

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
3/15/2021	3.9	Updates made to eCTD Validation Criteria, form-type.xml, and File Format Specification; Removal of valid-values v2.2 and v3.0 which are no longer supported
5/28/2021	4.0	Updates made to File Format Specification and eCTD Validation Criteria
6/24/2021	4.1	Updates made to Transmission Specification and eCTD Validation Criteria
8/16/2021	4.2	Updates made to the eCTD Validation Criteria; Date Requirement Begins listed for M1 v. 2.5 and Supportive Files and M1 v. 2.5 Attribute List
10/1/2021	4.3	Updates made to Technical Conformance Guide and File Format Specification

Date	Version	Summary of Changes
3/15/2022	4.4	Removal of M1 v1.3 and Supportive Files section (M1 Specification v1.3, eCTD CTOC v1.2.2, US Regional DTD 2.01, US Regional Stylesheet v1.1); Updates to eCTD Validation Criteria and eCTD Technical Conformance Guide
5/11/2022	4.5	Updates made to eCTD Validation Criteria
8/12/2022	4.6	Updates made to File Format Specification
11/4/2022	4.7	Updates made to the eCTD Technical Conformance Guide and Lorenz docuBridge tool version

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: 11/04/2022										
Documentation and Resources										
eCTD Technical Conformance Guide	eCTD			1.8	Final Guidance for Industry: Providing Regulatory Submissions in Electronic Format – eCTD Specifications	11/4/2022				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	4.4		5/11/2022		5/5/2017 (for NDA, ANDA, BLA) 5/5/2018 (IND Commercial, MF)		Specifications for eCTD Validation Criteria Version 4.4 (PDF)
				4.4		5/11/2022				Specifications for eCTD Validation Criteria Version 4.4 (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	1.9		6/14/2021		5/5/2017 (for NDA, ANDA, BLA) 5/5/2018 (IND Commercial, MF)		Transmission Specifications
File Format Specifications	eCTD		FDA	8.0		8/12/2022		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	eCTD		ICH	1.0	ICH M2 technical specification, eCTD IWG Question and Answer and Specification Change Request Document	3/1/2005				Guidance for Industry: eCTD Q&A and Change Requests
										Current eCTD v3.2.2 Q&A 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)		https://admin.ich.org/sites/default/files/inline-files/ich-ectd-3-2_dtd_0.zip
ICH eCTD Stylesheet	eCTD	XML	ICH	2		11/1/2004		5/5/2017 (for NDA, ANDA, BLA) 5/5/2018 (IND Commercial, MF)		https://admin.ich.org/sites/default/files/inline-files/ectd-2-0_0.xsl

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ICH-STF DTD	eCTD	XML	ICH	2.2		8/1/2003		5/5/2017 (for NDA, ANDA, BLA) 5/5/2018 (IND Commercial, MF)		https://admin.ich.org/sites/default/files/inline-files/ich-stf-v2-2_dtd_0.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)		https://admin.ich.org/sites/default/files/inline-files/ich-stf-stylesheet-2-3.xsl
Valid Values xml	eCTD	XML	FDA	5.0		11/10/2016		5/5/2017 (for NDA, ANDA, BLA) 5/5/2018 (IND Commercial, MF)		https://admin.ich.org/sites/default/files/inline-files/valid-values-v5_0.zip
M1 v. 2.5 and Supportive Files	M1 is a requirement in all eCTD submissions.									
M1 Specifications	eCTD	XML	FDA	2.5		11/9/2020		3/1/2022		The eCTD Backbone Files Specification for Module 1 Version 2.5
eCTD TOC	eCTD	XML	FDA	2.3.3		11/9/2020		3/1/2022		Comprehensive Table of Contents Headings and Hierarchy Version 2.3
Addendum to M1 Specifications	eCTD	XML	FDA	2.3		6/15/2015		3/1/2022		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		3/1/2022		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		3/1/2022		us-regional-v3-3.dtd
US Regional Stylesheet	eCTD	XML	FDA	2.2		6/15/2015				us-regional.xsl
M1 v. 2.5 Attribute List										
applicant-contact-type	eCTD		FDA	1.2		6/15/2015		3/1/2022		applicant-contact-type.xml
telephone-number-type	eCTD		FDA	1.1		6/15/2015		3/1/2022		telephone-number-type.xml
application-type	eCTD		FDA	1.1		6/15/2015		3/1/2022		application-type.xml
submission-type	eCTD		FDA	1.3		7/27/2020		3/1/2022		submission-type.xml
submission-sub-type	eCTD		FDA	1.1		6/15/2015		3/1/2022		submission-sub-type.xml
supplement-effective-date-type	eCTD		FDA	1.1		6/15/2015		3/1/2022		supplement-effective-date-type.xml
form-type	eCTD		FDA	1.4		3/15/2021		3/1/2022		form-type.xml
promotional-material-audience-type	eCTD		FDA	1.1		6/15/2015		3/1/2022		promotional-material-audience-type.xml
promotional-material-doc-type	eCTD		FDA	1.2		6/15/2015		3/1/2022		promotional-material-doc-type.xml
promotional-material-type	eCTD		FDA	1.3		8/15/2019		3/1/2022		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	21.2	7/27/2020	See Specifications for eCTD Validation Criteria (above)	Specifications for eCTD Validation Criteria (PDF)
Pinnacle 21 Enterprise	SDTM, SEND, ADaM, ASCII, Define, XML	3.2	11/4/2017	FDA Business Rules and FDA Validator Rules	Study Data Standards Resources