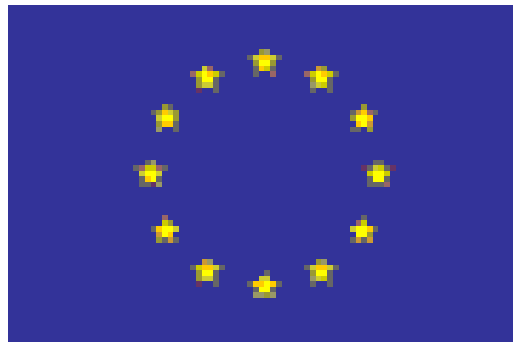


**Revised Implementation guide for
EU Module 1 Specification, version 3.1**

and

EU eCTD Validation Criteria, version 8.0



EU eCTD M1 Specification v3.1

A new version of the EU eCTD M1 Specification, version 3.1, was published on 18 June 2024 on the [eSubmission website](#).

The version 3.1 sees the introduction of 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). Other changes include:

- Editorial changes to explain the use of authentication measures (electronic signatures)
- Clarifications added in several area of the EU Implementation Guide (e.g. example for Withdrawal and use of the Related Sequence).
- Updates of multiple Appendixes (e.g. addition of language code for Irish (“ga”, addition of country code “xi”, new submission type (Article 18), new submission unit (re-examination), English names for all agencies).

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)

EU eCTD Validation Criteria v8.0

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 transition period is between **1 December 2024** and **28 February 2025** during which eCTDs compliant with EU M1 v3.0.4 or v3.1 and validation criteria v7.1 or v8.0 are accepted.

The earlier version of the criteria version 7.1 will be withdrawn by close of business on **28 February 2025**. Therefore, it is important that applicants plan their submissions very carefully around this date to prevent problems in the validation.

The changes in the **Validation criteria** relate to the following rules:

- 15.1 – Changed to Best Practise, Renamed to 15.BP1.1, content updated
- 15.2 – Changed to Best Practise, Renamed to 15.BP2.1, content updated
- 15.BP1 – Change of size to 500MB
- 15.BP6 – New (refers to the maximum size for the individual video files)
- 15.11 – Tracking table mandatory for all submission types
- 15.12 – Tracking table naming explanation
- 16.BP11 - New B/P validation criteria added
- 15.BP6 - New B/P validation criteria added
- 16.3 and 16.4 - updated
- 15.BP1 - updated

Picklist Values changes:

- Line 38 –added “xi” (UK(NI))
- Line 50 – added Irish (“ga”)

Transitional period

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.

