eSubmission

eCTD v3.2

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The Common Technical Document (CTD) describes the organisation of modules, sections and documents to be used by an Applicant for a Marketing Authorisation for a medicinal product for human use agreed by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The electronic Common Technical Document (eCTD) allows for the electronic submission of the Common Technical Document (CTD) from applicant to regulator. While the table of content is consistent with the harmonised CTD, the eCTD also provides a harmonised technical solution to implementing the CTD electronically. In other words, an eCTD is the submission of PDF documents, stored in the eCTD directory structure, accessed through the XML backbone and with the files integrity guaranteed by the MD5 Checksum.

The current version of the eCTD specification to be used for CTD modules 2-5 is the Electronic Common Technical Document Specification V3.2.2 (PDF). More information about the standard can be found at the ICH eCTD webpage.

For eCTD submissions within EU, the EU Module 1 eCTD Specification (see link below) should be used.

The eCTD format is mandatory to use for all submission types related to Marketing Authorisation for products within all EU procedures (i.e. Centralised, Decentralised and Mutual Recognition Procedures). In accordance with the eSubmission Roadmap, Mandatory eCTD format is also stepwise introduced for National Procedures.

28-11-2025

eCTD 3.2.2 - EU M1 v3.1.1 and Validation Criteria v8.2 mandatory from 1st December

As previously announced, the updated EU M1 specification v3.1.1 and the related Validation Criteria v8.2 were accepted from 1st October 2025, and the mandatory use of the updated specification and validation criteria will commence on 1st December 2025.

The changes are reflected in the Release Notes.

16-09-2025

eCTD 3.2.2 - EU M1 v3.1.1 and Validation Criteria v8.2 accepted from 1st October

As previously announced, the updated EU M1 specification v3.1.1 and the related Validation Criteria v8.2 are accepted from **1st October 2025** kicking off 2 months transitional period during which both the current and the new specification and validation criteria can be used. The **mandatory** use of the updated specification and validation criteria will commence on **1st December 2025**.

The changes are reflected in the Release Notes.

02-06-2025

eCTD 3.2.2 - new package available

A new version of the EU eCTD M1 Specification, version 3.1.1 , is now published on the eSubmission website . The version 3.1.1 sees the introduction of a small number of changes in the specification, related to the tracking table for EDQM and new examples of product numbers and procedure numbers for work-sharing and super-grouping. The changes are reflected in the Release Notes .

A new version of the validation criteria v8.2 has been published on the eSubmission website. The version is related to the EU Module 1 Specification version 3.1.1 and should be used in case of submitting a new sequence according to EU M1 specification v3.1.1. The new validation criteria will be used for the technical validation for all v3.1.1 electronic submissions received **as of 1 December 2025** to the NCAs and EMA. The changes are reflected in the Release Notes.

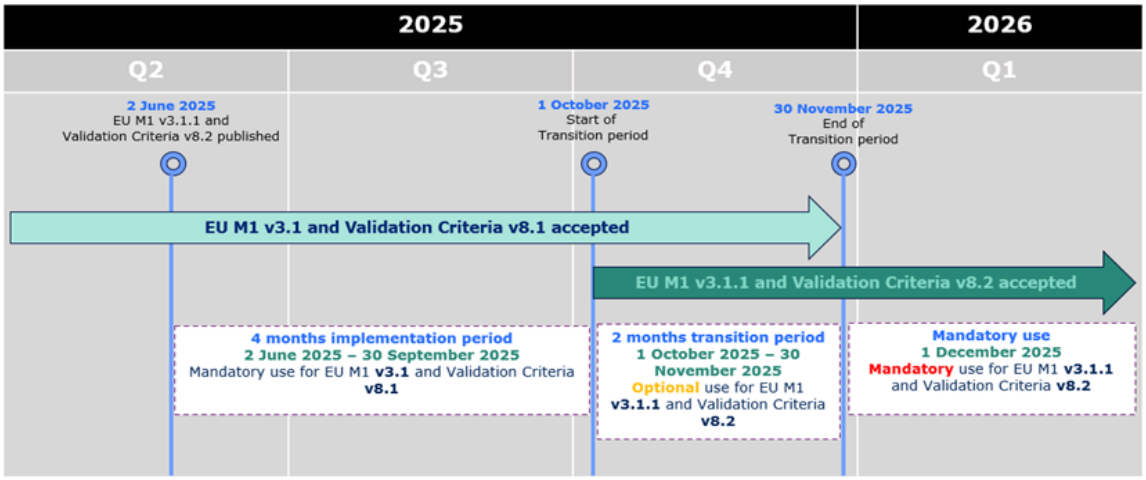
A new version of the Harmonised guidance eCTD 6.0.1 was published together with the new version of the specification and the validation criteria

Note: The Util files remain the same

During the initial period of 4 months from **2 June 2025 to 30 September 2025**, applicants can **only** submit eCTD format submissions compliant with EU M1 v3.1 and validation criteria version 8.1.

From **1 October 2025** eCTDs compliant with EU M1 v3.1 or v3.1.1 and validation criteria v8.1 or v8.2 are accepted.

From **1 December 2025 only** eCTDs compliant with EU M1 v3.1.1 and validation criteria v8.2 are accepted.



10-12-2024

eSubmissions Gateway – naming of the working documents folder

When submitted with an eCTD, the Working Documents should always be provided in a separate folder called "xxxx-workingdocuments" on the same submission zip package containing the eCTD, where the number (xxxx) matches the number of the eCTD sequence being submitted.

Any deviation will lead to a failed submission, and the package will have to be resubmitted with the correct naming. For example, if sending sequence "0007", which contains working documents, the separate folder should be named "0007-workingdocuments".

More details can be found in chapter 2.9.10 of the Harmonised guidance eCTD - version 6.0.

05-12-2024

EU Harmonised technical eCTD guidance version 6.0 now available

A new updated version of the eCTD EU Harmonised technical guidance is now available here, together with the Release notes.

The EU Harmonised technical guidance is aligned with the EU M1 eCTD Specification v3.1 and the Validation Criteria v8.1.

The timeline for implementation is as follows:

- (**optional** use): From 1 December 2024 eCTDs compliant with EU M1 v3.0.4 **or** v3.1 and validation criteria v7.1 or v8.1 are accepted.
- (**mandatory** use): From 1 March 2025 **only** eCTDs compliant with EU M1 v3.1 and validation criteria v8.1 are accepted.

28-10-2024

Minor update to the published EU Validation criteria

An updated version of the validation criteria to add further clarification the has been published on the eSubmission website. The version is related to the EU Module 1 Specification version 3.1 and should be used in case of submitting a new sequence according to EU M1 specification v3.1. The new validation criteria will be used for the technical validation for all v3.1 electronic submissions received **as of 1 March 2025** to the NCAs and EMA. The changes are reflected in the Release Notes.

From **1 December 2024** eCTDs compliant with EU M1 v3.0.4 **or** v3.1 and validation criteria v7.1, 8.0 **or** v8.1 are accepted.

From **1 March 2025** only eCTDs compliant with EU M1 v3.1 and validation criteria v8.1 are accepted.

18-06-2024

eCTD 3.2.2 new package available

A new version of the EU eCTD M1 Specification, version 3.1, is now published on the eSubmission website

The version 3.1 sees the introduction of a number of changes across the specification, however, more specifically, the introduction of a new annex detailing the list of accepted file formats
(Reminder: the generally accepted file format is the PDF, however, in specific cases, other formats will be exceptionally accepted in the eCTD modules). The changes are reflected in the Release Notes.
The same changes are reflected in the additional files of the EU M1 Implementation Guide package (i.e. eu-envelope.mod, eu-regional.dtd, eu-regional.xsl)

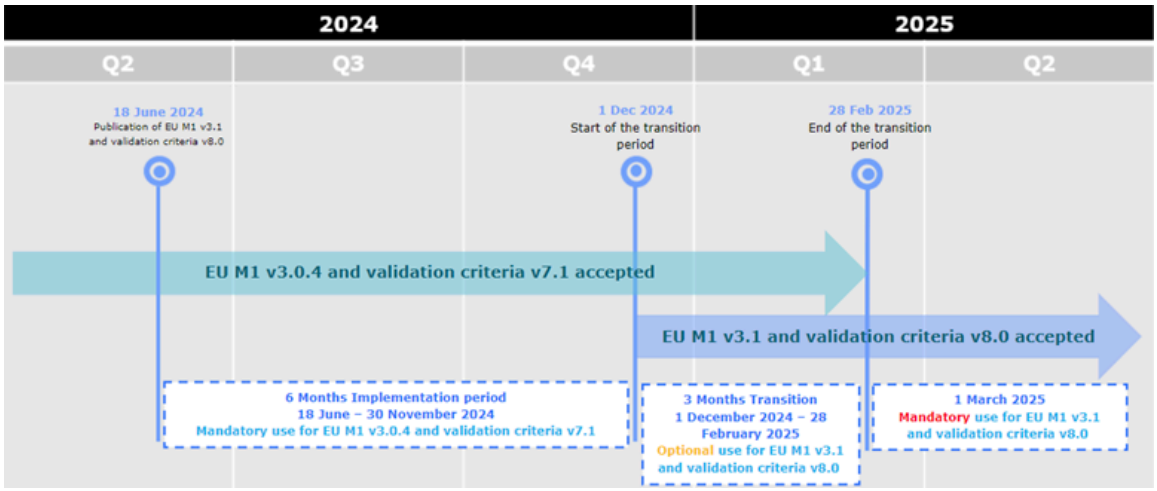
A new version of the validation criteria has been published on the eSubmission website. The version is related to the EU Module 1 Specification version 3.1 and should be used in case of submitting a new sequence according to EU M1 specification v3.1. The new validation criteria will be used for the technical validation for all v3.1 electronic submissions received **as of 1 March 2025** to the NCAs and EMA. The changes are reflected

in the Release Notes.

During the initial period of 6 months from **18 June 2024 to 30 November 2024**, applicants can **only** submit eCTD format submissions compliant with EU M1 v3.0.4 and validation criteria version 7.1.

From **1 December 2024** eCTDs compliant with EU M1 v3.0.4 **or** v3.1 and validation criteria v7.1 **or** v8.0 are accepted.

From **1 March 2025** only eCTDs compliant with EU M1 v3.1 and validation criteria v8.0 are accepted.



Documentation

- EU M1 eCTD Specification v3.1.1 and Release Notes for the specification **(june 2025)** **NEW**
- EU M1 eCTD Validation Criteria v8.2 and Release Notes for the validation **(june 2025)** **NEW**
- Implementation Timeline for EU M1 IG v3.1.1 and validation criteria v8.2 **NEW**
- The EU Harmonised technical eCTD guidance version 6.0.1 **(june 2025)** **NEW**
- The EU Harmonised technical eCTD guidance version 6.0 **(December 2024)**
- Release Notes detailing the changes on the Harmonised technical eCTD guidance v6.0 **(December 2024)**
- EU M1 eCTD Specification v3.1 and Release Notes for the specification (June 2024)
- EU M1 eCTD Validation Criteria v8.1 and Release Notes for the validation criteria (September 2024)
- Annex: EU Accepted File Formats for eCTD June 2024
- Implementation Timeline EU M1 IG v3.1 and validation criteria v8.0
- Util.zip (June 2024)
- EU M1 eCTD Specification v3.1 with track changes (June 2024)
- eCTD EU Module 1 Specification EU Module 1 v3.0.4 (April 2021)
- Release notes including **practical implementation details** related to the eCTD EU M1 Specification v3.0.4 (April 2021)
- The EU Harmonised technical eCTD guidance version 5.0 **(December 2021)**
- Release notes detailing the changes on the Harmonised technical eCTD guidance v5.0 **(December 2021)**
- The EU Harmonised technical eCTD guidance version 4.0
- eCTD validation criteria v7.1 and Release notes - 02.03.2018. Entered into force on 1st of September 2018.
- Variations in eCTD format Q&A document covering practical issues for variations in eCTD format
- Validation criteria Q&A 06.04.2017
- The CMDh Best Practise Guide for use of eCTD in MRP/DCP (April 2020)
- Q&A on how to handle ongoing procedures in relation to mandatory eCTD format - (May 2020)
- Q&A on mandatory eCTD in National Procedures (NP) - (May 2020)
- Q&A on merging or splitting eCTD lifecycles for different strengths and/or forms of medicinal products - (March 2020)
- Q&A on the use of UUID in eCTD - (March 2020)

NeeS format

NeeS has been used as a transitional format towards the mandatory use of eCTD and is now only accepted in some specific cases.

- The TIGes Harmonised NeeS guidance document version 4.0 can be found here and Release notes here
- NeeS Validation Criteria v4.3 and Release notes - 02.03.2018. Entered into force on 1st of September 2018.

For the UK, as from 1.1.2021, EU Law applies only to the territory of Northern Ireland (NI) to the extent foreseen in the Protocol on Ireland/NI.