

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

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: 04/01/2019										
<b>Documentation and Resources</b>										
eCTD Technical Conformance Guide	eCTD			1.3	Final Guidance for Industry: Providing Regulatory Submissions in Electronic Format – eCTD Specifications	11/30/2018				<a href="#">eCTD Technical Conformance Guide</a>
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)		<a href="#">eCTD Backbone File Specification for Modules 2 through 5 3.2.2</a>
STF Specification	eCTD	XML	ICH	2.6.1		6/3/2008		5/5/2017 (for NDA, ANDA, BLA) 5/5/2018 (IND Commercial, MF)		<a href="#">The eCTD Backbone File Specification for Study Tagging Files 2.6.1</a>
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)		<a href="#">Specifications for eCTD Validation Criteria Version 3.8 (PDF)</a>
				3.8		1/22/2019				<a href="#">Specifications for eCTD Validation Criteria Version 3.8 (XLS)</a>
PDF Specifications	eCTD		FDA	4.1		9/21/2016		5/5/2017 (for NDA, ANDA, BLA) 5/5/2018 (IND Commercial, MF)		<a href="#">Portable Document Format Specifications</a>
Transmission Specifications	eCTD		FDA	1.8		4/1/2019		5/5/2017 (for NDA, ANDA, BLA) 5/5/2018 (IND Commercial, MF)		<a href="#">Transmission Specifications</a>
File Format Specifications	eCTD		FDA	3.0		11/15/2017		5/5/2017 (for NDA, ANDA, BLA) 5/5/2018 (IND Commercial, MF)		<a href="#">Specifications for File Format Types Using eCTD Specifications</a>
eCTD Q&A and Change Requests					ICH M2 technical specification, eCTD IWG Question and Answer and Specification	3/1/2005				<a href="#">Guidance for Industry: eCTD Q&amp;A and Change Requests</a>
										<a href="#">Current eCTD v3.2.2 Q&amp;A document</a>

	eCTD		ICH	1.0	Specification Change Request Document				<a href="#">ICH website containing links to Q&amp;A and Change Request Form</a>
<b>Supportive Files</b>									
ICH eCTD DTD	eCTD	XML	ICH	3.2		11/1/2003		5/5/2017 (for NDA, ANDA, BLA) 5/5/2018 (IND Commercial, MF)	<a href="http://estri.ich.org/eCTD/ich-ectd-3-2_dtd.zip">http://estri.ich.org/eCTD/ich-ectd-3-2_dtd.zip</a>
ICH eCTD Stylesheet	eCTD	XML	ICH	2		11/1/2004		5/5/2017 (for NDA, ANDA, BLA) 5/5/2018 (IND Commercial, MF)	<a href="http://estri.ich.org/eCTD/ectd-2-0.xsl">http://estri.ich.org/eCTD/ectd-2-0.xsl</a>
ICH-STF DTD	eCTD	XML	ICH	2.2		8/1/2003		5/5/2017 (for NDA, ANDA, BLA) 5/5/2018 (IND Commercial, MF)	<a href="http://estri.ich.org/STF/ich-stf-v2-2_dtd.zip">http://estri.ich.org/STF/ich-stf-v2-2_dtd.zip</a>
ICH STF Stylesheet	eCTD	XML	ICH	2-3		6/1/2017		5/5/2017 (for NDA, ANDA, BLA) 5/5/2018 (IND Commercial, MF)	<a href="http://estri.ich.org/STF/ich-stf-stylesheet-2-3.xsl">http://estri.ich.org/STF/ich-stf-stylesheet-2-3.xsl</a>
Valid Values xml	eCTD	XML	FDA	2.2		8/1/2008		5/5/2017 (for NDA, ANDA, BLA) 5/5/2018 (IND Commercial, MF)	<a href="http://www.accessdata.fda.gov/static/eCTD/valid-values-2-2.xml">http://www.accessdata.fda.gov/static/eCTD/valid-values-2-2.xml</a>
Valid Values xml	eCTD	XML	FDA	3		4/30/2013		5/5/2017 (for NDA, ANDA, BLA) 5/5/2018 (IND Commercial, MF)	<a href="http://www.accessdata.fda.gov/static/eCTD/valid-values.xml">http://www.accessdata.fda.gov/static/eCTD/valid-values.xml</a>
Valid Values xml	eCTD	XML	FDA	5.0		11/10/2016		5/5/2017 (for NDA, ANDA, BLA) 5/5/2018 (IND Commercial, MF)	<a href="http://estri.ich.org/STF/valid-values-v5.zip">http://estri.ich.org/STF/valid-values-v5.zip</a>
<b>M1 v. 1.3 and Supportive Files</b>									
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 is not required.									
M1 Specifications	eCTD	XML	FDA	1.3		12/1/2006		5/5/2017 (for NDA, ANDA, BLA) 5/5/2018 (IND Commercial, MF)	<a href="#">eCTD Backbone Files Specification for Module 1</a>
eCTD CTOC	eCTD		FDA	1.2.2		11/30/2018		5/5/2017 (for NDA, ANDA, BLA) 5/5/2018 (IND Commercial, MF)	<a href="#">FDA eCTD Table of Contents Headings and Hierarchy</a>
US Regional DTD	eCTD	XML	FDA	2.01		8/1/2003		5/5/2017 (for NDA, ANDA, BLA) 5/5/2018 (IND Commercial, MF)	<a href="#">us-regional-v2-01.dtd</a>

US Regional Stylesheet	eCTD	XML	FDA	1.1		9/1/2003		5/5/2017 (for NDA, ANDA, BLA) 5/5/2018 (IND Commercial, MF)	<a href="#">us-regional.xml</a>
<b>M1 v. 2.4 and Supportive Files</b>	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 is not required.								
M1 Specifications	eCTD	XML	FDA	2.4		11/30/2018			<a href="#">The eCTD Backbone Files Specification for Module 1 Version 2.4</a>
eCTD CTOC	eCTD	XML	FDA	2.3.2		11/30/2018			<a href="#">Comprehensive Table of Contents Headings and Hierarchy Version 2.3</a>
Addendum to M1 Specifications	eCTD	XML	FDA	2.3		6/15/2015			<a href="#">Addendum to the eCTD Backbone Files Specification for Module 1 Version 2.3</a>
Addendum 2 to M1 Specifications	eCTD	XML	FDA	2.3		6/15/2015			<a href="#">Addendum 2 to the eCTD Backbone Files Specification for Module 1 Version 2.3</a>
Example Submissions using M1 Specifications	eCTD	XML	FDA	2.3		6/15/2015			<a href="#">Example Submissions using the eCTD Backbone Files Specification for Module 1 Version 1.4</a>
US Regional DTD	eCTD	XML	FDA	3.3		6/15/2015			<a href="#">us-regional-v3-3.dtd</a>
US Regional Stylesheet	eCTD	XML	FDA	2.2		6/15/2015			<a href="#">us-regional.xml</a>
<b>M1 v. 2.4 Attribute List</b>									
<a href="#">applicant-contact-type</a>	eCTD		FDA	1.2		6/15/2015			<a href="#">applicant-contact-type.xml</a>
<a href="#">telephone-number-type</a>	eCTD		FDA	1.1		6/15/2015			<a href="#">telephone-number-type.xml</a>
<a href="#">application-type</a>	eCTD		FDA	1.1		6/15/2015			<a href="#">application-type.xml</a>
<a href="#">submission-type</a>	eCTD		FDA	1.2		11/30/2018			<a href="#">submission-type.xml</a>
<a href="#">submission-sub-type</a>	eCTD		FDA	1.1		6/15/2015			<a href="#">submission-sub-type.xml</a>
<a href="#">supplement-effective-date-type</a>	eCTD		FDA	1.1		6/15/2015			<a href="#">supplement-effective-date-type.xml</a>
<a href="#">form-type</a>	eCTD		FDA	1.1		6/15/2015			<a href="#">form-type.xml</a>
<a href="#">promotional-material-audience-type</a>	eCTD		FDA	1.1		6/15/2015			<a href="#">promotional-material-audience-type.xml</a>
<a href="#">promotional-material-doc-type</a>	eCTD		FDA	1.2		6/15/2015			<a href="#">promotional-material-doc-type.xml</a>
<a href="#">promotional-material-type</a>	eCTD		FDA	1.2		6/15/2015			<a href="#">promotional-material-type.xml</a>

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
GlobalSubmit Validate	eCTD	8.2.6	8/28/2017	See Specifications for eCTD Validation Criteria (above)	<a href="#">Specifications for eCTD Validation Criteria Version 3.6 (PDF)</a>
Pinnacle 21 Enterprise	SDTM, SEND, ADaM, ASCII, Define, XML	3.2	11/4/2017	FDA Business Rules and FDA Validator Rules	<a href="https://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm">https://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm</a>