EU Change Control Process for Change Requests in the Entire Area of Electronic Submissions for Human Medicinal Products

Version 2.1
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Document Control

Change Record

Version	Date	Author(s)	Comments
0.1	10 September, 2003	Miguel Bley	Draft
0.2	11 September, 2003	Miguel Bley	Draft
0.3	23 September, 2003	Miguel Bley	Draft
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1.0	1 July, 2004	Miguel Bley	Adopted by the TIGes for publication on NtA
1.1	8 December 2006	Miguel Bley	Change of submission address to ectd@emea.europa.eu adopted at TIGes meeting on 20 November 2006
2.0	23 November 2010	Klaus Menges	Complete revision due to the newly established change control process for changes requested in the entire area of electronic submissions, CR or Q&A referring to e.g. eCTD EU M1, eAF, EudraCT, RDM, Eudrapharm, etc.
2.1	05/05/11	Liesbeth Versteeg	Revision due to the newly established emailbox to separate change requests from other ectd communications and small changes requested to the change control process. References to PIM have been struck from the guidance since the project has been closed. Addition of Annex 2 Electronic Submission Change Request Process

Reviewers

Version	Name	Organisation
0.1	All participants in the meeting	TIGes
0.2	Miguel Bley	TIGes
0.3	All	TIGes/NtA-TIGes Interlinking
0.4	All	TIGes/NtA-TIGes Interlinking
0.5	All	TIGes/NtA-TIGes Interlinking/JIGes
1.1	Juan Rueda	EMEA
2.0	All	Joint TIGes-Industry Group
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Distribution

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2.1	08 June 2011	Joint TIGes-Industry Group	For review

INTRODUCTION

The eCTD Specification was signed by the ICH Steering Committee in September 2002 and adopted by the CPMP in November 2002. The Telematics Implementation Group for Electronic Submission (TIGes) validated the position of the EU regulators delegation at the ICH-M2 Expert Working Group (ICH-M2 EWG) that produced the eCTD standard. The TIGes administers EU eCTD standards including the regional specification on Module 1 and its task is to facilitate the implementation of eCTD by both applicants and Competent Authorities in the European Economic Area (EEA) as well as several surrounding projects in the entire area of electronic submission, e.g. eAF, EudraCT, RDM, Eudrapharm, etc.

Changes to the eCTD Specification are managed by the ICH-M8 Implementation Working Group (ICH-M8 IWG) and to the Module 1 (also M2.3.R. and M3.2.R.) by the Notice to Applicants Working Group through a harmonised Change Control Process. A larger number of other standards and guidance documents in use can be covered by a broader meaning of electronic submission. This also includes aspects of change regarding application forms (eAF), the submission guidances and validation criteria. As with the eCTD Specification, the EU standards in this area are likely to change due to technological progress, new concepts (i.e. for administrative forms and product information) and experience gained with the implementation of eCTD and of electronic submissions in general. For successful implementation of electronic submissions and processing, change control should be in place to effectively communicate and execute changes to the EU electronic submission standards and guidance documents. To manage this task a close collaboration and continuous communication between the eSubmission Change Control Board (CCB), the TIGes, the NtA via the Interlinking Group as well as the Harmonisation Group and other subgroups of the TIGes are pre-requisites.

SCOPE

This document establishes the change control process for EU eSubmission standards in the EEA, namely CR or Q&A referring to e.g. eCTD M1, eAF, EudraCT, RDM, Eudrapharm, etc., managed by the CCB. The purpose of the CCB is to accelerate decisions and results, improve the organisation and traceability of change requests, ensure follow-up of open items and improve performance of change request discussions at the TIGes meetings. The scope is all change requests for electronic submissions requirements and related guidances. With regard to change requests for harmonised aspects of the eCTD Specification in Modules 2 to 5, except M2.3.R and M3.2.R., the ICH-M8 IWG should be consulted.

PURPOSE

The TIGes is authorised by the Heads of Medicines Agencies (HMA) and steered by the Telematics Steering Committee (TSC) as part of a structure for the management of EU IT projects in the pharmaceuticals regulatory area endorsed by the Pharmaceutical Committee to administer changes to the EU eCTD and electronic submission standards. Change control is established to serve the following purposes:

- Evaluate and approve or disapprove proposed changes to the specification
- Ensure implementation of approved changes
- Represent the interest of all groups who may be affected by the changes

The change control process applies to all change requests for electronic submissions requirements and related guidances.

CHANGE CONTROL PROCESS

EU Electronic Submission Standards and Guidance Documents Questions and Change Requests

All change requests and questions regarding should be submitted by the requester to ectd.changerequests@ema.europa.eu in the CR Form (as attached in Annex 1 to this document and published on the electronic submission website http://esubmission.emea.europa.eu/tiges/index.htm as well). Questions regarding eCTD submissions and the day to day business should still be sent to eCTD@ema.europa.eu. The steps of the process for electronic submission changes are described in Annex 2.

Change Control Form

Each change request should minimally contain the following information:

- Title, which should specify the topic the CR or Q&A refers to, e.g. eCTD EU M1, eAF, EudraCT, RDM, Eudrapharm, etc
- Contact information
- Question or Change Request
  - Category
  - Level of urgency
  - Summary of the problem, including rationale
  - Submit date
  - Item to be changed / question
  - Version number and date of the EU eCTD standard or guidance document
  - Detailed explanation of the problem, including results of any testing
  - Recommended solution, if any
  - Preferred implementation date according to the level of urgency

The EMA will check confidentiality and completeness of content and send to the CCB. Rapporteurs of the relevant standard or guidance document should validate the content in advance to the next scheduled meeting of the CCB, normally 7 days before the meeting date.

Change Control Board Meetings

The CCB undertakes a preliminary analysis on the CR. A preliminary solution is proposed by the CCB, recorded in the CR Form and will be monitored in the Change Request Tracking Table. A consultation with relevant experts is possible as well as an escalation to contact the requester for clarifications whenever necessary or the direct referral to another group as detailed below.

In any case, the tracking table will be updated accordingly for internal use only until a final decision is taken at the TIGes-Joint quarterly meeting and then published. The table for publishing will be numbered with the next full sequence, e.g. 1.22, 1.23; numbering for internal use will follow the sequence 1.22.1, 1.22.2, 1.22.3.

Questions and Change Requests Review

The CR will be assigned to one of the following paths:

1. Defined as **out of scope** include:
   - Is not relevant
   - Issues related to Modules 2-5, except 2.3.R and 3.2.R., or to ICH-M2 eCTD guidance which are both under the auspices of the ICH-M8 IWG should be forwarded according to the ICH Change Control Process for eCTD via the respective representative in TIGes-J.
2. Defined as **in scope** after presentation and discussion of the change request for further review and testing so that it can be assessed and finally decided by the TIGes Group include:
   - for technical related CRs forwarding to TIGes-J
   - for regulatory content related CRs on CMD(h) and NtA WG owned electronic business guidance such as the BPG for use of eCTD in MRP/DCP and the Variations Application Form forwarding to NtA-TIGes Interlinking Group.

- for CRs related to EU electronic guidance e.g. on eCTD and ASMF including validation criteria forwarding to the Harmonisation Task Force
- for CR referring to other areas, e.g. EudraCT, RDM, Eudrapharm, etc., forwarding to the respective working group

Additional testing may be called for before a question or change request can be fully evaluated. The question or change request would stay on the CCB agenda and be presented at the next meeting for additional review.

However, the TIGes will take the final decision on the CR.

CR and – as appropriate – the proposed solution will be forwarded in advance to the next scheduled meeting of the respective group as mentioned above, normally 7 days before the meeting date. The most relevant meeting dates will be provided in the internal tracking table. CR received between the distribution date and the meeting date will not be discussed at the upcoming meeting, but instead at the following meeting. At the discretion of the CCB chair in collaboration with the TIGes chair urgent CRs may be forwarded directly to the appropriate contact and not first triaged by the CCB. Furthermore, in exceptional cases, the CCB can request that the chairman of the TIGes schedule an emergency meeting to decide on the respective change request avoiding any undue delay.

Preparing for the Final Decision

The TIGes Joint Group has the responsibility to make the final decision on the CR. Therefore, the CR needs to be added to the agenda of the TIGes-J meeting at least 7 days in advance of the meeting date. The evaluation and proposal for solution of the CR will be presented by a CCB representative. The decision of the TIGes-J will be recorded in the CR-form and the tracking table. The requester will be informed accordingly by EMA.

The updated tracking table will be published on the eSubmission web site http://esubmission.emea.europa.eu/tiges/index.htm by EMA within 14 days after the TIGes-J meeting.

Approved Change Requests

Change requests approved by the TIGes would either be addressed in the Q&A spreadsheet or implemented into the EU eCTD standards or respective guidance documents at appropriate intervals. The version number and date will be updated in that case and an indication will be provided on transition periods for implementation. Time periods for implementation will vary depending from the CR: Updated guidances may come into force more rapidly than changes of the standard e.g. of EU M1. In exceptional urgent cases, also the standard will be updated immediately.

Documentation

The following documentation will be posted on the Commission's web site in the relevant location of the Notice to Applicants.

- Updated version of the EU eCTD standards adopted by the NtAWG.
- Updated Q&A and Change Request Tracking Table adopted by the NtAWG that includes the status of active or closed [disposition of rejected, duplicate, or withdrawn].

Working drafts of the above documents adopted by the TIGes will be posted on the eSubmission web site: http://esubmission.emea.europa.eu/tiges/index.htm. They will become official guidance when posted on the Commission's web site.

EU STANDARDS RELEASE STRATEGY

Stability of the EU Standards, e.g. for eCTD, is important to ensure that industry and regulators can develop or procure efficient tools. In order to provide this stability and in line with the release strategy for the ICH eCTD specifications, the EU eCTD Standards will follow a specific release strategy that allows software application developers and managers to plan for the future. These principles will be

applicable to other electronic standards as well. To ensure traceability of changes, descriptive release notes should accompany the publication of revised standards. Whenever possible, it would be ideal to submit an official change request, following this process, to ensure proper processing of revisions and enhance traceability.

Major Releases

Major new releases of EU eCTD Standards will be announced at least two years before they occur. Major releases include changes that significantly impact DTDs, major modifications to architecture, or significantly impact the software applications being used. These major releases will be addressed by the Joint TIGes-Industry eCTD Implementation Group and follow the Change Control Process described in this document.

Major releases will be identified by a new numbering sequence (e.g., 2.0, 3.0).

Minor Releases

In between major releases of EU eCTD Standards, the Joint TIGes-Industry eCTD Implementation Group could also propose minor releases of the standards. The scope of these minor releases will be to correct minor issues with the specifications that hinder standards implementation or software application development. For minor modifications to the EU eCTD Standards, notification will occur when the minor release is published on the Notice to Applicant.

eCTD should always mirror the ICH CTD structure. Modifications introduced in the EU eCTD Standards to comply with CTD guidance will be considered minor releases and proposed by the NtA-TIGes Interlinking Group.

Minor releases will continue the numbering sequence of the last major release (e.g., 2.1, 2.2).

Bug Fixes

In case of necessary bug fixes of EU eCTD Standards, the Joint TIGes-Industry eCTD Implementation Group will propose sub-minor releases of the standards. The scope of these bug fixes will be to correct issues with the specifications that hinder usability of the standard and prevent technically the functioning of software. For bug fixes of the EU eCTD Standards, notification will occur when the bug fix is published on the Notice to Applicant.

Bug fixes will continue the numbering sequence of the last minor release (e.g., 2.1.1, 2.2.1).

Version Compatibility

Backwards compatibility will be considered for each EU eCTD Standards release. Descriptions of the scope of each change will be provided with each new release.

ANNEX 1 ELECTRONIC SUBMISSION CHANGE REQUEST/Q&A FORM

Contact Information

Organisation Name:	
Organisation Address:	
Contact Name:	
Address:	
Telephone Number:	
E-mail Address:	

Question or Change Request

Unique Id *(from the tracking table)*	
Category	*Business/Technical*
Level of urgency	*Low/Medium/High*
Summary	*This should be a short summary of the problem submitted including rationale.*
Submit Date	*Date you submit the change request (YYYY-MM-DD)*
Item to be Changed/ Question	*Reference to the Product Name of the specification to be changed (e.g., the eCTD DTD, the written specification, the M2 eCTD style sheet)*
Version Number and Date	*Indicate the specific version and date of the Specification or standard, system, guidance, etc., for which the change is proposed.*
Description	*Provide a detailed explanation of the problem, and steps on how to recreate the error, if applicable. If this is a new requirement or enhancement, please provide the reason for the requirement or enhancement and any known solutions. If you have any sample output, sample code or other examples to help clarify the description, attach the samples to this form. You should also provide a detailed description of any testing or research that was done to support the solution(s) being proposed and any advice on backward compatibility issues.*
Recommended solution, if any	*Provide a detailed explanation of any known solutions*
Preferred Implementation Date	*Following the level of urgency, provide the preferred implementation date*
Evaluation Assessment	*To be filled in by the Evaluation Committee. Provide additional information to clarify the description of the CR given by the change requestor if applicable.*
Implementation Proposal	*To be filled in by the Implementation Committee. Provide a summary of the proposed implementation.*

Submit a completed electronic copy of this form to esub.changerequests@ema.europa.eu.

Alternatively send it by post at the following address:

European Medicines Agency
Information and Communications Technology
7 Westferry Circus, Canary Wharf - UK - London, E14 4HB

[1]Title should specify the *Product Name* the CR or Q&A refers to, e.g. eCTD EU M1, eAF, EudraCT, RDM, Eudrapharm, etc.

ANNEX 2 ELECTRONIC SUBMISSION CHANGE REQUEST PROCESS

N	Action	Responsable	Timeline
1	The requester submits the Change Requests to esub.changerequests@ema.europa.eu in the CR Form published on the electronic submission website http://esubmission.emea.europa.eu/tiges/index.htm	Anybody	Anytime
2	Check confidentiality and completeness of content and send to CCB Rapporteurs of the relevant standard should validate the content.	EMA	7 days before CCB meeting
3	The Change Control Board (CCB), that meets regularly, undertakes a preliminary analysis on the CR. A preliminary solution is proposed by the CCB (recorded in the CR Form) or direct referral to another group, e.g. Interlinking Group. Consultation with relevant experts is possible. Update the CR/Q&A tracking table with the new CR forms or progress information on existing requests. A CCB member can be escalated to contact the requester for clarifications whenever necessary.	CCB (if confidential, then EMA)	During the CCB meeting
4	Distribute CR to relevant subgroups: • TIGes-J for technical related CRs • Interlinking Group for regulatory content related CRs (CMD(h) and NtA WG owned electronic business guidance such as the BPG for use of eCTD in MRP/DCP and the Variations Application Form) • Harmonisation Group for CRs related to EU electronic guidance e.g. eCTD and ASMF. CR received between the distribution date and the meeting date will not be discussed at the next meeting, but for the meeting following after the next.	CCB (if confidential, then EMA)	7 days before the TIGes-J meeting
5	Add Change Requests to the draft agenda of TIGes-J meeting and distribute the agenda to the meeting invitees.	Chair	7 days before the TIGes-J meeting
6	Evaluate the CR and the analysis made by the CCB. Presentation, discussion and decision.	TIGes-J	At the TIGes-J meeting
7	Recording of TIGes-J decisions in the CR Form.	CCB (if confidential, then EMA)	At the TIGes-J meeting
8	Send the CR Forms (now containing also the decision by TIGes-J) back to the requester.	CCB (if confidential, then EMA)	Within 7 days after the TIGes-J meeting
9	Update the CR/Q&A tracking table with the decisions reached at the TIGes-J meeting, or pursue resolution of outstanding questions/issues; distribute to the TIGes-J.	CCB	Within 7 days after the TIGes-J meeting
10	Publish on the e-Submission site the CR/Q&A tracking table.	EMA	Within 14 days after the TIGes-J meeting