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EMA CIO Office

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 topics 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 EMA, the National Competent Authorities and the Commission (the Network) in the value streams.

1. Role of the Board

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

- Provides input on technology needs, priorities, and policies from NCA and/or Industry
 - Advice on technology implementation choices across the Network
 - Input on interoperability requirements across the Network
 - Input and advice on 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 Network and in resolving technical issues impacting the Network.
- Facilitates the NCA IT Directors and Experts – liaising with the relevant IT experts in the NCA, including IT Directors, Architects and other relevant experts, and bringing the consolidated point of view to NICTAC.

2. Composition

Composition and role of the NICTAC members is as follows:

- NCA representatives (4)
- EC/DG Digit 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 Board 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 Group 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 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 CIO office 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 from Autumn 2021.

Every two years, NICTAC must evaluate its compliance with board composition rules (rotation, members). This process is coordinated by the Agile Portfolio Office (PMO) and the results should be shared with the MB.

3. Performance and compliance

Every year, the Office of the CIO will measure board 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 board retrospective workshop facilitated by the Office of the CIO.

4. Meetings

The meeting cadence of the NICTAC will consist of six meetings per year, with two being face-to-face.

In addition, the NCA Vice-chair member 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 event

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 Committee needs to communicate relevant topics (when necessary) to the NCA IT Directors and Experts. 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. Secretariat

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