

Date	Version	Summary of Changes
5/8/2015	1.0	Initial Version
9/21/2016	2.0	Update to PDF Specifications, M1 v2.3 Specifications for eCTD Validation Criteria
9/29/2016	2.1	Update to eCTD Technical Conformance Guide
11/7/2016	2.2	Update to the M1 Specifications for eCTD Validation Criteria
3/2/2017	2.3	Update to the Specifications for File Format Types Using eCTD Specifications, the Technical Rejection Criteria for Study Data, and the M1 Specifications for eCTD Validation Criteria
3/29/2017	2.4	Update to the Technical Rejection Criteria for Study Data
4/5/2017	2.5	Updated made to PDF version of eCTD Validation Criteria to correct error
6/22/2017	2.6	Update made to the Specifications for eCTD Validation Criteria (now located in the top section) , the Transmission Specifications, and both versions of the eCTD CTOC (See M1 v. 1.3 and Supportive Files and M1 v. 2.3 and Supportive Files sections)
11/15/2017	2.7	Update made to the Technical Conformance Guide and the Specifications for File Format Types Using eCTD Specifications. Updated ICH STF Stylesheet and Valid Valus xml added. Validation tools GS Validate and Pinnacle 21 added.
6/21/2018	2.8	Update made to eCTD Validation Criteria
11/30/2018	2.9	Update made to Technical Conformance Guide v1.3, M1 v2.4 Specifications, eCTD CTOC, and Submission-type (M1 Attribute List).
1/22/2019	3.0	Update made to eCTD Validation Criteria; eCTD Q&A and Change Requests added
4/1/2019	3.1	Update made to the Transmission Specifications
7/12/2019	3.2	Update made to promotional-material-type M1 v. 2.4 Attribute List
8/15/2019	3.3	Update made to File Format Specification and promotional-material-type M1 v. 2.4 Attribute List
12/12/2019	3.4	Update made to Technical Conformance Guide v1.4
7/27/2020	3.5	Update made to eCTD Validation Tool, update to submission-type.xml for REMS Supplement
9/9/2020	3.6	Date support ends listed for valid-values.xml version 2.2 and version 3
10/1/2020	3.7	Update to form-type.xml for Form 3988
11/9/2020	3.8	Date support ends listed for M1 v. 1.3 and Supportive Files, updates made to M1 v2.4 Specification and CTOC

Use	Standard	Exchange Format	Standards Development Organization	Supported Version	Implementation Guide Reference	Date Support Begins (yyyy-mm-dd)	Date Support Ends (yyyy-mm-dd)	Date Requirement Begins	Date Requirements Ends	Regulatory References
This table contains a listing of the specifications and supportive files for eCTD submissions to both CDER and CBER. Last updated: 11/9/2020										
Documentation and Resources										
eCTD Technical Conformance Guide	eCTD			1.5	Final Guidance for Industry: Providing Regulatory Submissions in Electronic Format – eCTD Specifications	7/27/2020				eCTD Technical Conformance Guide
eCTD Specifications	eCTD	XML	ICH	3.2.2	M2 eCTD: Electronic Common Technical Document Specifications	7/16/2008		5/5/2017 (for NDA, ANDA, BLA) 5/5/2018 (IND Commercial, MF)		eCTD Backbone File Specification for Modules 2 through 5 3.2.2
STF Specification	eCTD	XML	ICH	2.6.1		6/3/2008		5/5/2017 (for NDA, ANDA, BLA) 5/5/2018 (IND Commercial, MF)		The eCTD Backbone File Specification for Study Tagging Files 2.6.1
Specifications for eCTD Validation Criteria	eCTD		FDA	3.8		1/22/2019		5/5/2017 (for NDA, ANDA, BLA) 5/5/2018 (IND Commercial, MF)		Specifications for eCTD Validation Criteria Version 3.8 (PDF)
				3.8		1/22/2019				Specifications for eCTD Validation Criteria Version 3.8 (XLS)
PDF Specifications	eCTD		FDA	4.1		9/21/2016		5/5/2017 (for NDA, ANDA, BLA) 5/5/2018 (IND Commercial, MF)		Portable Document Format Specifications
Transmission Specifications	eCTD		FDA	1.8		4/1/2019		5/5/2017 (for NDA, ANDA, BLA) 5/5/2018 (IND Commercial, MF)		Transmission Specifications
File Format Specifications	eCTD		FDA	4.0		8/15/2019		5/5/2017 (for NDA, ANDA, BLA) 5/5/2018 (IND Commercial, MF)		Specifications for File Format Types Using eCTD Specifications
eCTD Q&A and Change Requests					ICH M2 technical specification, eCTD IWG Question and Answer and	3/1/2005				Guidance for Industry: eCTD Q&A and Change Requests
										Current eCTD v3.2.2 Q&A document

	eCTD		ICH	1.0	Specification Change Request Document					ICH website containing links to Q&A and Change Request Form
Supportive Files										
ICH eCTD DTD	eCTD	XML	ICH	3.2		11/1/2003		5/5/2017 (for NDA, ANDA, BLA) 5/5/2018 (IND Commercial, MF)		http://estri.ich.org/eCTD/ich-ectd-3-2_dtd.zip
ICH eCTD Stylesheet	eCTD	XML	ICH	2		11/1/2004		5/5/2017 (for NDA, ANDA, BLA) 5/5/2018 (IND Commercial, MF)		http://estri.ich.org/eCTD/ectd-2-0.xsl
ICH-STF DTD	eCTD	XML	ICH	2.2		8/1/2003		5/5/2017 (for NDA, ANDA, BLA) 5/5/2018 (IND Commercial, MF)		http://estri.ich.org/STF/ich-stf-v2-2_dtd.zip
ICH STF Stylesheet	eCTD	XML	ICH	2-3		6/1/2017		5/5/2017 (for NDA, ANDA, BLA) 5/5/2018 (IND Commercial, MF)		http://estri.ich.org/STF/ich-stf-stylesheet-2-3.xsl
Valid Values xml	eCTD	XML	FDA	2.2		8/1/2008	8/12/2020	5/5/2017 (for NDA, ANDA, BLA) 5/5/2018 (IND Commercial, MF)		http://www.accessdata.fda.gov/static/eCTD/valid-values-2-2.xml
Valid Values xml	eCTD	XML	FDA	3		4/30/2013	8/12/2020	5/5/2017 (for NDA, ANDA, BLA) 5/5/2018 (IND Commercial, MF)		http://www.accessdata.fda.gov/static/eCTD/valid-values.xml
Valid Values xml	eCTD	XML	FDA	5.0		11/10/2016		5/5/2017 (for NDA, ANDA, BLA) 5/5/2018 (IND Commercial, MF)		http://estri.ich.org/STF/valid-values-v5.zip
M1 v. 1.3 and Supportive Files										
M1 is a requirement in all eCTD submissions. You must use either M1 v. 1.3 or M1 v. 2.4, although use of 2.4 will be required March 1, 2022.										
M1 Specifications	eCTD	XML	FDA	1.3		12/1/2006	3/1/2022	5/5/2017 (for NDA, ANDA, BLA) 5/5/2018 (IND Commercial, MF)		eCTD Backbone Files Specification for Module 1
eCTD CTOC	eCTD		FDA	1.2.2		11/30/2018	3/1/2022	5/5/2017 (for NDA, ANDA, BLA) 5/5/2018 (IND Commercial, MF)		FDA eCTD Table of Contents Headings and Hierarchy
US Regional DTD	eCTD	XML	FDA	2.01		8/1/2003	3/1/2022	5/5/2017 (for NDA, ANDA, BLA) 5/5/2018 (IND Commercial, MF)		us-regional-v2-01.dtd

US Regional Stylesheet	eCTD	XML	FDA	1.1		9/1/2003	3/1/2022	5/5/2017 (for NDA, ANDA, BLA) 5/5/2018 (IND Commercial, MF)		us-regional.xml
M1 v. 2.4 and Supportive Files	M1 is a requirement in all eCTD submissions. You must use either M1 v. 1.3 or M1 v. 2.4, although use of 2.4 will be required March 1, 2022.									
M1 Specifications	eCTD	XML	FDA	2.5		11/9/2020				The eCTD Backbone Files Specification for Module 1 Version 2.5
eCTD CTOC	eCTD	XML	FDA	2.3.3		11/9/2020				Comprehensive Table of Contents Headings and Hierarchy Version 2.3
Addendum to M1 Specifications	eCTD	XML	FDA	2.3		6/15/2015				Addendum to the eCTD Backbone Files Specification for Module 1 Version 2.3
Addendum 2 to M1 Specifications	eCTD	XML	FDA	2.3		6/15/2015				Addendum 2 to the eCTD Backbone Files Specification for Module 1 Version 2.3
Example Submissions using M1 Specifications	eCTD	XML	FDA	2.3		6/15/2015				Example Submissions using the eCTD Backbone Files Specification for Module 1 Version 1.4
US Regional DTD	eCTD	XML	FDA	3.3		6/15/2015				us-regional-v3-3.dtd
US Regional Stylesheet	eCTD	XML	FDA	2.2		6/15/2015				us-regional.xml
M1 v. 2.4 Attribute List										
applicant-contact-type	eCTD		FDA	1.2		6/15/2015				applicant-contact-type.xml
telephone-number-type	eCTD		FDA	1.1		6/15/2015				telephone-number-type.xml
application-type	eCTD		FDA	1.1		6/15/2015				application-type.xml
submission-type	eCTD		FDA	1.3		7/27/2020				submission-type.xml
submission-sub-type	eCTD		FDA	1.1		6/15/2015				submission-sub-type.xml
supplement-effective-date-type	eCTD		FDA	1.1		6/15/2015				supplement-effective-date-type.xml
form-type	eCTD		FDA	1.2		10/1/2020				form-type.xml
promotional-material-audience-type	eCTD		FDA	1.1		6/15/2015				promotional-material-audience-type.xml
promotional-material-doc-type	eCTD		FDA	1.2		6/15/2015				promotional-material-doc-type.xml
promotional-material-type	eCTD		FDA	1.3		8/15/2019				promotional-material-type.xml

Validation Tools and Electronic Submission Validation Criteria in Use					
Tool Name	Standard(s) Being Validated	Tool Version in Use	Tool in Use as of Date	Validation Criteria	Link to Validation Criteria
Lorenz eValidator	eCTD	20.1.1	7/27/2020	See Specifications for eCTD Validation Criteria (above)	Specifications for eCTD Validation Criteria Version 3.8 (PDF)
Pinnacle 21 Enterprise	SDTM, SEND, ADaM, ASCII, Define, XML	3.2	11/4/2017	FDA Business Rules and FDA Validator Rules	https://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm