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## European Union Network Data Board Terms of Reference

### 1. Remit, vision and mission

The European Union Network Data Board (EUNDB) 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 (e.g. EDQM, EC and other non-EU regulatory authorities).

EUNDB reflects the programme agreed by the EU Telematics Management Board (EU TMB) and Head of Medicines Agency (HMA) to manage the policies, principles and quality that will ensure access to accurate and risk-free data and information. EUNDB will propose standards, accountabilities, and responsibilities, and ensure that data and information usage achieves maximum value to the EU/EEA Regulatory Agencies. EUNDB will promote the increased use of structured data across the network and support the consistent, integrated and coordinated use of common data and information across the network. The scope of EUNDB currently covers both Human and Veterinary medicinal products.

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 **MISSION** (to support the vision) of the EUNDB 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.

It is important to note that in this document the terms 'data' are used in the broadest possible sense, i.e. all recorded information:

- data may be recorded electronically, on paper or in any other form, by a person, machine, automatically or otherwise;
- data may or may not be organised in databases or files, and it may be structured, semi-structured or unstructured.

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See websites for contact details



EUNDB proposals will have also to show value by means of tangible direct benefit like:

- Improvement in efficiency (e.g. integration, faster information delivery).
- Reduction in risk (e.g. improved data quality, data security, incorrect decisions brought about by inaccurate or inconsistent data, liability by failing to track key documents or respond to a request for documents).

## **2. Membership**

### **2.1. *Permanent Members***

Members of the EUNDB consist of both business and IT representatives from NCAs, Agency, EC and EDQM that understand the data needs of the business, and the technological constraints of the existing IT infrastructure and applications. They should be very familiar with the European data policies, procedures, IT systems and practices.

All members have been appointed by their Head of Agency and confirmed by the EU TMB and have the authority to make proposals to the EU TMB and take actions in the area of data and information, as described in sections 1 and 4. It should be noted however that although the Board Members are nominated by their Head of Agency they do not represent their Member State only; instead they are supposed to act in the European Union objectives and to try to find win-win solutions for both the NCAs and the EU.

The members are:

- 15 NCAs, ensuring good balance between different sizes of human (12 expertise with 6 business data experts and 6 IT experts) and veterinary agencies (3 expertise with 1 business data expert and 2 IT experts).
- 1 member from EC.
- 1 member from EDQM.
- 8 members from EMA:
  - 5 representing business;
  - 3 representing IT.

Additionally, Swissmedic has been appointed as an observer.

### **2.2. *Invitees***

Subject matter experts can be invited on ad-hoc basis and will be called to present their topic.

### **3. Modus Operandi**

The EUNDB will be co-chaired by the Head of Business Data and Analytics Department and NCA representative.

The Board will have at least every 2 months a remote meeting via Adobe Connect and/or teleconference facilities and at least once a year a face to face meeting will be organised.

In case of an urgent need, ad-hoc meetings could be arranged.

Meeting preparation, agenda preparation, document circulation and action minutes to be prepared by the Board co-chairs or delegated proxy.

When necessary, a preparatory meeting with the veterinary representatives will be organised before the EUNDB face to face meeting.

#### **3.1. Agenda**

The agenda of a typical EUNDB meeting will include the following items:

- Topic.
- Presenter's name.
- Purpose of tabling the topic (Adoption, Decision, Discussion, Information).
- Short (2-3 sentences) summary of the topic to serve as the basis of the minutes.
- Background documents.
- Anticipated time required for presentation at EUNDB.

If EUNDB members wish to add a topic to the agenda, they are requested to send the above listed information to EUNDB secretariat 2 weeks prior to the meeting.

#### **3.2. Minutes**

Typical minutes will consist of:

- topic description;
- discussions;
- risk, action, issue, decision description;
- assigned owner;
- deadline.

RAID (Risks, Actions, Issues, and Decisions) matrix will be updated after each meeting and will be based on Minutes outcome. RAID Matrix will be distributed to EUNDB Members as an excel table after each meeting.

### **4. Mandate**

#### **4.1. Objectives for the EU Network Data Board**

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.
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.

EUNDB needs to accomplish also the following:

8. Identify where it can support business directly (such as risk avoidance).
9. Identify where data/information (the EUNDB 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.).

#### ***4.2. Critical Success factor for EUNDB and Data in Europe***

1. Data Governance is mandatory for the successful implementation of any project or initiative that uses data and/or information. Any project requiring reports, business intelligence, cleaning of data or development of a “single source of the truth” requires Data Governance to be sustainable and successful.
2. Data Governance has to show value explicitly. This means that NCAs and the Agency cannot do data governance in a vacuum. Something has to be governed, even if it is data quality and you implement data governance as a means to improve data quality
3. Data Governance has to manage the organisational culture change. The EUNDB is created to resolve some historical problems in the area of data and information. Therefore, something needs to be changed. The EUNDB has to orient, train, educate, communicate, hold hands, encourage and offer incentives.
4. Data governance must be viewed as an EU effort. It may be implemented in segments but it must always have European perspective in order to avoid conflicting standards and accountabilities.

#### ***4.3. Governance Model***

The EUNDB acts as the reference point for matters escalated by EMA and NCAs in accordance with the established criteria and experience. The EUNDB will also agree and act on criteria for escalation to EU TMB.

