

EU Accepted File Formats for eCTD

Version 1.0

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The generally accepted file format is the **PDF**, however, in **specific** cases, other formats will be **exceptionally** accepted in the eCTD modules.

This document provides details on which file formats are **exceptionally** allowed within eCTD submissions in EU. It is a list of accepted file types and the eCTD locations in which those file types should be provided.

Unless specifically requested, the documents should only be provided in **one** format, **once** in the lifecycle (hence, only once in the sequence).

These file formats should not be embedded within a PDF file but submitted as standalone files.

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-1, PDF/A-2, 1.4, 1.5, 1.6, 1.7
<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>				
	.mp4	MPEG-4 Part 14	M1.3, M2, M5	Labelling, M2 summaries & overviews, CSRs
<i>Coding Language</i>				
	.dtd	Document Type Definition	M1 (\util\dtd folder)	\util\dtd folder
	.mod	Document Type Definition	M1 (\util\dtd folder)	\util\dtd folder

File Type	File Format	Format Name	Expected Location(s) in eCTD	Permissible Uses / Comments
	.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
Data				
	.csv	Comma Separated Values file	M5.3.3.5	Population PK Studies
	.svg	Scalable Vector Graphics	M3 – M5	
	.xpt	SAS Transport file	M3 – M5	
	.txt	Text file	M5	Datasets
	.xlsx	Microsoft Excel Open XML document	M5	Datasets No macros to be included in the file

References:

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