eSubmission expert group
Terms of Reference

This document describes the terms of reference (ToR) of the eSubmission expert group and its key user groups (formerly known as maintenance groups). It needs to be read in conjunction with the EU Telematics Change Management Board terms of reference (See doc "EMA/620721/2017").

1. Description

The eSubmission expert group coordinates issues of its key user groups. The eSubmission expert group is subordinated to the IT Directors Executive Committee (ITDEC) and IT Directors Group for all business related topics, and should also report to the Telematics Change Management Board (CMB) for any system related technical matters. The group aims to have an overview of the non-technical implementation activities in the eSubmission key user groups and have an overall decision making role for eSubmission related specifications and guidance documents that are drafted within the key user groups.

The eSubmission expert group consists of European Medicines Regulatory Network (EMRN) IT and business representatives both from the European Medicines Agency (EMA) and National Competent Authorities (NCAs) and should have knowledge and experience of eSubmission within the regulatory framework. Members of the eSubmission expert group are elected as permanent members. New members can be nominated by any NCA when a member leaves the group and are confirmed by the ITDEC following a call for interest.

Industry stakeholders' knowledge and opinions are taken into account in the respective key user group, where they have roles as experts or observers.

2. Mandate

2.1 General

The eSubmission expert group is responsible for:

- Processing drafts and adopting new and updated harmonised guidance, eCTD and VNeeS specifications, validation criteria and other relevant eSubmission documents and planning for activities related to business implementation

- Liaising between the different key user groups, business groups and with stakeholders

- Initiating or giving input to development projects within the eSubmission area

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See websites for contact details

- Observing changes in the business, legislative and standard landscape of the eSubmission domain to keep Telematics systems and related documents up to date in this respect

- Taking overall ownership of the implementation roadmap for related systems

The eSubmission expert group deals with process matters, harmonisation of implementation and user guidance documents. They also assist the Network Data Board and business bodies like the Coordination Group for Mutual Recognition and Decentralised Procedures – Human and Veterinary (CMDh and CMDv) in these matters when needed. The same applies to specification development (e.g. eCTD or VNeeS).

The eSubmission expert group is also responsible for drafting of updates of eSubmission Roadmap related to the Telematics strategy and to follow up on its implementation.

2.2 eSubmission expert group subject domains

- Maintenance and harmonisation of implementation of e-submission telematics systems;

- Draft, review and adoption of guidance documents.

The subject domains are the following:
- Human Harmonisation of specifications and guidance

- Veterinary Harmonisation of specifications and guidance

- Electronic application form (eAF) / Common European Single Submission Portal (CESSP) project

- Common Repository

- eCTD v.4

- PSUR Repository

- Gateway v.3

2.3 Key user groups

The eSubmission expert group gets continuously oral reports from each related key user group. For the general responsibilities of the key user groups, please refer to the Telematics CMB ToR.

The keys user groups that are connected to the eSubmission expert group are the ones related to the subject domains mentioned above.

3. Composition

3.1 eSubmission expert group

The composition of the eSubmission expert group consists of the chair, vice-chair(s) and members. The chair and vice-chair(s) are NCA and EMA representatives so that neither party can hold both positions. Preferably one of them has an IT and the other one a business background.

There should be up to 10 NCAs (proportionally representing human and vet and business and IT) and up to four EMA representatives (human, vet, IT development and IT data) as members, ideally a balanced mix of IT and business experts. They together should have a good understanding of the whole life-cycle of medicinal products. They must be in a position to be able to observe the legislative

and standard landscape of their subject domain to keep Telematics systems up to date in this respect. They should be able to take a holistic view of business and systems and have the willingness to co-operate across organisational boundaries.

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

The eSubmission expert group is a regulators only group.

eSubmission expert group members are elected as permanent members by the ITDEC on the basis of personal competence. New members can join when old members leave or there is a need for new competence to be added to the group. Acceptance of members is done after nomination by NCAs and EMA for candidates for chair, vice-chairs and members. Those with most support will be elected after getting their personal and superior's approval. More pinpoint queries will be done in case no-one gets a majority support. The ITDEC has the mandate to appoint a chair and/or a vice-chair on the basis of personal competence if the nomination cannot be done otherwise. Exchange of members could also be approved by ITDEC after proposal from the group.

At least one member in the eSubmission expert group should also be a member of the Telematics CMB.

Replacements may not change the balance between EMA and NCA members.

There is a need to regularly liaise with certain groups such as CMDh and CMDv. Therefore, the following liaison roles are defined and will be fulfilled by eSubmission expert group members:

➢   eSub expert group - CMDh Liaison

➢   eSub expert group - CMDv Liaison

CMDh and CMDv will also be asked for nomination to relevant key user groups related to the eSubmission expert group

3.2 Key user groups

Each key user group that is related to the eSubmission expert group must have a Chair from an NCA or EMA (IT or Business) that is a member of the eSubmission expert group that report on major topics and also present any documents that should be adopted by the eSubmission expert group. The members must be experts of the system(s) or document area in question.

Chair, vice-chairs and members must have explicit sponsorship from their management.

Representatives of other organisations, including industry, can be invited to key user groups as experts or as observers. They should have good understanding of the subject domain in question and sufficient IT and/or regulatory skills 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 EMRN and industry stakeholders or stakeholder processes are considered.

The maximum size of the groups is up to the chair to decide to assure effective working.

Key user group members are always appointed on the basis of direct selection by the Key user group Chair.

4. Co-operation and Reporting

4.1 Co-operation

The eSubmission expert group chair and vice-chair should be invited to at least one meeting per year to the IT Directors Executive Committee. The Telematics Secretariat co-ordinates the invitation.

The co-operation between the eSubmission expert group and the telematics CMB is handled through the common membership.

4.1.1   Reporting from Ongoing Projects

The eSubmission expert group will be kept informed on eSubmission related ongoing projects. To that end, where appropriate, project managers will be invited to informally brief the eSubmission expert group if not already covered through the key user groups chairs (being members of the eSubmission expert group).

5.   Working Practices

The aim in decision making is to find a common understanding. In case a consensus cannot be found the alternative supported by the majority of the eSubmission expert group members will win. If two or more alternatives have equal support, the one supported by the chair is chosen. Urgent decisions can be taken via written procedure if required.

The Telematics Secretariat will assist the eSubmission expert group in meeting arrangements. Other aspects of meetings (e.g. minute taking) will be organised by the chair and co-chair.

The eCollaboration Programme at EMA will also provide support for meetings of the key user groups in terms of meeting arrangements; other aspects of key user group meetings (e.g. minute taking) will be organised within the key user groups themselves.

Relevant information and adopted documents will be published on the eSubmission website.

6.   Meetings

6.1 eSubmission expert group meetings

eSubmission expert group meets virtually on a bi-weekly basis with potentially one face-to-face meeting per annum after approval by ITDEC. Meeting agendas are prepared by chair and vice-chair(s) and circulated together with the meeting invitation. Action points and post-meeting documentation will be distributed within a week after the meeting.

Recurrent agenda items are review reports from related key user groups including keeping track of needs for updates of documents supervised or adopted by the the PMS target operating model. The eSubmission expert group chair or an appointed member should report at least once a year to the ITDEC.

The documents related to the meetings of the eSubmission expert group will be published in the EMA MMD system, accessible to all members.

At least 50% of the members must take part in the eSubmission expert group meeting for the eSubmission expert group to be quorate.

eSubmission expert group virtual meetings are facilitated by EMA.

About This Document

Document History

Version	Who	Date	What
1.00	OS	16 Jun 14	Adaptation of the generic ToR based on the discussions in the eSub CMB meeting on 15 May 14
01.02	KP	17 Jun 14	As proposed to the eSub CMB for discussion
01.05	OS	15 Jul 14	Integrated feedback eSub CMB Members
01.06 - 01.08	OS	28 Jul 14	Integrated more feedback eSub CMB Members
01.09	KG	10 Jan 2018	Reworked version due to changes in the Telematics structure. eSubmission CMB to be renamed Expert Group and to have a coordination role for the related Maintenance Groups (key user groups) and direct responsibilities only in terms of new and updated documents within the remit and implementation of the eSubmission Roadmap.
01.10	eSubmission CMB members	13 Apr 18	Finalisation of the review of the complete document, clarifying the fact that the eSubmission expert group reports directly to the ITDEC and reports for specific topics to the Telematics CMB.
02.00	Telematics CMB / ITDEC	06 Jun 18 / 07 Jun 18	Adoption