



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Information Management

# Task Force for the implementation of International Standards on Identification of Medicinal Products in the EU (i.e. EU IDMP/SPOR Task Force)

## Terms of Reference

### 1. Remit, vision and mission

The Task Force for the implementation of International Standards on Identification of Medicinal Products use in the EU is an expert working group/advisory group co-chaired by an EMA representative, National Competent Authority (NCA) representative and European Pharmaceutical Industry representative. The implementation of ISO IDMP standards follows a master data management methodology based on four domains (i.e. Substances, Products, Organisations and Referentials), which is applicable for both Human and Veterinary medicinal products. Therefore, the expert working/advisory group is named EU IDMP/SPOR Task Force and comprises of participants for both Human and Veterinary medicinal products from the European Medicines Agency (EMA), Member States, experts nominated by European Pharmaceutical Industry Associations, Software Vendors and interested parties with full understanding of the terminology, the ISO IDMP standards, the European data policies, regulatory procedures and requirements including the data submission practices and the technological constraints of the existing IT infrastructure and applications.

The remit of the EU IDMP/SPOR Task Force group embraces the definition of common principles for the ISO IDMP standards implementation in the EU as well as endorsing the data operating model for data exchange. This includes the development and implementation of an agreed EU ISO IDMP Road Map and EU Implementation Guide as a major milestone to be achieved by the group.

This forum will be responsible for advising on aspects related to planning, development, implementation and maintenance of the ISO IDMP Standards in the EU in line with the requirements defined at international level and based on the agreed EU Implementation Guide principles. The EU IDMP/SPOR Task Force will deliver recommendations on the implementation strategy such as endorsement of timelines for the implementation of specific components within the ISO IDMP standards in line with the regulatory requirements and legislative timelines. The group will also act as communication channel towards all external stakeholders affected by the implementation of the ISO IDMP standards in the EU.



The recommendations made by EU IDMP/SPOR Task Force will be adopted by the Data Integration Steering Committee in accordance with the Data Integration programme and Telematics governance model (see section 4.1).

The **VISION** of the EU IDMP/SPOR Task Force is to develop the common EU strategy for the ISO IDMP standards implementation in response to a worldwide demand for internationally harmonised specifications for medicinal products.

The **MISSION** of the EU IDMP/SPOR Task Force is to have an on-going dialogue between the main EU stakeholders which plan to develop and implement of the ISO IDMP standards.

## 2. Membership

Members of the EU IDMP/SPOR Task Force consist of both business and IT representatives with an in-depth understanding of the ISO IDMP standards and that familiar with the European data policies, regulatory procedures and requirements including the data submission practices and the technological constraints of the existing IT infrastructure and applications.

To ensure that the Task Force meetings are constructive and productive, participation of limited number of nominated experts is distributed as follow:

- Members of the EU Regulatory Network nominated as follow:
  - Full members of the EUNDB who might be accompanied by one expert per EUNDB member from NCAs, EC and EDQM.
- 24 members nominated by the following Industry Associations representing human sector (up to 3 representatives per each association ):
  - European Federation of Pharmaceutical Industries and Associations (EFPIA);
  - Vaccines Europe (VE);
  - European Biopharmaceutical Enterprises (EBE);
  - European Confederation of Pharmaceutical Entrepreneurs (EUCOPE);
  - EuropaBio;
  - Medicines for Europe;
  - Eye Care Industries European Economic Interest Grouping (ECI – EEIG);
  - Association of the European Self-Medication Industry (AESGP).

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.

- 3 members nominated by the following Industry Associations representing veterinary sector (1 representative per each association):
  - European Group for Generic Veterinary Products (EGGVP);
  - International Federation for Animal Health Europe (IFAH Europe);
  - The Association of Veterinary Consultants (AVC).

- 10 interested parties expressing interest to participate and having provided proves of expertise as required by the Call for Expression of Interest as launched by the Agency. The interested parties include representatives of terminology maintenance organisations, software vendors, service providers and developers of medicinal product dictionaries/databases solutions.
- 7 members from EMA:
  - 4 representing business;
  - 3 representing IT.

Based on the meeting agenda, additional specialists may be invited to present their area of expertise.

### **3. Modus Operandi**

The EU IDMP/SPOR Task Force will meet up to three times per year at the EMA and may also convene ad-hoc meetings via conference calls/webinars. The meetings will be coordinated by four co-chairs: the representative of the Agency, an EUNDB delegate from NCAs, EC or EDQM, an expert nominated by Pharmaceutical Industry and an expert representing Veterinary area.

In order to ensure efficient progress in specific topic areas, smaller working groups comprising dedicated topic experts may be created. These sub-groups will present findings/recommendations back to the full group for review and final adoption.

The EU IDMP/SPOR Task Force will agree on proposals by consensus. The recommendations delivered by this group have to be finally adopted by the EU Telematics Management Board (EUTMB).

All participants will bear their own costs and expenses related to their participation in the EU IDMP/SPOR Task Force, to the exception of representatives of the NCAs whose costs and expenses will be reimbursed in accordance with the EMA "Rules for reimbursement of expenses for delegates and experts attending meetings" (EMA/MB/270654/2014).

Secretarial support to this meeting will be provided by the Agency, including meeting schedule and logistical arrangements, agenda and supporting documents circulation, recording of action and minutes. The minutes and presentations of the EU IDMP/SPOR Task Force will be published on the EMA corporate website to ensure transparency.

RAID (Risks, Actions, Issues, Decisions) matrix will be maintained based on the meeting outcome and will be distributed to Task Force members as an excel table following each meeting.

### **4. Mandate**

Objectives for the EU IDMP/SPOR Implementation Task Force include:

1. 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.
2. Contribution to the development and endorsement of the EU ISO IDMP Road Map including the implementation plan and strategy.
3. The implementation and migration plan from current Article 57 database into the Master Data Management (MDM) system as defined by the EMA Roadmap, that includes:

- 3.1. Contribution to and endorsement of the gap analysis of Article 57 format (i.e. xEVPRM) vs ISO IDMP.
- 3.2. Contribution to and endorsement of the data submission and maintenance business processes based on the agreed EU operating model and data governance.
- 3.3. Contribution to and endorsement of the business processes to enrich the additionally required data.
- 3.4. Contribution in establishing an ISO IDMP data quality control methodology.
4. Contribution to the necessary documentations as regards the EU ISO IDMP implementation aspects such as EU ISO IDMP Implementation Guide, technical specifications and any other relevant guidance.
5. Contribution to the Organisation master data management and Referentials in line with the EMA Roadmap.
6. Communication channel for all external stakeholders affected by the implementation of the ISO IDMP standards in the EU; with a strong emphasis on systematic dialogue with regulators outside the EU.
7. In addition, this forum may provide recommendations and views on initiatives impacted by the ISO IDMP such as:
  - 7.1. Horizon 2020;
  - 7.2. Falsified Medicines Directive;
  - 7.3. Regulatory Submissions;
  - 7.4. Clinical Trials.

#### **4.1. Governance Model**

The recommendations made by EU IDMP/SPOR Task Force will be adopted by the Data Integration Steering Committee in accordance with the Data Integration programme (Project and Maintenance group in the below diagram).

