

EU Accepted File Formats for eCTD November 2023

This document provides details on which file formats are allowed when using eCTD specifications. It is a list of accepted file types and the eCTD locations in which those file types should be provided (the generally accepted file format is the PDF, however, in specific cases, other formats will be exceptionally accepted in the eCTD modules).

Documents should be provided in PDF searchable format. Images and other document types should be rendered into PDF format and retain searchable text whenever possible.

File Type	File Format	Format Name	Expected Location(s) in eCTD	Permissible Uses / Comments
<i>Documents</i>				
	.pdf	Portable Document Format	M1 – M5	PDF/A highly recommended
	.docx	Microsoft Word Open XML document	M1.3, M1.8.2, M2	Labelling, RMP, Response to Questions, M2 summaries & overviews
	.txt	Text file	M5	Datasets
	.xls	Microsoft Excel document	M5	Datasets
	.xlsx	Microsoft Excel Open XML document	M5	Datasets
<i>Images</i>				
	.bmp	Bitmap Graphics	M1.3.2, M1.3.3	Mock-Ups / Specimens
	.gif	Graphics Interchange Format	M1.3.2, M1.3.3	Mock-Ups / Specimens
	.jpg, .jpeg	Joint Photographic Experts Group	M1.3.2, M1.3.3	Mock-Ups / Specimens
	.png	Portable Network Graphics	M1.3.2, M1.3.3	Mock-Ups / Specimens
<i>Audio/Video</i>				
	.avi	Audio Video Interleaved	M1.3, M2, M5	Labelling, M2 summaries & overviews, CSRs
	.mpeg	Moving Picture Experts Group	M1.3, M2, M5	Labelling, M2 summaries & overviews, CSRs
	.mp4	MPEG-4 Part 14	M1.3, M2, M5	Labelling, M2 summaries & overviews, CSRs

File Type	File Format	Format Name	Expected Location(s) in eCTD	Permissible Uses / Comments
	.wmv	Windows Media Video	M1.3, M2, M5	Labelling, M2 summaries & overviews, CSRs
<i>Coding Language</i>				
	.dtd	Document Type Definition	M1 (\util\dtd folder)	\util\dtd folder
	.xml	Extensible Markup Language	M1.2, M1.3, M4, M5	eAF, Labelling, Datasets, ePI
	.xsd	XML Schema Definition	M4, M5	Clinical (ISS) datasets
	.xsl	Extensible Stylesheet Language	M1, M4 - M5	\util\style folder, data
<i>Data</i>				
	.csv	Comma Separated Values file	M5.3.3.5	Population PK Studies
	.svg	Scalable Vector Graphics	M3 – M5	
	.xpt	SAS Transport file	M3 – M5	

References:

[ICH Official web site : ICH](#) -> File Format criteria document ([m2-file-format-criteria-v1-november-2014_3.pdf \(ich.org\)](#))