

Release notes for version 3.1.1 of the EU eCTD M1 Specification (minor update)

June 2025

Changes in the Implementation Guide

Section of the document	Change
General architecture of Module 1	Mention related to "super-grouping" (page 10)
General architecture of Module 1	New examples provided for the pre-submission phase product number
Appendix 1: The EU Module 1 XML Submission	Element "number": examples updated for worksharing and super-grouping (based on the new EMA case management system (IRIS))
Appendix 2: Directory / File Structure for Module 1, Element 6	Exception added to tracking table for EDQM submissions