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## Telematics Enterprise Architecture Board

### Terms of reference

The European Union Telematics Enterprise Architecture Board is the information technology architecture governance body that operates on behalf of the European Medicines Regulatory Network. In this context, the Network comprises the European Medicines Agency (EMA), the network of EU national competent authorities as represented by the Heads of Medicines Agencies (HMA), and the European Commission, as represented by DG SANCO.

The high-level mandate of the Telematics Enterprise Architecture Board is to:

- Define the EU Telematics Enterprise Architecture (both as is and to be) referring major strategic issues as necessary
- Provide Enterprise Architecture advice to the IT Directors and EU TMB
- Check compliance of projects delivered by project teams and maintenance activities

The Board reports to the IT Directors Group represented by its Executive Committee.

#### **1. Composition**

1.1 The Board consists of:

- The EMA CTO
- Five representatives of five distinct National Competent Authorities nominated by HMA
- Three EMA representatives
- One European Commission representative (ISA DIGIT).

1.2 The Board is chaired by the CTO of EMA.

1.3 The Board members are appointed for a three year period (renewable) or until such time as they no longer represent the organisation which they represented on appointment. Should a member be unable to attend meetings for a continuous period of 12 months, their membership shall terminate.

1.4 No substitution for members unable to attend the meeting will be accepted.

1.5 The Board will be supported by the Telematics PMO and the Telematics Secretariat.

## **2. The role of the Board includes:**

- 2.1 Facilitating and stimulating interoperability between the systems and IT environments of EMA, the National Competent Authorities and the Commission (the Network), taking into account the differences of capacity to adapt among the partners of the network in order to be as inclusive as possible.
- 2.2 Promoting cost efficiency, simplicity and transparency in design and development of IT solutions for the network.
- 2.3 Proposing standards approaches and, where appropriate, solutions to the Network in order to allow the partners involved in this Network to benefit from:
  - Re-use by all the interested parties of existing systems or services in any of the partner's (or groups of partners) systems' catalogues
  - Avoidance of duplicated efforts for a single function within the network
  - Mutualisation of functions of general interest for the Network (implementation e.g. development of business and IT solutions of common interest, shared reference resources, coordinated data dissemination, services, etc.)
  - Better and effective exchange of data across the Network
  - Interoperability of the Network's common core business processes with domains in which not all the participants across the Network currently have a remit (e.g. Medical Devices)
  - Bringing technical expertise to the Network to reach the above objectives.
  - Encouraging adoption of the EA solutions within the Network.

In order to reach these objectives, the Enterprise Architecture Board will define, agree or undertake the following activities:

- 2.4 Document the AS-IS situation.
- 2.5 Propose and develop a Target Enterprise Architecture for the Network covering strategy, business, systems and data, aligned to the future needs and opportunities of the Network's members and needs.
- 2.6 Propose and develop a roadmap to achieve the Target Enterprise Architecture, including a short-term, cost effective Baseline Enterprise Architecture for the Network covering strategy, business, basic systems and data, aligned to the needs and opportunities of the Network's members and needs.
- 2.7 Prepare and submit for adoption a multi-annual Enterprise Architecture programme to the IT Directors; this programme will be updated and re-submitted annually.
- 2.8 Report the progress of the EA programme to the IT Directors Meeting.
- 2.9 Advise the IT Directors Meeting and the IT Directors Executive Group on interoperability and use of services issues and opportunities.
- 2.10 Be consulted prior to the start of each new project (at draft Vision document stage) proposed or included in the Network in order to ensure the alignment of IT project with the Baseline and Target EA and avoid the occurrence of duplicate business functions (for cost efficiency and simplification reasons).

- 2.11 Identify and report non-compliance issues according to the Baseline Enterprise Architecture.
- 2.12 Advise the IT Directors Meeting on potential exception requests.
- 2.13 Respect the [European Interoperability Framework](#) principles.
- 2.14 Liaise with the EU ISA programme (Interoperability Solutions for European Public Administrations) in order to reuse any existing approaches, strategic choices or solutions.

### **3. Meetings**

- 3.1 Meetings will be held monthly by teleconference and by face-to-face meetings as necessary.
- 3.2 Members of the Board will be reimbursed for travel and per- diem by the EMA in accordance with the Agency's reimbursement rules.
- 3.3 Meetings are convened by the Board Chair or at the request of at least 3 members.
- 3.4 All documentation relating to the meeting will normally be circulated a minimum of 5 working days in advance of the meeting date.
- 3.5 Minutes of the meeting will be taken by the Secretariat and will normally be circulated to all members of the Board for comment within 2 weeks of the meeting date. Minutes shall be approved by written procedure.
- 3.6 The quorum for Board meetings is at least 66% of members. At least three representatives of NCAs and two representatives of EMA must be present in order for the meeting to be quorate.
- 3.7 Agreement shall be reached by consensus wherever possible. Where this is not possible, decisions shall be taken by simple majority vote. Proxy votes are accepted.