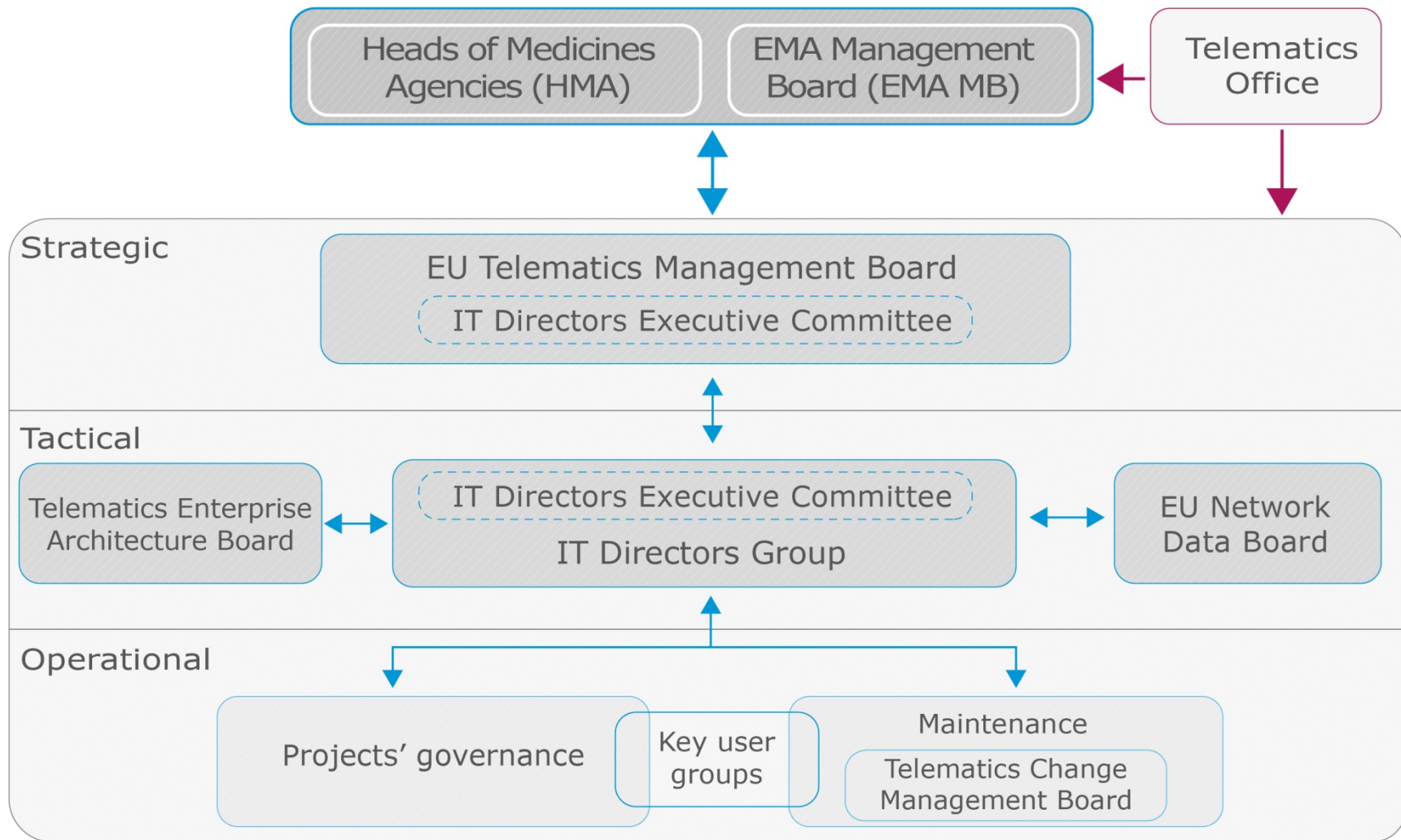
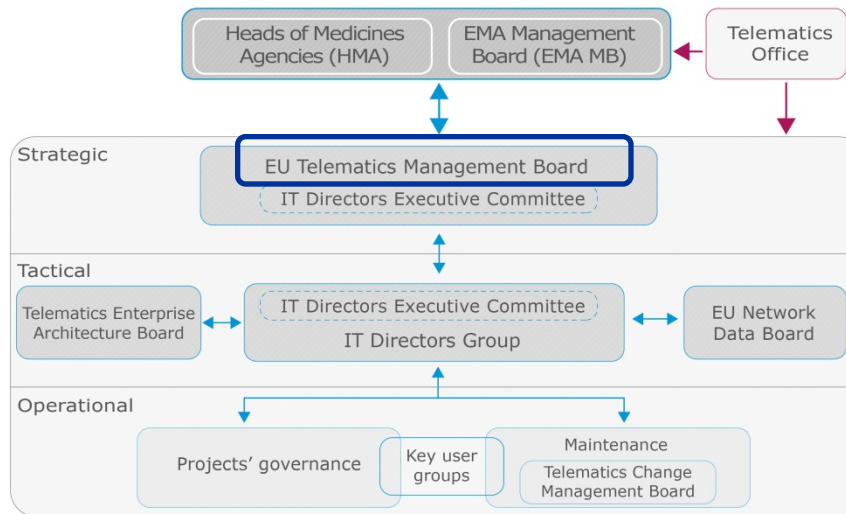


Telematics Governance

Telematics Governance Model



EU Telematics Management Board (EU TMB)



Terms of Reference



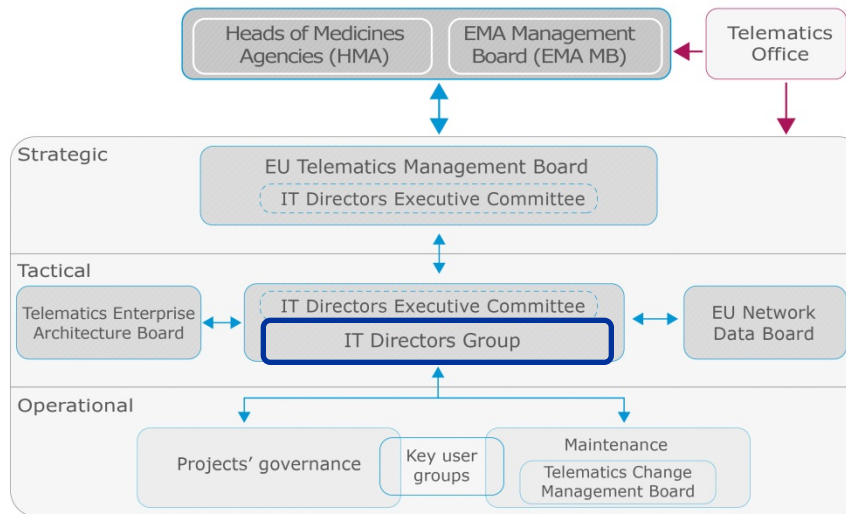
Composition

- Chair (NCA), Vice-Chair (EMA)
- 3 HMA
- 3 EMA Management Board incl. EC and Civil society
- 3 EMA
- IT Directors Executive Committee
 - 3 EMA IT
 - 3 NCA IT Directors
- 1 EMA IT Liaison Officer

Role:

- The EU TMB is a strategic governance body principally responsible for establishing the EU Telematics strategy and then providing strategic governance as to its implementation
- The Board operates on behalf of the European Medicines Regulatory Network
- The EU TMB reports and advises on IT related topics to the EMA Management Board and Heads of Medicines Agencies (HMA)

IT Directors Group



Terms of Reference



Role:

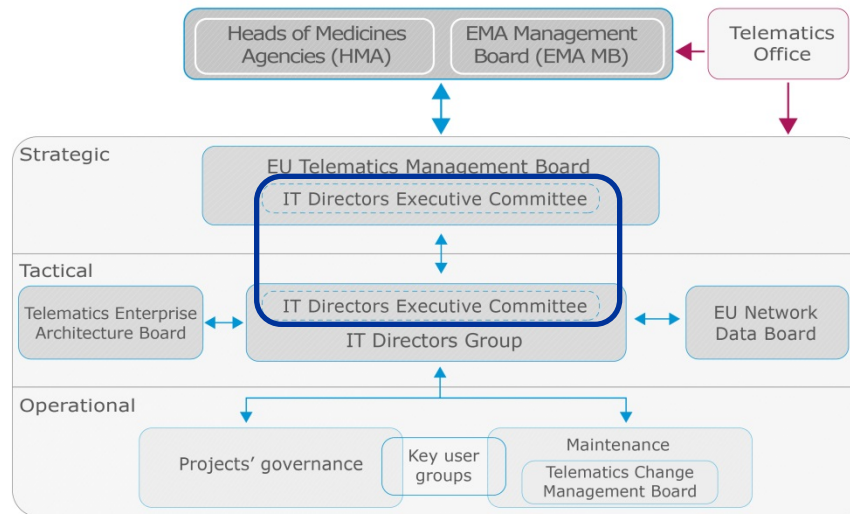
- The IT Directors Group functions at the tactical level within the Telematics governance structure and oversees both project and operational activities
- The Group is mandated to agree and implement the EU Telematics strategy through a series of programmes and projects
- It also provides forum for exchange of ideas, experience and vision within the network

Composition

Chair (EMA), Vice-Chair (NCA): rotates every 2 years

- 1 IT Director per NCA
- 1 EC (DG SANTE)
- 3 EMA IT
- 1 EMA IT Liaison Officer

IT Directors Executive Committee (IT DEC)



Terms of Reference



Role:

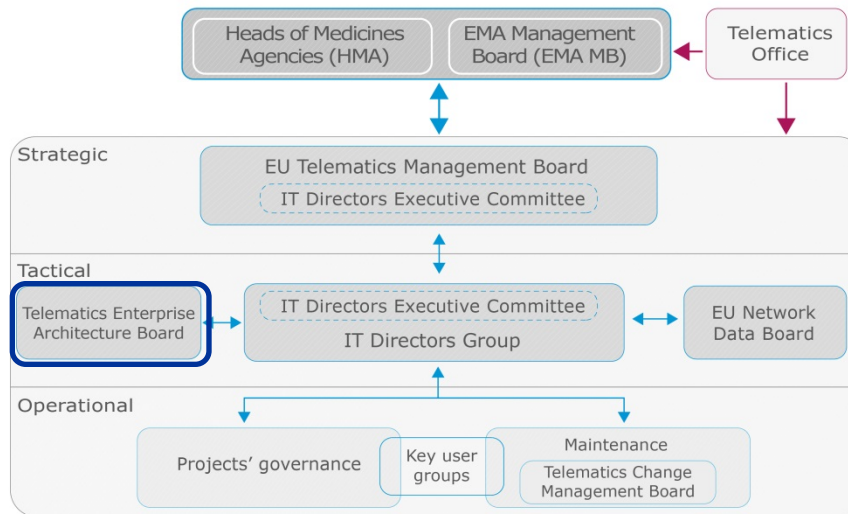
- The Committee acts as a core group within the IT Directors Group
- It forms part of the EU TMB and provides a liaison between the IT Directors Group and the EU Telematics Management Board
- The IT Directors Executive Committee executes the approved vision and strategy as decided upon by the EU TMB and the IT Directors Group

Composition

Chair (EMA), Vice-Chair (NCA): rotates every 2 years

- 3 EMA IT
- 3 NCA IT Directors

Telematics Enterprise Architecture Board (TEAB)



Terms of Reference



Composition

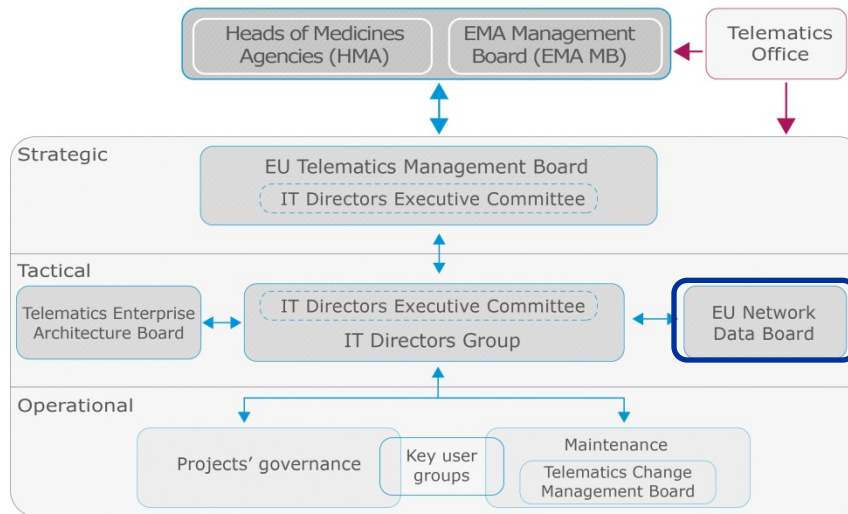
Chair (EMA)

- 4 EMA
- 5 NCA
- 1 EC (ISA DIGIT)

Role:

- The Telematics Enterprise Architecture Board develops and manages the EU Telematics enterprise architecture and the information architecture
- It sets standards and provides advice to partners within the Network intended to promote adoption of a common architecture where possible or at least inter-operability where integration is not possible or desirable

EU Network Data Board (EU NDB)



Terms of Reference



Composition

- Chair (EMA), Co-chair (NCA)
 - 15 NCA
 - 7 EMA (4 business and 3 IT)
 - 1 EC
 - 1 EDQM (European Directorate for the Quality of Medicines)
 - 1 Observer

Role:

- EU NDB is an advisory body which 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
- The Board is responsible for the development of the data management strategy, data related standards, including alignment with international standards, and the quality of master referential data (SPOR)

Projects governance

- The aim is to establish structures to assure the joint project delivery of the Telematics portfolio in the most efficient manner possible
- Governance of the Telematics projects run by the EMA and NCAs may differ
- Requirements gathering and consultation is undertaken through key user groups established for the purpose in the context of the projects' objectives
- After the project closure a key user group may be required to continue overseeing maintenance activities of the new system
- There is a continuous interaction between the projects governance and Telematics governance via regular reporting

Key user groups

Experts groups set up to support the delivery of new Telematics systems (typically projects) and on-going maintenance activities of those systems if required.

Composition: EMA, NCAs and Industry (when required)

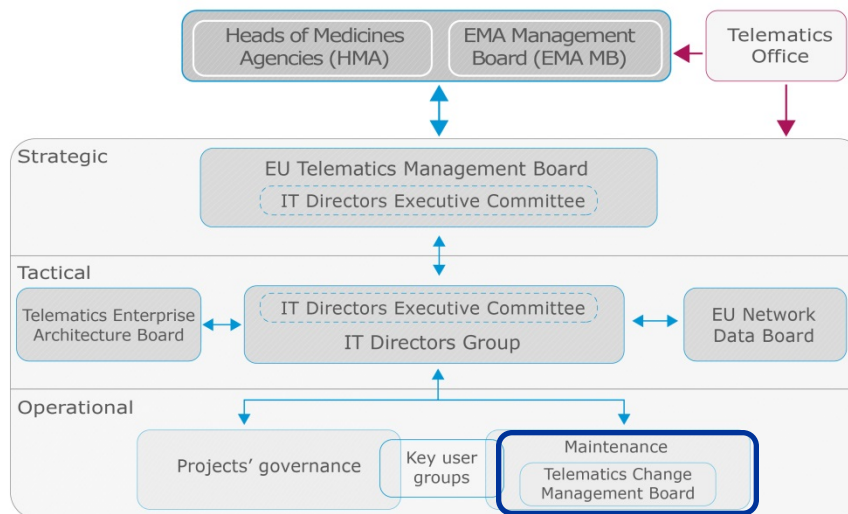
Programmes	Key User Groups*
eCollaboration	PSUR Repository Maintenance Group*, eSubmission CMB, eAF MG*, Harmonisation Group-H*, Harmonisation Group-V*, eCTD v.4 MG*, Common Repository MG*, Common Repository WG for Veterinary Implementation
Pharmacovigilance	Eudravigilance Expert WG*, Pharmacovigilance Business Team
Clinical Trials	Clinical Trial Programme Subgroups: SG 1*, SG 2, SG 3, SG 4*, SG 5*, SG 6*
Data Integration	EU IDMP/SPOR Task Force Group*, sub-groups S&P*
Veterinary	Consultative group for Veterinary Medicinal Product Data Systems, Consultative Group on Veterinary PhV systems*

* Industry involvement

Maintenance

Maintenance activities of Telematics systems focus on the delivery of appropriate service levels, coordination of change requests and enhancements control.

Telematics Change Management Board (CMB)



Terms of Reference

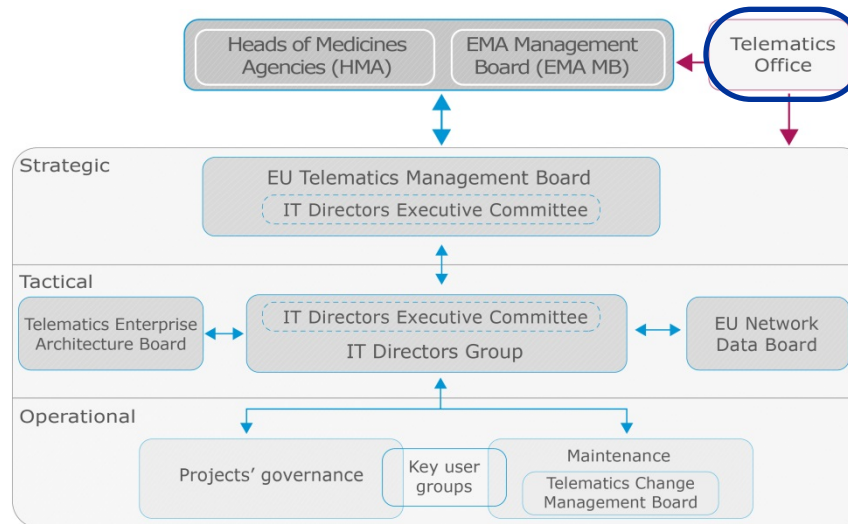


Role:

- Assist in the classification of business change requests and review the prioritisation of business change requests across services, including business prioritisation criteria
- Propose major changes or development project when these change requests cannot be handled under maintenance activity
- Review the development and implementation roadmaps for systems life-cycle across services to ensure alignment with the Telematics strategy

Telematics Office

The Telematics governance is supported by the Telematics Office which coordinates between the governance bodies.



Role:

- Ensures appropriate coordination between the Telematics governance bodies
- Oversees the link between the Telematics governance, EMA MB and HMA via regular reporting
- Provides administrative support to the Telematics governance bodies
- Supports implementation of the Telematics roadmap
- Acts as a main point of contact for Telematics related enquiries
- Assists in relation management with partners and stakeholders and communication and training activities