ISO IDMP and the AI FA roadmap

Workshop: Does IDMP fit the purpose of bridging Clinical Practice with Regulatory Oversight?

Genova, 16th International HL7 Interoperability Conference

Giovanni Ferretti

June 14, 2016
Public Declaration of transparency/interests*

The view and opinions expressed are those of the individual presenter and should not be attributed to AIFA

<table>
<thead>
<tr>
<th>Interests in pharmaceutical industry</th>
<th>NO</th>
<th>Current</th>
<th>From 0 to 3 previous years</th>
<th>Over 3 previous years</th>
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<tbody>
<tr>
<td><strong>DIRECT INTERESTS:</strong></td>
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<tr>
<td>1.1 Employment with a company: pharmaceutical company in an executive role</td>
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<td>1.2 Employment with a company: in a lead role in the development of a medicinal product</td>
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<td>1.3 Employment with a company: other activities</td>
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<td>2. Consultancy for a company</td>
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<td>3. Strategic advisory role for a company</td>
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<td>4. Financial interests</td>
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<td>5. Ownership of a patent</td>
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<td><strong>INDIRECT INTERESTS:</strong></td>
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<td>6. Principal investigator</td>
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<td>7. Investigator</td>
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<td>8. Grant or other funding</td>
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<td>9. Family members interests</td>
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*Giovanni Ferretti, in accordance with the Conflict of Interest Regulations approved by AIFA Board of Directors (25.03.2015) and published on the Official Journal of 15.05.2015 according to EMA policy /626261/2014 on the handling of the conflicts of interest for scientific committee members and experts.

N.B. < I am not receiving any compensation>
Outline

- EU Telematics strategy
- EU Telematics Governance at a glance
- EU Network Data Board (remits, vision, ToR)
- Legal background – Data Integration programme
- EMA ISO IDMP roadmap and milestones
- AIFA roadmap
- Conclusions
EU Telematics strategy

✓ An independent review of EU Telematics on behalf of EMA MB started in 2013
✓ The review’s results suggested new governance structures be put in place to address the varying level of success of previous EU Telematics programmes
✓ This new structure is built on the strengths of the previous approach and aims to address identified weaknesses
✓ The single strategy endorsed by the Network (NCAs, EC and EMA) will provide the framework for cooperation in EU Telematics
EU Telematics strategy

✓ The last revised single strategy and the implementation roadmap were endorsed by HMA in July 2015, and by EMA MB in August 2015

✓ The new strategy identifies a common programme for development of IT systems whilst recognising the distinct mandates of all members of the Network, and the needs of their stakeholders

✓ The EU Telematics strategy is a “living document”
The strategy recognises that the EU regulatory system operates within an international context.

A multi-year Master Data Management strategy, based on interoperability, for the use of medicinal product data specifically related to Substance, Product, Organisation and Referential (SPOR) is essential to ensure the uniformity, accuracy, and consistency of medicinal product data which supports key business processes;

The implementation of the ISO IDMP standards will support master data management for the Network.
EU Telematics strategy

The Network’s vision of EU Telematics:

“A European IT collaboration that will deliver a broad range of cost-effective, efficient and interoperable services to the European Medicines Regulatory Network and its stakeholders, ultimately improving the quality and effectiveness of their business activities.”
Key to interoperability are the standards: they encompass semantic and processes.

Interoperability

Organizational Alignment
Process Alignment
Semantic Alignment

Technical Interoperability

Syntax
Interaction
Transport
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EU Telematics governance model

EMA MB ➔ HMA

EU TMB ➔ IT Dir. Group ➔ EU NDB ➔ TEAB ➔ Projects & Maintenance

Strategic

Tactical

Operational
The EU Telematics governance model is supported by the Telematics PMO and the Telematics Secretariat. Projects and Maintenance, where at the operational level the aim is to establish structures to assure joint project delivery and maintenance support in the most efficient manner possible.

The Telematics governance is supported by the Telematics PMO and the Telematics Secretariat.

Adapted from the EMA joint EU Telematics governance model
Telematics Systems Life-cycle

Source: EMA joint EU Telematics governance model
IT Directors Executive Committee

- **eSubmissions CMB**
  - eSubmission Roadmap
  - EMA, NCA & industry members
  - Systems & guidelines
  - CR management

- **Hum Medicines CMB**
  - Whole life-cycle of medicines
  - EMA, NCA & industry members
  - Systems, data & guidelines
  - CR management

- **Vet Medicines CMB**
  - Whole life-cycle of medicines
  - EMA, NCA & industry members
  - Systems, data & guidelines
  - CR management

Maintenance (EMA or NCA)

- Maint Group Syst 1
- Maint Group Syst 2
- Maint Group Syst 3
- Maint Group Syst 4

Source: EMA joint EU Telematics governance model

Telematics CAB

Into production

Operations and user support (EMA or NCA)

Release calendar
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EU Network Data Board

✓ The EU NDB is an **advisory body** co-chaired by the Head of Business Data and Support Department (EMA) and a National Competent Authority (NCA) representative and comprising members representing Member States, the Agency and other key parties (*i.e.*, EDQM, EC and other non-EU regulatory authorities)

✓ The **VISION** (aspiration) is that the EUNDB will work with the regulatory network to establish appropriate data standards and supporting terminologies, necessary to support the sharing and analysis of data/information as an important asset for the network through its life cycle.
The EU NDB MISSION (to support the vision) is to inform and support the regulatory networks implementation of data standards in a coordinated manner to optimise the value of its investment in data/information assets, support effective and efficient operations, mitigate legal and regulatory risk and improve the delivery of services and of proactive & reactive data analysis to its stakeholders and customers.

Even though its members are nominated by their Head of Agency, they do not represent their MS only but they are supposed to act in the EU objectives and to try to find WinWin solutions for both the NCAs and the EU.
EU Network Data Board - composition

a) 14 NCAs with good balance of different sizes of human (11 expertise with 5 business data experts and 6 IT experts) and veterinary representatives (3 expertise with 1 business data expert and 2 IT experts):
   7 NCAs from large countries;
   4 NCAs from medium countries;
   3 NCAs from small countries;

b) 1 member from EC

c) 1 member from EDQM

d) 6 members from EMA (3 representing business and 3 representing IT)
EU Network Data Board - mandate

1) Ensure that data and information assets are known, usable, reusable, and can be accessed and integrated when and where needed.

2) Propose common policies, procedures, architecture and standards to maximise the sharing and investment in data and information.

3) Identify opportunities to coordinate and leverage existing EU investments in data and information.

4) Provide metrics and dashboards on the state of the EU data management performance.
EU Network Data Board - mandate

5) Provide **advice to the network** on appropriate security and privacy policies to protect data assets.

6) Establish collaborative and cooperative relationships with stakeholders and consumers (i.e., industry and patients) to invest strategically in data and information assets and **promote reusability**.

7) Define European business requirements for business intelligence solutions/reports and for both proactive and reactive data analysis outputs.

8) Identify where it can support business directly (such as risk avoidance).
9) Identify where data/information (the EU NDB should be also responsible for information and unstructured data) is used to move the business forward.

10) Associate Data Governance with those Information Management activities (Master Data Management, Business Intelligence, Data Analytics, etc.).

Data governance must be viewed as an EU effort, and it must always have European perspective in order to avoid conflicting standards and accountabilities.
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Data Integration programme

Regulation (EU) No. 520/2012 on the performance of pharmacovigilance activities….

CHAPTER IV “Use of terminology, formats and standards”

Art. 25 - Use of internationally agreed terminology
Art. 26 - Use of internationally agreed formats and standards

CHAPTER IX “Final provisions”

Art. 40 - Transitional provisions. The obligation on the part of MAH, NCAs and the Agency to use the terminology provided for in points (c) to (g) of Article 25 shall apply from 1 July 2016.
The IDMP implementation especially needs to meet the following objectives:

- Facilitate the pharmacovigilance activities of medicines regulatory Agencies worldwide.
- Support standardisation of data across NCAs databases.
- Support operational efficiency within the Network.
Data Integration programme

- Adopt a **phased implementation approach** and **Target Operating models**, in order to provide realistic project milestones and manageable budgets.
- Prioritization of implementation steps to meet EU legal requirements, while also considering continued alignment with global implementation.
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To allow codification and management of Organisation information (as an underlying component of the ISO IDMP standards)

Based on ISO IDMP 11239, 11240 (UCUM), containing terminologies to support identification of Substances and Products such as dose forms, route of administration, etc

Based on ISO IDMP 11238 standard and related ISO Technical Specification

Based on ISO IDMP 11615 and 11616 standards and related ISO Technical Specification

EMA SPOR MDM services
Phased implementation of IDMP through SPOR

- The focus for 2016 is on implementation of Referentials and Organisations

- Referentials and Organisations will lay the data foundations for Products & Substances

<table>
<thead>
<tr>
<th>2016</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
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<tr>
<td><strong>Preparation Phase</strong></td>
<td><strong>Maintenance Phase</strong></td>
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<td>RMS</td>
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<td>• Build technical services</td>
<td>• Terminology alignment</td>
<td>• Terminology alignment</td>
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<tr>
<td>• Develop controlled vocabularies</td>
<td>• Registration of new terms</td>
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<td></td>
<td>• Expand and manage content of lists</td>
<td>• Expand and manage content of dictionaries</td>
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<td></td>
<td>• Begin implementation of the Referential operating model</td>
<td>• Begin implementation of the Organisations operating model</td>
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<td>OMS</td>
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<tr>
<td>• Build technical services</td>
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<tr>
<td>• Develop initial organisation dictionary</td>
<td>• Registration of new terms</td>
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<td></td>
<td>• Begin implementation of the Organisations operating model</td>
<td>• Begin implementation of the Organisations operating model</td>
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SPOR MDM Benefits

Data captured and submitted only once

Re-use of data for other purposes

SPOR Database EMA

Re-use of data for other processes

Marketing Authorisation, Applications, Variations, etc.

EU Agencies

Industry data entry
SPOR Benefits

Benefits:
- Efficiency
- Efficacy
- Transparency

Business Cases
- Clinical Trials
- CESSP/eAF
- GMP/Inspections
- PhV
- PSUR
- Referrals
- Falsified Medicines
- eHealth

Foundation
- Master Data Management
  (Substance, Product, Organisation, Referentials)
The need of standards

- **Pharmacovigilance.** Medicines save lives but can cause side effects: standardising data about authorised products will improve signal detection and speed of response, thus helping to save lives.

- **ePrescription.** Prescriptions will use standardised data to describe medicines enabling patients to get hold of the right products when outside their home country.

- **Falsified medicines.** Standardised data will help determine the authenticity of a medicine.

- **Shortages.** Standardised data will mean substances and products can be described accurately enabling faster response to address shortages.

- **Batch recalls.** Standardised data will mean substances and products can be described accurately enabling faster identification and withdrawal.

- **Support the activities of medicines regulatory Agencies worldwide.**
• ISO IDMP define the elements and their conceptual relationship for the unique identification of products globally

• HL7 provides the message format that transfer data between systems
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AIFA Roadmap

ISO 11240 Units of measurement (R)

ISO 11238 (S)

ISO 11616 (P)

ISO 11615 (P)

- ISO 11238 (S)
- ISO 11240 Units of measurement (R)
- ISO 11616 (P)
- ISO 11615 (P)

(R) + (O)
dose forms, route of administration, unit of presentation, MAHs, sponsors, etc
AI FA Roadmap

Key task for AI FA is the **data mapping**, before the EMA RMS and OMS systems go-live:

- Identify what data elements need mapping (against EMA EU TCT and/or xEVMDP) and develop the process for how to undertake the mapping in line with your initial data mapping approach (e.g. manual or semi automated)
- Human intervention may still be required to **verify data matches**
- Each NCA will have a very different data profile and will require mapping tools appropriate to their own data requirements. EMA can only therefore provide guidance on processes, and will not be providing any data mapping tools
AI FA Roadmap

Some of the (ongoing) activities regarding R (ISO 11239, 11240)

[Pharmaceutical form]

• Insertion of the concept of **state of matter** (solid, semi-solid, liquid, gas);
• Insertion of the concept of **basic dose form** (tablet, gel)
• Pharmaceutical dose form (check CVs, standard terms)
• Adding concepts of “ReleaseCharacteristics” and Trasformation
• Checking congruence of the terms regarding the route of administration class
Some of the (ongoing) activities regarding \( R \) (ISO 11239, 11240)

[Pharmaceutical form]

- Intended site (e.g., ocular, oral)
- Administration method (e.g., application, inhalation)
- Adding some packaging category class
- CVs for arbitrary units
Some of the activities regarding S and P (ISO 11238, 11615, 11616)

- Population of the (empty) fields: molecular formula, CAS-NUMBER, Molecular weight
- Whenever possible, splitting/merging/recovering/addition (for S and P) from the (old) silos in the new DB, in order to be compliant with the ISO IDMP.
IT framework - Next steps

A – AIFA application domain layer
B – Infrastructural interoperability layer
C – Shared knowledge layer

Ext. Web services (EMA)

National Governative Institutions (Ministry of Health, Regions…)

Administrative, Query and Maintenance REST API based on HL7 related standards
Conclusions

1. Any adaptive changes or interventions related to the SPOR roadmap would affect only the shared knowledge layer (C)

2. The AIFA IT architecture (A) won’t be affected, but will be optimized with the Data Virtualization Server solution

3. Easy interaction with “shared services” (i.e., OMS, RMS, CESSP/CESP 3.0)

4. Budget savings, for instance throughout the reduced MAC/MEV within the informative systems.

5. FTE savings, reallocation of the internal resources
Conclusions

6. Data are entered once and can be reused many times, (operational savings and increased efficiency, reuse as much you can)
7. Increase in quality of data and simplification of the process
8. Access to EMA RMS/OMS via web interface or API
Thank you!!

CONTACTS

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