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EMA CIO Office
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Network ICT Advisory Committee

Terms of Reference

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The Network ICT Advisory Committee (NICTAC) promotes cost efficiency, simplicity and transparency in design and development of IT solutions for the Network through standardization of IT solutions to the Network. It ensures that the European Interoperability Framework and European Interoperability Reference Architecture are respected. It fosters the adoption of international standards, as appropriate to the needs of the network, and act as the forum for discussing/creating interoperability related epics in relation to the Network. Furthermore, it fosters the technological alignment, as well as facilitates and stimulates interoperability between the systems and IT environments of the European Medicines Agency (EMA), the National Competent Authorities (NCA) and the European Commission (all together referred to as "the Network") in the Value Streams.

1. Role of the Committee

Within the joint Network governance framework, the NICTAC serves as an advisory body that:

- Provides input on technology needs, priorities, and policies from NCA's
 - Advice on technology implementation choices across the Network to enable portfolio objectives agreed by the EMA Portfolio Board and Network Portfolio Advisory Group (NPAG)
 - Input on interoperability requirements across the Network
 - Ensures adherence to data standards, data model design and implementation
 - Advice on dependencies (system and resource) across Network initiatives
- Acts as change agent towards the NCA's for changes within the Network and in resolving technical issues impacting the Network.
- Facilitates the NCA IT Directors and Experts community – liaising with the relevant IT experts in the NCAs, including IT Directors, Architects and other relevant experts, and bringing the consolidated point of view to NICTAC.

2. Composition

Composition of the NICTAC members is as follows:

- NCA representatives (4)
- European Commission representative (1)
- Head of EMA I-Division (1)
- Head of I-Division CIO Office (1)
- EMA I-Division Enterprise architect (1)
- EMA Head of Information security (1)
- Head of EMA I-Division Strategic Platforms Department (I-SP) (1)

3. Committee appointment, terms and renewal

NCA NICTAC members:

The four NCA representatives are nominated by the Heads of Medicines Agencies. The Committee membership should represent both human and veterinary agencies and have a broad geographical spread. They can include IT Directors, Enterprise / Data Architects, or other IT experts.

Terms and renewal:

The Committee members are initially appointed for a two-year period. After two years there should be an annual review to ensure that the membership remains appropriate with adequate rotation and to ensure other Member States have the opportunity to participate.

Chair and Vice-Chair:

A Chair and Vice-chair should be nominated. The chairing roles will rotate between the Head of the EMA I-Division and an NCA representative every two years. For the first term, EMA will assume the chair role and one NCA IT Director will assume the Vice-chair role as of Autumn 2021.

Every two years, NICTAC must evaluate its compliance with the committee composition rules (rotation, membership). This process is coordinated by the CIO Office in I-Division and the results should be shared with the EMA Management Board.

3. Performance and compliance

Every year, the Office of the CIO will measure committee performance to determine performance and compliance with their own roles, responsibilities and terms of reference. If any gaps are identified, a specific action plan should be drafted during a yearly retrospective workshop facilitated by the Office of the CIO.

4. Meetings

The meeting cadence of the NICTAC will consist of six meetings per year, including 2 face-to-face meetings.

In addition, the NCA members of the NICTAC can attend the following Agile ceremonies as an observer on a voluntary basis:

- Quarterly Portfolio Sync
- Quarterly Strategic Portfolio Review
- System Demo
- Programme Increment Planning

5. NICTAC interactions

The NICTAC is responsible for the interaction with:

- **National Competent Authorities IT Directors and Experts community:** The NICTAC represents the Network and its technological needs; as a result the NICTAC needs to communicate relevant topics (when necessary) to the NCA IT Directors and Experts community. In return, the NICTAC handles the topics put forward by the NCA IT Directors and Experts community.
- **Enterprise Architecture Board (EAB):** The NICTAC acts as an escalation line on interoperability impediments for the Value Streams. It should identify non-compliance issues

according to the Baseline Enterprise Architecture and Architecture Principles and escalate to the EAB when relevant. These can include

- Input regarding technical needs stemming from NCA (local) IT implementation roadmaps, interoperability requirements, data requirements, and system and resource dependencies within the Network initiatives
- Advice on policy proposals

6. NCA IT Directors and Experts community

In collaboration with the HMA, EMA will maintain a distribution list of representatives of the NCA IT Directors and Experts community to ensure regular communication on Information Management (IM) related matters. These communications will include updates related to cyber-security matters, materials from the Portfolio ceremonies and System Demos, updates from NICTAC meetings, relevant EMA events and other IM activities as relevant, as well as invitations to any meeting hosted by the country holding the presidency of the Council of the European Union for the community.

Meetings of the NCA IT Directors and Experts community will be arranged in collaboration with the respective EU Presidency. When the meeting is taking place in a face-to-face format, EMA will reimburse one representative per National Competent Authority for their attendance to the meeting (travel, accommodation and daily allowance included), for a maximum of two face-to-face meetings per year.

7. Secretariat

The Secretariat is managed by the CIO Office of the EMA. This includes meeting organisation, agenda, outcomes, and communication with the various NICTAC stakeholders.