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## Change management governance for EU Telematics systems

This document describes the Terms of Reference (ToR) of the Telematics Change Management Board (CMB) and its key user groups (when applicable).

### 1. Change Management Governance

The Telematics Change Management Board is a body of the European Telematics Governance Structure, subordinate to the IT Directors Group and the IT Directors Executive Committee.

Its main task is to oversee Business Change Requests (BCR - changes (addition, modification or removal of anything that could have an effect on IT services) that involve business applications) that are approved and classified by Service Delivery Manager (SDM)/Service Technical Manager (STM) which affect Telematics IT systems in production (i.e. after being handed-over from projects to operations).

For systems maintained by EMA, change requests are handled by the SDM and the STM in accordance with a Service Delivery Model. The SDM manages the life-cycle of operating Telematics systems clustered into services and is the contact point between the key user groups, the Telematics CMB and the STM. The SDM is responsible for approving the proposal for business change requests in the EMA Service Desk Portal. The STM provides technical expertise, solution and timelines on the Telematics systems he/she is overseeing. The STM is also responsible for ensuring communication between SDM and the Change Authorisation Board (CAB), body responsible for supporting the authorization of changes and assisting change management in the assessment, prioritization and scheduling of changes. The STM keeps the SDM informed of the status of implementation and deployment of the changes requests by the CAB.

For Telematics systems not maintained by EMA, the NCA maintaining the system should provide an overview of change requests to the Telematics CMB.

### 2. Key User groups mandate and composition

Key user groups are set up to act as subject matter expert groups to support the delivery of new Telematics systems or major evolutions of systems (typically projects) and on-going maintenance activities of systems. They can also deal with process matters, harmonization and guidance.

A key user group is set up to support a project and ceases to exist at the closure of a project unless the group is required for the maintenance activity for the system which cannot be undertaken by another existing key user group. The composition of the project key user group could however at that time be revised to support maintenance activities.

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See websites for contact details

Key user groups consist of the European Medicines Regulatory Network (EMRN), business representatives and, if relevant, also IT representatives. They are nominated by querying NCAs and EMA for candidates for chairs, vice-chairs and members. User groups' members must be experts of the system(s) or processes in question. They are preferably persons who have been involved in the development and/or are daily users of the system. Members must have explicit sponsorship from their management.

Representatives of other organisations, including industry, can be invited to the key user groups' meetings as experts or as observers. They should have a good business understanding of the subject domain in question and sufficient IT experience relevant to the task at hand. Members from industry associations represent their association, rather than specifically their own company. Observers should be appointed at least in cases where changes having a major impact on interfaces between the EMRN and stakeholders or stakeholder processes are considered.

Each key user group may develop its own Terms of Reference (with a standard format), which should be reviewed by the Telematics CMB, the IT Directors Executive Committee and the IT Directors group.

Working in close collaboration with the SDM, the responsibilities of key user groups members include:

- Reviewing and approving the proposal for change requests based on their benefits, risks if the change is not implemented, urgency and deadline for delivery.
- Prioritising the business change requests pertaining to individual Telematics systems (based on defined business prioritisation criteria).
- Promoting the full utilisation of Telematics systems within EMRN
- Liaising between each other and stakeholders (e.g. CMDh, CMDv, PRAC, etc.)
- Initiating or giving input to development projects
- Observing the legislative and standard landscape of their subject domain to keep Telematics systems up to date in this respect
- Providing subject matter expertise for their system(s)
- Taking ownership of the development and implementation roadmap for their system(s)
- Informing users about changes to the systems
- Developing and maintaining guidance documents related to systems
- Developing and maintaining guidance documents related to standards and development and update of new standards.

SDMs overlooking key user groups report on their activities to the Telematics CMB on a quarterly basis.

## **3. Telematics Change Management Board**

### **3.1 Mandate**

The mandate of the Telematics CMB is:

- To review and advise on the business process for Change requests management of Telematics systems
- To review and advise on the prioritisation of business change request across services

- To propose major changes or development projects to the IT Directors Executive Committee when they cannot be handled under the applications maintenance responsibility
- To approve the development and implementation roadmaps for systems life-cycle across services and to ensure alignment with the Telematics strategy
- To agree and advise on how the different business change requests coming from the key user groups should be consolidated to ensure consistency and alignment with the Telematics strategy
- To advise on the impact of proposed business change requests on the existing processes, systems and resources in the EMRN
- To review harmonisation guidance and guidance related to standards
- To provide guidance on change management aspects (e.g. training, communication) related to the approved business changes request, service roadmaps or similar to the Network.

### **3.2 Composition and working practices**

The composition of the Telematics CMB consists of a chair, a vice-chair, members and observers. It is important that the group covers both IT and business understanding/knowledge. The maximum size of the groups is twelve (12) to ensure effective working. The chair is a business EMA representative and the vice-chair should be an NCA representative with an IT background. There should be up to five (5) NCAs (representing the human and veterinary business domain) and up to seven (7) EMA and NCAs SDM representatives as members. Members of the Telematics CMB should have a good understanding of the whole life-cycle of medicinal products and a holistic view of the Telematics systems. They should have the capability to understand the interfaces to other Telematics systems, the impacts of change requests and be able to prioritise them across services.

Other experts (EMA, NCAs or industry) could be invited to participate in discussions as and when required.

The NCA members represent all NCAs, not only their national agency.

CMB members are elected for two year periods by the ITDEC on the basis of personal competence. Election is done by querying NCAs and EMA for candidates for chairs, vice-chairs and members. The IT Directors Executive Committee has also the mandate to appoint a chair and/or a vice-chair on the basis of personal competence if the nomination cannot be done otherwise.

CMB chair and vice-chair will decide whether a replacement is needed if a member leaves the board. The replacement will be asked from NCAs with the best possible expertise of the system and will be elected by the ITDEC on the basis of personal competence. The nomination procedure is always started if the chair or vice-chair leaves. Replacements may not change the balance between EMA and NCA members.

The Telematics CMB reports the IT Directors Executive Committee on a quarterly basis and the IT Directors group (standing agenda item). The report is forwarded to all SDMs for distribution within their key user groups and discussion when required.

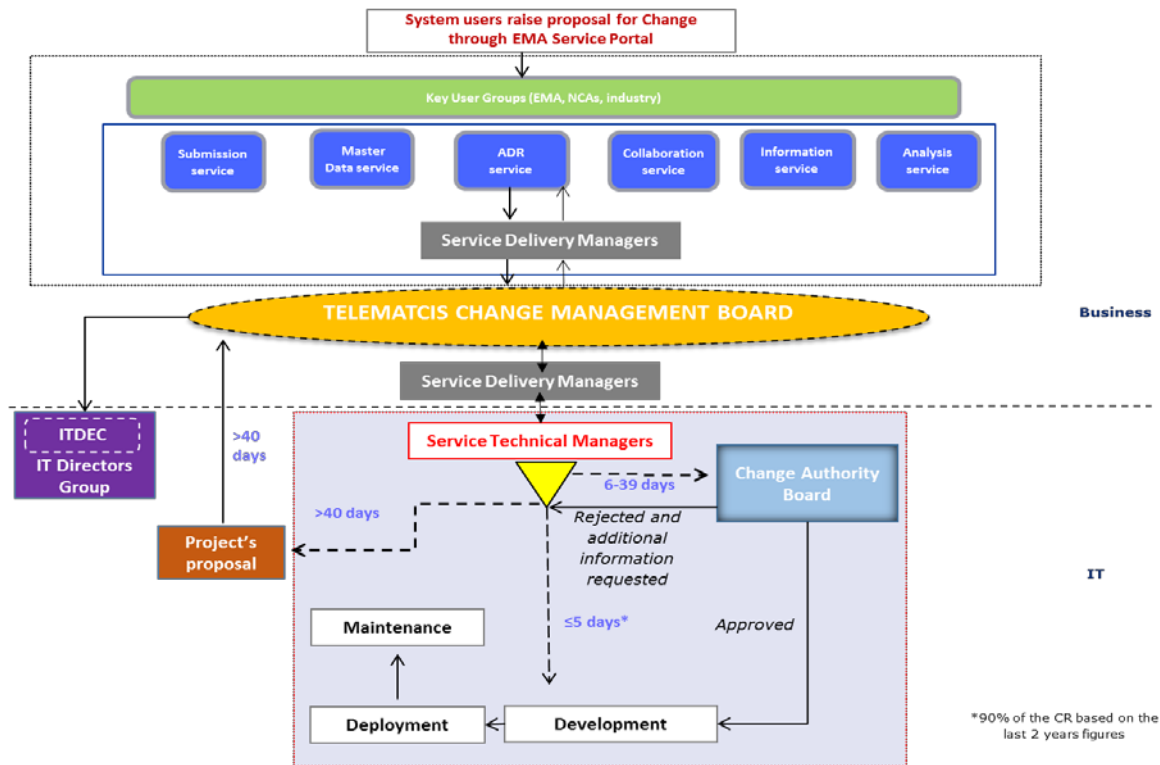
### **3.3. Meetings**

Telematics CMB meets via virtual meetings on a quarterly basis.

Standard meeting agendas are prepared by the chair and vice-chair and circulated together with the meeting invitation and any agenda updates and related materials should normally be sent at least one week in advance.

# Annexes

## - Change request process



## - Telematics governance

