

17 October 2013
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IT Directors Group

Terms of reference

Within the joint EU Telematics governance framework, the IT Directors Group plays a crucial role in the realisation of the joint endeavour aiming at an improved collaboration for Telematics projects, maintenance and operations.

The **IT Directors Group** functions at the tactical level within the Telematics governance structure to agree, jointly coordinate and supervise the Telematics activities (points a and b below). The group also has a broader ambition (point c):

- a. Tactical EU Telematics portfolio management
- b. IT operations and maintenance of EU Telematics IT services
- c. Forum for exchange of ideas, experience and vision within the network

It has been agreed that a core group within the IT Directors Group, known as the **IT Directors Executive Committee**, provides a liaison between the full IT Directors Group and the EU Telematics Management Board (EU TMB).

1. Composition

1.1. The **IT Directors Group** consists of:

- One IT Director per NCA, as nominated and agreed by each relevant NCA
- One representative of the European Commission (DG SANCO)
- Three EMA representatives (including CIO and IT managers)
- The EMA IT Liaison Officer

Membership criteria

- Individual

The representative should be a Director of Information Technology, or equivalent. He should be empowered, in liaison with the business, to represent the competent authority on IT matters of strategic importance and be in a position to influence the development of the planning of the authority represented.



- Organisation being represented

The organisation should be either a National Competent Authority responsible for the regulation of Medicinal Products for human and/or veterinary use in the European Economic Area or the European Medicines Agency or The European Commission.

A National Competent Authority is an authority within one of the Member States of the European Economic Area that is empowered by the laws of that state to execute at least two of the three following functions:

- to issue a marketing authorization for a medicinal product for human and/or veterinary use valid for that state;
- to authorise and supervise the conduct of clinical trials in that state; and
- To regulate medicinal products through pharmacovigilance activities.

The chair and vice-chair will rotate between the EMA CIO and an NCA IT Director every two years. For the first term, EMA will assume the chair role and one NCA IT Director will assume the vice-chair role in July 2013. The chair and vice-chair will also act as chair and vice-chair of the IT Directors Executive Committee.

Substitution for delegates unable to attend the meeting will be authorised by the Chair following receipt of a written request from the Head of the relevant agency. It is expected that alternates will be empowered to vote and to take decisions on behalf of the body they represent.

Should a nominated member be unable to attend meetings for a continuous period of 12 months, the relevant Head of Medicines Agency will be informed of the members' inactive participation.

The group will be supported by the Telematics Project Management Office (PMO) and the Telematics Secretariat.

Communications with all stakeholders will be managed by the IT Liaison Officer and channelled via the Telematics Secretariat.

1.2. The **IT Directors Executive Committee** consists of six individuals who will also sit on the EU TMB:

- Three representatives of three distinct National Competent Authorities as nominated by the IT Directors Group, and agreed by their relevant NCA
- Three EMA representatives (including CIO and IT managers)

The Chair and Vice-chair will rotate between the EMA CIO and an NCA IT Director every two years. For the first term, EMA will assume the chair role and one NCA IT Director will assume the Vice-chair role in July 2013. The chair and vice-chair will also act as chair and vice-chair of the IT Directors Group.

The Group members are initially appointed for a two year period. After that period there should be an annual review to ensure that the membership remains appropriate whilst ensuring adequate rotation.

The group will be supported by the Telematics PMO and the Telematics Secretariat

Communications with all stakeholders will be managed by the IT Liaison Officer and channelled via the Telematics Secretariat.

2. Role of the IT Directors Group includes:

- 2.1. Execution of the approved vision and strategy as decided upon by the EU Telematics Management Board.
- 2.2. Fostering alignment in joint IT cooperation.
- 2.3. Feedback on projects and operations to the EU TMB and assuring that the execution of EU Telematics activities fits with the approved EU Telematics strategy.
- 2.4. Tactical EU Telematics portfolio management will be driven by the IT Executive Committee:
 - Tactical portfolio management, meaning the supervision of the entire Telematics program portfolio, which includes:
 - Establishment and maintenance of the project prioritisation process for EU Telematics with a strong focus on the business case
 - Application of the prioritisation process; establishment and maintenance of the project pipeline for annual review by the EU TMB
 - Ensuring that IT proposals are consistent with legal frameworks at EU & national level.
 - Reviewing and approving specific program structures and associated boards.
 - Escalation of prioritisation or funding issues to the EU TMB.
 - Acting as a point of escalation to the EU TMB in respect of the impact of legislative changes on the EU Telematics programme.
 - Ensuring that the EU TMB is fully briefed with regard to the status of the portfolio and the execution of the strategy.
 - Presenting the recommendations of the IT Directors Group and supporting the business case to the EU TMB where funding is required
 - Reporting to the IT Directors Group and representing that group within the EU Telematics Management Board.
- 2.5. The IT Directors Group will supervise IT Operations and maintenance of EU Telematics IT services:
 - Supporting the IT services at operational level, making sure that they are well secured and controlling their maintenance by making sure that:
 - changes are made when needed;
 - there is an alignment across the network.
 - Developing scenario based evaluations and impact analyses of the effect of proposed new legislation through the EU TMB in order to inform the HMA, EMA MB and the European Commission of the likely impact of legislative changes on the EU Telematics programme.
 - Ensuring that dependencies & risks are considered from the perspective of the impacted stakeholders.
 - Identifying the EMA, NCA and external stakeholder resource requirements required to support the various Telematics initiatives.
 - The IT Directors may seek independent technical advice, as appropriate.
- 2.6. The IT Directors Group will also be a forum for exchange of ideas, experience and vision within the network

- Reviewing the status of the applications portfolio.
- Informing impact analysis associated with the portfolio.
- Ensuring that project portfolio information is shared effectively with the wider EU network and to support appropriate consultative and feedback mechanisms.
- Ensuring that cross-project dependencies are fully addressed.
- Ensuring that feedback from the EU TMB via the IT Directors Executive Committee is shared with the network as a whole.
- Exchanging experience of implementation and reconciling processes.

3. Meetings

For the IT Directors Group:

- 3.1. The group meets a minimum twice per year.
- 3.2. All documents will be circulated to the members of IT Directors Group not less than 10 working days in advance of each meeting.
- 3.3. Agreements should be reached by simple majority vote to reflect the wishes and intentions of the larger group. While agreements are not binding on any Member State, IT Directors Group members agree to validate agreements within their organisation and provide direct feedback in respect of their ability to implement agreed positions. Voting by proxy is permitted, but maximum one proxy per member.
- 3.4. Minutes of the meeting will be taken by the Secretariat and will be circulated to all members of the Committee for comment within 2 weeks of the meeting date. Minutes should be approved by written procedure.
- 3.5. Each member of the IT Directors Group will be reimbursed for travel and per diem by the Agency in accordance with the Agency's reimbursement rules whether the meeting will be taking place at or outside EMA.
- 3.6. The Telematics PMO will co-ordinate the preparation of the necessary materials for project reporting to the IT Directors Group.
- 3.7. The quorum for the Group meetings is at least 50% of members.

For the IT Directors Executive Committee:

- 3.8. Meetings will be held monthly by teleconference and face-to-face as necessary.
- 3.9. The Committee will also attend the meetings of the EU Telematics Management Board.
- 3.10. Decisions should be agreed by unanimous consensus.
- 3.11. Members of the IT Directors Executive Committee will be reimbursed for travel and per diem by the Agency in accordance with the Agency's reimbursement rules whether the meeting will be taking place at or outside EMA.
- 3.12. The IT Directors Executive Committee minutes and outcomes will be circulated to the IT Directors Group.
- 3.13. All documents will be circulated to the members of the IT Directors Executive Committee not less than 5 working days in advance of each meeting.

- 3.14. Any member of the EU TMB, IT Directors Group or Telematics Enterprise Architecture Board can propose a Telematics project for approval with a business case to the IT Directors Executive Committee. The project should be supported by at least one representative of the IT Directors Executive Committee. This representative will make sure that the project is in line with Telematics and Enterprise Architecture strategies. The committee may escalate it to the EU TMB if needed.
- 3.15. An impact analysis on the full portfolio and a quantitative appraisal to the proposal must be provided by the Telematics PMO. Every proposal needs to be submitted 30 days before the next IT Directors Executive Committee meeting to be studied for 2 weeks and the amended document has to be submitted 5 working days before the meeting. The Telematics PMO will propose the process.
- 3.16. Minutes of the meeting will be taken by the Secretariat and will normally be circulated to all members of the Committee for comments within 2 weeks of the meeting date. Minutes shall be approved by written procedure.
- 3.17. The Telematics PMO will co-ordinate the preparation of the necessary materials for project reporting to the IT Directors Executive Committee.
- 3.18. The quorum for Committee meetings is at least 66% of members.