WORKSHOP 3: How to successfully prepare electronic submissions for CEPs

EU eSubmission Roadmap

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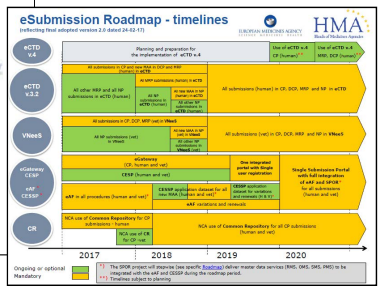
eSubmission Roadmap



HMA eSubmission Roadmap

- Final HMA eSubmission Roadmap (adopted) The final updated version of the eSubmission Roadmap 2.0 was adopted by the EU TMB on and endorsed by the HMA on the 24th of February 2017. Roadmap will be published to reflect further details on the practical implementation steps.
- eSubmission Roadmap (visual representation) The final updated version of the eSubmission Roadmap v2.0 visual representation of the timelines.

Annexes to the eSubmission Roadmap

- Annex 2 to the HMA eSubmission Roadmap on the implementation of mandatory use of eCTD format for regulatory submissions. This revised version of the annex 2 to the roadmap has been ado
- Annex VI to the HMA eSubmission Roadmap on the implementation of mandatory use of VNeeS format for Veterinary regulatory submissions. This revised version of the annex VI to the roadmap

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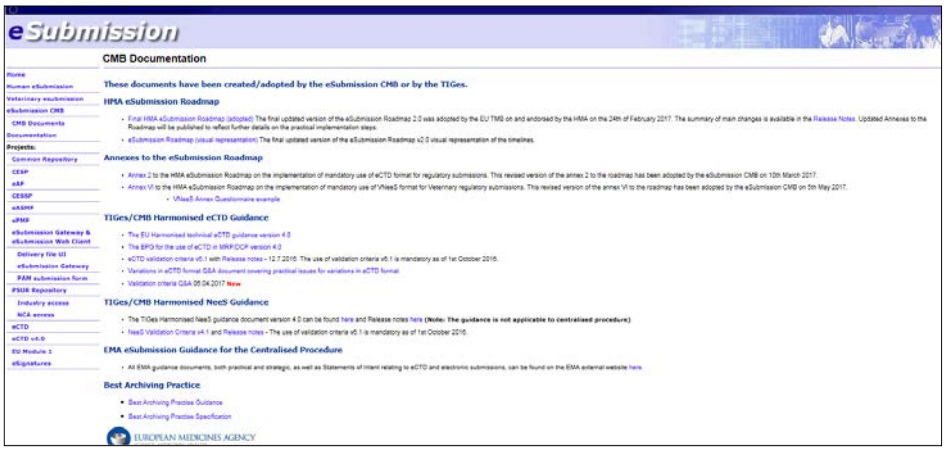
eSubmission website – CMB Documents



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eSubmission Roadmap - timelines

(reflecting final adopted version 2.0 dated 24-02-17)

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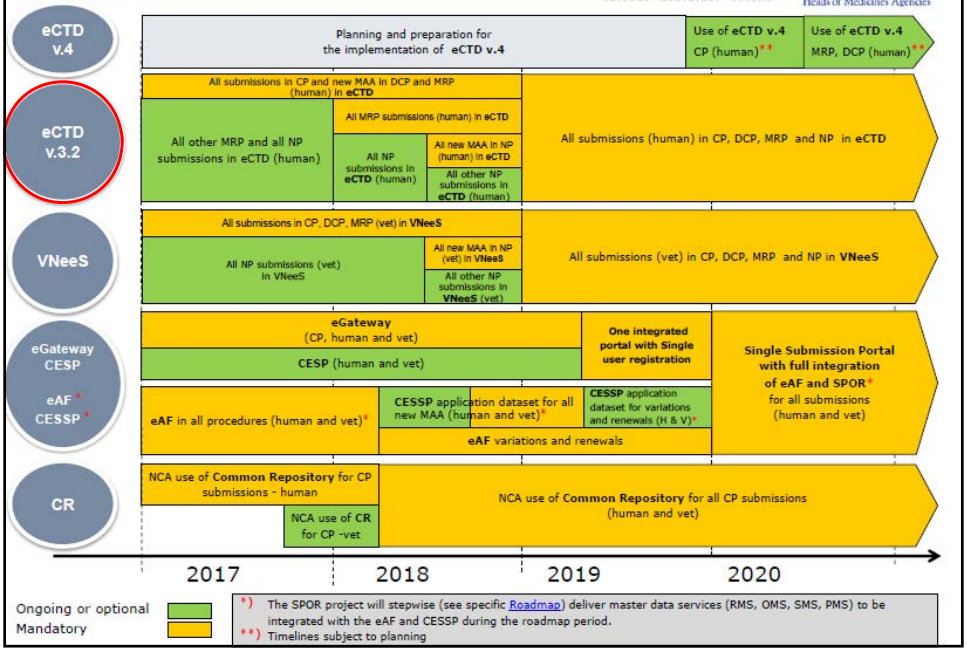

Annex II to the eSubmission Roadmap

10 March 2017

Annex 2 to the HMA eSubmission Roadmap: Implementation of mandatory use of eCTD format for regulatory submissions

Status: Final updated version adopted by the eSubmission CMB

Scope

This annex is intended for both applicants and national authorities and describes details:

- to be monitored during implementation;
- for additional guidance to support a smooth processing of eCTD submissions and to avoid uncertainties on how to handle eCTD correctly;
- on aspects to be mitigated to cover concerns and identified hurdles.

Stream II, which refers to the implementation of eCTD as per the HMA eSubmission Roadmap, only applies for products for human use, since veterinary products are handled in another stream. The outline of stream II defines different steps for implementation:

Mandatory eCTD in European Procedures

Use of eCTD for all regulatory activities in European procedures (DCP/MRP) by 1 January 2018

• This refers to all submission types for a dossier such as variations, renewals, PSURs, ASMFs and so on.

• No baseline submissions are required, however, it is recommended to consider a submission of baseline for module 3 in which case the relevant guidance should be followed.

Mandatory eCTD in National Procedures

Use of eCTD for new MAA in NP by 1 July 2018

•This step has been added to the updated version of the eSubmission Roadmap to strive for a harmonised approached within the EU….

Use eCTD for all regulatory activities in National Procedures (NP) by 1 January 2019

• This step refers to all submission types for a dossier such as variations, renewals, PSURs, ASMFs and so on..…… No baseline submissions are required, however, it is recommended to consider a submission of baseline for module 3 in which case the relevant guidance6 should be followed.

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From Annex II to the eSubmission Roadmap

- For ASMF in centralised procedure, the eCTD format has become mandatory on 1 July 2016.
- For MRP/DCP it will became the mandatory format as of 1 January 2018.
- The eCTD ASMF dossier will be submitted with its applicant part and restricted part by the ASMF holder and will have its own lifecycle.
- *The marketing authorisation application and the ASMF need not to have the same format. However, if the MAA is in eCTD format then the applicant's part of the ASMF should be included also in the MAA eCTD dossier.*

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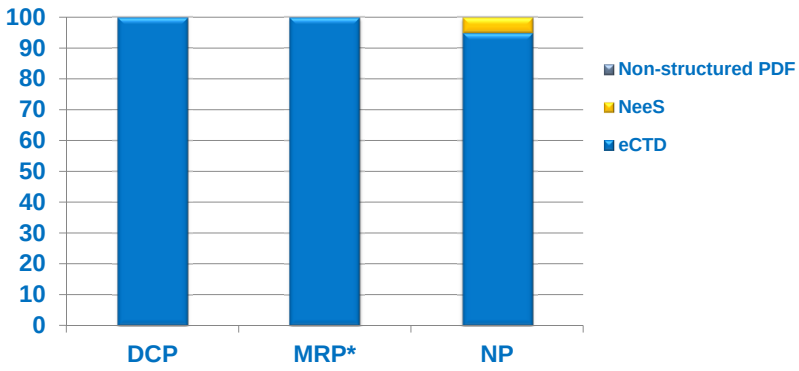
Statistics: New MAA submitted to the MPA Q1-2 2017 Format (% of total submissions)



Submissions in total: 119 in DCP, 22 in MRP and 21 in NP

**) MRP: Format by the start of the MR procedure*

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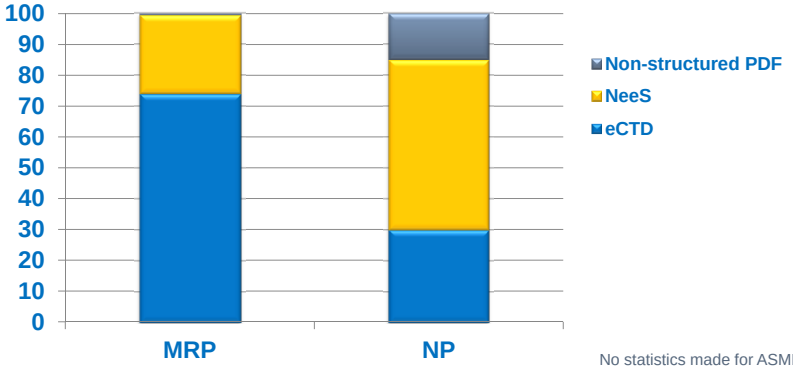
Statistics: Variations submitted to the MPA Q1-2 2017 Format (% of total submissions)



Submissions in total: 2330in MRP and 662 in NP

No statistics made for ASMF, but estimation is about 100% for WS-ASMF, about 50% for other ASMF in MRP/DCP and about 10% in NP

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EU Region eCTD Validation Criteria

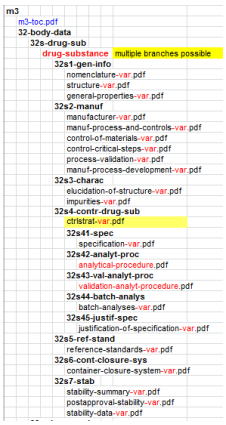
Version 6.1

March 2016

eCTD Validation criteria

Document Change Control | eCTD Validation Criteria | File-Folder Structure & Names | Files and Folders Q&A | Picklist Values

Number	Category	Validation Criterion	Type of check	Lifecycle needed? 'YES': (Y) *	Comments
1.1	ICH DTD	The specified filename is used	P/F		File is named ich-ectd-3-2.dtd
1.2	ICH DTD	The file is placed in the correct folder	P/F		In the folder /XX/XX/util/dtd
1.3	ICH DTD	A currently acceptable version of the DTD is used (checksum matches the published value)	P/F		Currently acceptable versions are described in the current ICH eCTD Specification. (The checksum for the DTD in eCTD v3.2 (ich-ectd-3-2.dtd) is 1dcf631cc6b63571014e378e51f79a27)
1.4	ICH DTD	The version number of the DTD/specification used in the sequence being tested is higher than or equal to the version of the DTD used in the sequence numerically preceding the incoming sequence in the eCTD lifecycle.	P/F	Y	With reference to any transition guidance, going back to an earlier version is not allowed when a newer version has already been used for that eCTD. The sequence numerically preceding the incoming sequence in the eCTD lifecycle' refers to the highest numbered sequence that is numerically lower than the incoming sequence. The criterion should only be tested if there are sequences with lower sequence numbers present.
1.5	ICH DTD	The version number of the DTD/specification used in the sequence being tested is lower than or equal to the version of the DTD used in the sequence numerically succeeding the incoming sequence in the eCTD lifecycle.	P/F	Y	This rule specifically tests in situations where sequences have been submitted out of order. 'The sequence numerically succeeding the incoming sequence in the eCTD lifecycle' refers to the lowest numbered sequence that is numerically higher than the incoming sequence. The criterion should only be tested if there are sequences with higher sequence numbers present.
2.1	ICH stylesheet	The specified filename is used	P/F		File is named ectd-2-0.xsl
2.2	ICH stylesheet	The file is placed in the correct folder	P/F		In the folder /XX/XX/util/style
2.3	ICH stylesheet	The checksum for the stylesheet used must match the published checksum for the stylesheet associated with the DTD used for the sequence	P/F		For example, the checksum corresponding to the stylesheet from eCTD specification v3.2 (ectd-2-0.xsl) is 3a07a202455e9f54a2eb203c5bb443f77
3.1	EU M1 DTD	The specified filename is used	P/F		File is named eu-regional.dtd
3.2	EU M1 DTD	The file is placed in the correct folder	P/F		In the folder /XX/XX/util/dtd



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Important eCTD related documents

- eCTD Specification (v 3.2)
- EU eCTD Module 1 Specification (v 3.0.2, April 2017)
- Harmonised Technical Guidance for eCTD Submissions in the EU (V 4.0, April 2016)
- eCTD Validation criteria (V 6.1, July 2016)
- *Draft* Practical Guidance on the use of the eCTD format for ASMF for Active Substance Master File Holders and Marketing Authorisation Holders MAHs (draft v 1.5)

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Thank you for your attention