The inclusion of a broad cross-section of stakeholders was highly appreciated by industry. Close collaboration to achieve the long term vision and develop a shared plan was highlighted as essential. It was also stressed that the direction of travel to structured data should be well planned in order to achieve full and clear picture of all benefits. The Road Map must reflect realistic timelines and scope, the way to move forward and listing all issues which need addressing was highlighted. Taking into account high costs of the implementation/transition a reduction of duplicating efforts is necessary. A phased implementation is crucial given extensive potential use and breadth of data elements within IDMP.

There was significant discussion around the "Initial Industry Analysis" aspect of this presentation. Specific issues were highlighted including the following:

- A request for even a single data field could cause significant effort for a company with a large product portfolio if that data element is not held within IT systems.
- Organisations that have grown through M&A activity may have a variety of IT solution with differing levels of data held in different parts of the organisation. Some data elements within the

IDMP standard are only held within documents and not in a structured way within IT systems. This is particularly the case for detailed substance data.

Actions:

- John to collect additional information from industry and provide consolidated feedback on possible opportunities to reduce duplicated information which is currently provided within regulatory submission documents and may potentially also be within IDMP based data submissions. This should consider also the frequency of change reflecting the reduced benefit in removing relatively static content from document based submissions.
- Francisco to consider the process to review regulatory document content to reduce the potential overlap with IDMP product data submissions (specifically Module 3 of the dossier).
- EMA, in the course of the ISO IDMP implementation, to analyse which IDMP data fields will be used and prioritise their collection and maintenance to guide a phased implementation.

Remco Munnik presented the industry view on behalf of EGA.

Item 3 EGA ISO IDMP_EGA presentati

Remco also emphasised the need of simplification of the current, complex workflow. He stated that in the future data should be captured and submitted only once. The submission of data in a structured form (such as IDMP) will duplicate data which is also requested in document form (e.g. Dossier) so moving to IDMP presents an opportunity to streamline this. Without gaining some efficiency such as removing some document based data submissions it is hard to see how efficiency benefits for industry will be achievable. Francisco proposed to investigate the approach to streamline data submissions via electronic message vs documents (such as Annex 3) (see actions).

Remco noted that the involvement of NCAs and vendors in the ISO IDMP Task Force is essential. He expressed an opinion that the July 2016 deadline is worrying and clear implementation priorities must be set up. It was also noted that all concerned stakeholders would need sufficient time for implementation so clear information on next steps is required as soon as possible.

Christoph Kox presented the industry perspective on behalf of AESGP.

Item 3 AESGP Presentations EU ISO

Christoph confirmed that the idea of close collaboration between all stakeholders for implementation of ISO IDMP is fundamental taking into account the complexity and cost involved. The need of global alignment was stressed. Christoph also stated that, during the transition period from Art.57 to ISO IDMP, overlapping of some resources may be identified as one of the potential difficulties. With regards to the implementation timelines, it was proposed to inform the EC, that due to ISO IDMP complexity, the July 2016 deadline is not feasible. It was noted that implementation of ISO IDMP is pending the availability of the ISO Implementation Guide.

Francisco summarised the discussion on industry perspective as follows:

- The common concern from industry and NCAs is the feasibility of the July 2016 deadline and definition of the transition period.
- Collectively we should carefully align processes, review content of regulatory documents and structured data to identify opportunities to decrease duplication of effort.
- Simplifying future workflow and applying a pragmatic approach should be objectives of the Task Force.
- The Task Force will create sub-groups with clearly defined objectives. The benefits and importance of close collaboration between NCAs, industry, vendors and EMA is fully recognised.
- EU implementation is a priority but the need of global synergies is acknowledged. Finding global solutions and involving international stakeholders (FDA) is fully recognised.

4. NCA perspective: benefits, risks and complexity

Perspective of a small NCA was presented by Triin Maesalu from Estonia.

Item 4 Estonia ISO IDMP.pdf

Triin informed the Task Force that major difficulties for small size NCAs are caused by budget and human resources limitations. It was stressed that the implementation timelines must take into account these restrictions; otherwise they would be unrealistic and unachievable. Smaller NCAs are open to jointly develop IT systems or use systems developed/offered by EMA (Estonia has experience with both), but the support for national languages becomes a key requirement in this case.

Ilaria clarified that Art.57 data will be made available for NCAs (QPPV, Product Data, and Master File Location) via EVDAS reports through the Data Warehouse by the end of 2015. As an interim solution, the Agency is currently finalising the creation of simplified tool enabling access to Art.57 data. It is estimated to have it ready by end of Q2 2015.

Giovanni Ferretti (Italy) presented the view of a large NCA.

Item 4 Italy 2015-03-31_EU-NDB_

Giovanni informed the Task Force about AIFA progress towards ISO IDMP Implementation. It was noted that Italy is progressing with an internal implementation Road Map to ensure that the key business case, the management of the pricing of medicines, is fulfilled.

Thomas Balzer shortly discussed the German perspective highlighting that with the big volume of applications processed by his Agency, the unstructured format of eAF is not feasible anymore.

Kevin Horan added that codification of free text values will be a challenge. He also said that in Ireland PhV database will be updated to be ISO IDMP compliant, but IDMP modification of the database to manage authorisations was not deemed as mandatory.

Joris Kampmeijer updated the Task Force on the recent NCAs/EMA workshop [also see agenda point 7]. The scope of the meeting was to establish the business value, benefits, impacts (on technology, processes, budget and resources), communication, concerns and needs around Substance, Product,

Organisation and Reference master data (SPOR) and ISO IDMP. During the meeting it was recommended to use common terminology and structured data among all NCAs. As soon as the workshop outcome is finalised, it will be shared with other NCAs and, subsequently, with EU ISO IDMP Task Force.

5. EMA perspective: benefits, risks and complexity

Ilaria Del Seppia presented the Agency's perspective of the ISO IDMP implementation.

Item 5 EMA - ISO IDMP BIR_4.pdf

Ilaria noted that with the ISO IDMP implementation it is aimed to build a common definition of the product and apply a "single" ISO IDMP implementation within the EU: based on one format and the same practices whether exchanging data with NCAs or the EMA. With regards to the transition period required to transfer Art.57 data to the ISO IDMP format, it was noted that the Art.57 data would need to be enriched during the migration process and the approach to this would depend on the possibility to integrate with existing data sources (such as the FDA's substance data) and the agreed on-going data maintenance processes.

In response to the request for an explanation of "data enrichment", Ilaria responded - Considering the gap in data elements between Art.57 and IDMP, we (collectively) need to consider how to make best use of the existing data and agree the approach to completing the missing data. This completion of missing data is the "enrichment" – to make it compatible with the IDMP standards.

In discussion following the presentation it was noted that new forms (such as eAF) need to be developed with IDMP in mind.

Francisco asked for the NCAs' view on the application of IDMP standards to veterinary medicinal products. Comments relating to this included that the terminologies used are different and that IDMP cannot be imposed on MAHs. However, standards are desired in this area and at the product level this may be faster to implement (than IDMP) for MAHs as the structure could be simpler.

Kevin commented that most agencies will have medicinal product data in structured form as it is provided to other parties. Additional structured data would lead to further simplification of processes. Data relating to indications/contra-indications was specifically highlighted. Data outside of the IDMP standards may also be of benefit – for example the "legal basis", as this had been requested by MAHs but is only available for many within documents and not within structured data in IT systems. Joris concurred adding that maintaining the full manufacturing record within structured data would, for example, allow a more expedient analysis of potential issues as soon as an issue with one CRO is identified.

6. EMA SPOR Road Map

Kepa Amutxastegi provided the Task Force with the latest information on EMA SPOR master data management Road Map.

Item 6 EMA SPOR MDM Roadmap_4.pdf

Kepa presented the group with the overview of the Road Map creation process. The work started a few months ago and initial input was provided by EMA and some NCAs. The EFPIA position paper submitted in October 2014 was also considered as a significant factor. The Road Map is currently based on indicative plans and milestones and will be revised periodically. The overall implementation strategy shows that it will follow a phased approach, with multiple iterations, in order to incrementally deliver master data services around SPOR. It was also stressed the importance of engaging with all stakeholders, including industry, throughout the implementation of the Road Map. The Road Map is expected to be published in April 2015 on the Agency's website. It was noted that there will need to be an alignment between the EU ISO IDMP implementation Road Map and the EMA Road Map with respect to the outlined implementation strategy. Answering one of the questions from the Task Force, Kepa confirmed that the services provided within SPOR will be free of charge. During the discussion, it was also stated that EMA will act as the EU maintenance organisation for substances (confirmation from Kevin that this was agreed at the EU TMB) and by means of using the software developed by NCATS/FDA with input from the GInAS consortium. The maintenance organisation(s) need to be agreed for reference data and currently EDQM is expected to continue with the lists they maintain that are used for Art.57 but the operating model needs to be agreed and this group can put forward recommendations.

Kepa informed the Task Force that the draft EMA Road Map has already supported the initiation of 'Referential' and 'Organisation' data management projects at EMA. It was stressed that the Agency is aiming to build the operating model on "O" based on open dialogue and consultation with the EU ISO IDMP Task Force once the internal EMA position is defined. Isabel reported that EMA started also mappings and initial analysis on Referential ("R"). It is planned to start working on Substance ("S") and Product ("P") data domains during Q2 2016.

Joris stated that NCAs and industry will not be able to meet the July 2016 date and a plan is needed for clarifying exactly what they need to do and by when. He also proposed that the initial implementation could be limited to XEVMPD data elements i.e. for July 2016. A question was directed to the representative from the EU commission with regards to the consequences for not being able to meet the July 2016 date the EC commission would investigate this (as per action on point 2 of this minute).

Overall, it was noted that taking into account the significant impact, corresponding workload and dependency on the availability of the ISO IDMP Technical Specifications and HL7 SPL R7 message, the July 2016 deadline will be hard to achieve. However, it was stressed that this timelines were set for pharmacovigilance purpose that cannot be undermined. It was agreed the following to be developed and escalated to the Heads of Medicines Agencies (HMA): analysis outlining possible impacts of not meeting the deadline and suggested, alternative phased approach and counter scenarios for ISO IDMP implementation. Subsequently, this should also be presented at EMA Management Board.

Action:

- Francisco to coordinate the preparation and presentation of the IDMP implementation analysis and suggested alternatives (including timelines for implementation) as defined by this Task Force at the July HMA meeting. This presentation will also include proposals on scope and timing for a phased implementation.

7. SPOR Workshop: defining of business case for the EU network

Francisco Penaranda briefed the Task Force on the SPOR Workshop, which took place at the Agency on 19 and 20 March 2015.

Item 7 SPOR Workshop_defining o

Francisco informed that it is planned to have final workshop conclusions on recommended operating models ready for the HMA meeting in July 2015. Prior to presentation at the HMA, the proposal with be discussed and adopted by the EU Network Data Board. It is foreseen to share the document with the EU ISO IDMP Task Force and comments from industry are welcome.

Action:

- EMA to share in sub-groups the outcome of the workshop and proposed options for operating models to confirm final "TO BE" solution.

8. Outline of the EU ISO Implementation Guide

Ilaria Del Seppia presented the update on ISO IDMP status and EU Implementation Guide.

Item 8 ISO IDMP status update - EU IG

Ilaria informed the Task Force about the ISO IDMP activities' schedule and confirmed, as mentioned earlier, that EMA will be the maintenance organisation for Substances (inc. Specified Substances) within the EU by means of using the software developed by NCATs/FDA within input from GInAS (the software is currently referred to as GSIS or G-SRS). The potential challenge with data confidentiality was noted, as according to current US legislation, the FDA cannot share all data on substances with the EU. Ilaria also confirmed that according to current plans, the work on the EU Implementation Road Map should start in April 2015 and in June 2015 drafting of the EU Implementation Guide is foreseen to begin, providing there is sufficient maturity of the ISO IDMP Technical Specifications.

In response to a question relating to potential use of the FDA substance data to enrich the current Art.57 substance data Ilaria responded that there are on-gong discussions with the FDA and that this will be assessed during development of the implementation Road Map. It was re-stated that there are also some potential confidentiality issues to be addressed.

9. EU ISO IDMP Task Force way forward – conclusions, actions, next steps

It was decided to create three working sub-groups:

1. Substance and Products (S&P)
2. Organisation (O)
3. Referential (R)

The objectives of the sub-groups are to draft the business cases, the EU operating model and the proposed timelines for implementation of the ISO IDMP as proposed alternative solution if not meeting the 16 July legal deadline.

The sub-groups will also summarise the pros and cons of the option 1 (i.e. implement ISO IDMP by July 2016) and the identified alternative.

Each sub-group will be formed by around 2 representatives from each party (i.e. 2 NCAs, 2 EMA, 2 industry Association members and 2 Vendors).

The sub-groups will de-brief and consult the full group with the aim of having an agreed analysis report and alternative proposal for the HMA meeting on 7th July.

It was agreed to organise working TCs and a 'take-stock' TC before the next ISO IDMP TF meeting. This will be defined according to the progress with the actual work and was left open to individual sub-group. It was confirmed that the sub-groups should start working shortly after the Easter break.

The interest of participating in the "R" sub-group was expressed by EDQM.

Claus Lyng Nielsen expressed the need to have a formal communication stating that we are not working to meet the July 2016 deadline. The Commission representative will investigate as per agreed action. **Actions:**

- Nominations for each sub-group to be coordinated by the EU ISO IDM TF co-chairs and finalised by 10 April.
- Sub-group leaders to be selected during first teleconference.
- EU ISO IDMP Task Force EMA topic leaders to agree on a detailed action plan during dedicated teleconference.
- Marta Terron Cuadrado to investigate internally with the EC the reason for setting up the July 2016 and provide feedback to the group.

The proposed dates of future EU ISO IDMP Task Force face to face meetings are following:

- 12 June 2015
- 25 September 2015
- 27 November 2015

Each meeting is subject to further confirmation. Ad hoc teleconferences might be organised if needed. The meeting schedule for 2016 is currently undefined.

It was confirmed that the Art.57 Implementation Working Group will continue with maintenance activities until all areas are transferred to the ISO IDMP Task Force. The duration of this transition is to be confirmed.

Vendors/service providers were selected from the call for expression of interest however, some were not able to participate in this meeting due to the selection completing shortly before the meeting date. They have however all received copies of presentations and will receive the meeting minutes.

10. A.O.B

ISO IDMP Information Day announcement

EMA advised the Task Force that an ISO IDMP Information Day is scheduled for 23 June 2015. The event will take place at the Agency's premises and is open to all interested parties. EMA is currently working on detailed programme and identifying potential speakers which should include participants from the Task Force. The finalised agenda will be published on EMA website. It is recognised that this may be a heavily over-subscribed event and participation via a web broadcast will be investigated, also additional dates may be planned.