Revised Implementation guide for
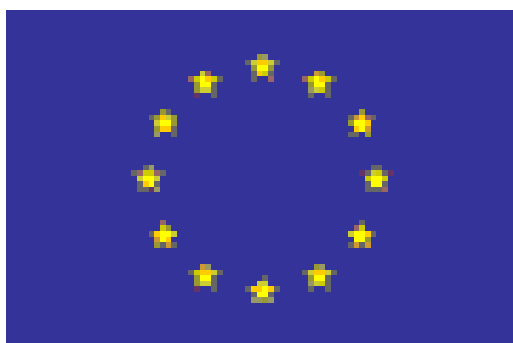
EU M1 Specification, version 3.1.1

and

EU eCTD Validation Criteria, version 8.2

EU eCTD M1 Specification v3.1.1

A new version of the EU eCTD M1 Specification, version 3.1.1, was published in June 2025 on the [eSubmission website](#).

The version 3.1.1 sees the introduction of a small number of changes across the specification, related to:
- Adding the exception for tracking table for submissions to EDQM
- Mentioning the super-grouping
- Adding more relevant examples for worksharing and super-grouping (based on the new EMA case management system (IRIS))

EU eCTD Validation Criteria v8.2

New version of the validation criteria has been published on the [eSubmission website](#). The version is related to the EU Module 1 Specification version 3.1.1 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 transition period is between **1 October 2025** and **30 November 2025** during which eCTDs compliant with EU M1 v3.1 or v3.1.1 and validation criteria v8.1 or v8.2 are accepted.

The earlier version of the criteria version 7.1 will be withdrawn by close of business on **30 November 2025**.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:
- 14.BP5, 14.BP7 - Clarifications added for Super-grouping
- 15.11, 15.12 - added clarification that the tracking table is not needed to EDQM Submissions
- 16.6 - Added more details on how to identify electronic application forms created with the PLM Portal and the ones created with the interactive PDF
- 16.7 - New rule to check there are no attachments in the interactive pdf eAF

Transitional period

During the initial period of 4 months from **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.

2025			2026
Q2	Q3	Q4	Q1

2 June 2025
EU M1 v3.1.1 and
Validation Criteria v8.2 published

1 October 2025
Start of
Transition period

30 November 2025
End of
Transition period

EU M1 v3.1 and Validation Criteria v8.1 accepted

EU M1 v3.1.1 and Validation Criteria v8.2 accepted

4 months implementation period
2 June 2025 – 30 September 2025
Mandatory use for EU M1 **v3.1** and Validation Criteria **v8.1**

2 months transition period
1 October 2025 – 30 November 2025
Optional use for EU M1 **v3.1.1** and Validation Criteria **v8.2**

Mandatory use
1 December 2025
Mandatory use for EU M1 **v3.1.1** and Validation Criteria **v8.2**