Release notes for version 8.0 of the EU eCTD M1 Validation Criteria (major update)
June 2024

Comparison of the new major version (8.0*) with the current version (7.1)

Criterion number in 7.1	Criterion number in 8.0*	Change
9.9	9.9	Clarification added in the comment (The UUID is unique for each Dossier and is identical with the most recent sequence sent)
15.1	15.BP1.1	Rule changed from P/F to BP and content updated due to the new Annex on the accepted file formats. (The files provided in the folders for Module 1 are in acceptable formats)
15.2	15.BP2.1	Rule changed from P/F to BP and content updated due to the new Annex on the accepted file formats. (The files provided in the folders for Module 2-5 are in acceptable formats)
15.BP1	15.BP1	Content updated (size changed to 500MB)
-	15.BP6 (new)	New BP Validation criterion (Individual video files do not exceed 1GB in size)
15.11	15.11	Content changed and rule extended to all procedure types: new P/F check for Tracking table for Centralised Procedures
15.12	15.12	Clarification added for the naming on the location of the tracking table files.
16.3	16.3	Clarification added for signed documents (This validation criterion does not apply to and will not reject certified or any other type of digitally signed documents.)
-	16.BP11 (new)	New BP Validation criterion (For labelling documents (Module 1.3) the Description of the documents is filled in.)
Picklist values	Picklist Values	Added "xi" for countries and "ga" for languages
Files and Folders Q&A	Files and Folders Q&A	Content Updated (removed reference to NeeS)

Version 8.0 contains the draft intermediate versions 7.2 and 7.3