

Recommended Contents of a Sample eCTD v4.0 Forward Compatibility Submission

Please follow the sample guidelines below so that we may provide you with a meaningful, comprehensive analysis of your submission and help to ensure you are able to submit according to specifications. *(Note: if you have already successfully submitted a sample eCTD, it is not necessary to submit a second sample.)* This validating phase does not involve any regulatory review of the content of the submission. It is intended only to resolve technical issues.

An initial eCTD v3.2.2 sample should include the following items, and those items must comply with FDA and ICH specifications:

At a minimum Module 1 information must be included, but information in Modules 2-5 is optional to be included	
Us-regional.xml according to eCTD Backbone Files Specification for Module 1 DTD 3.3	
Us-regional.xml and FDA form (e.g., 356h, 1571, or 3938) contain the same 6-digit application number, submission type, submission sub-type, and submission date. Submissions to NDA, BLA, ANDA and Commercial IND require an FDA fillable form.	
All submission documents adhere to FDA and ICH specifications	

Modules in the sample should contain the following:		
Module 1	Cover letter stating what type of sample you are submitting (eCTD v4.0 Forward Compatibility, CDISC)	
	The appropriate FDA form (e.g., 356h, 1571, or 3938)	
Module 2	Include at least one leaf	
Module 3	Include at least one leaf within the 3.2.p section with appropriate attributes applied	
Module 4	Include one study in section 4.2.3.1, 4.2.3.2, or 4.3.2.4. Refer to the eCTD Backbone File Specification for Study Tagging Files , the Valid Values.xml , and the Specifications for eCTD Validation Criteria listed in the eCTD Data Standards.	
Module 5	Include one study in section 5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, or 5.3.5.2. Refer to the eCTD Backbone File Specification for Study Tagging Files , the Valid Values.xml , and the Specifications for eCTD Validation Criteria listed in the eCTD Data Standards.	

A second sample using eCTD v4.0 Forward Compatibility should include the following items, and those items must comply with FDA and ICH specifications:

At a minimum Module 1 information must be included, but information in Modules 2-5 is optional to be included	
submissionunit.xml according to FDA Implementation Guide	
submissionunit.xml and FDA form (e.g., 356h, 1571, or 3938) contain the same 6-digit application number, submission type, submission sub-type, and submission date. Submissions to NDA, BLA, ANDA and Commercial IND require an FDA fillable form.	
All submission documents adhere to FDA and ICH specifications	

Modules in the sample should contain the following:	
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Module 1	Cover letter stating what type of sample you are submitting (eCTD v4.0, CDISC, Document Reuse)	
	The appropriate FDA form (e.g., 356h, 1571, or 3938)	
Module 2	Include at least one context of use using forward compatibility reference	
Module 3	Include at least one context of use using forward compatibility reference within the 3.2.p section with appropriate keywords applied	
Module 4	Include one study in section 4.2.3.1, 4.2.3.2, or 4.3.2.4. Refer to the ICH eCTD v4.0 Implementation Guide , the controlled vocabulary , and the Specifications for eCTD v4.0 Validation Criteria .	
Module 5	Include one study in section 5.3.1.1, 5.3.1.2, 5.3.3.1, 5.3.3.2, 5.3.3.3, 5.3.3.4, 5.3.4, 5.3.5.1, or 5.3.5.2. Refer to the ICH Implementation Guide , the controlled vocabulary , and the Specifications for eCTD v4.0 Validation Criteria .	

Note: If we are unable to evaluate your sample, load it onto our server, perform eCTD validation, or cannot view the sample, you will be contacted and asked to resubmit according to specifications.

Submitting a successful sample will help ensure successful submissions in the future.

If you have questions about eCTD format, please contact the electronic submissions staff for CDER at esub@fda.hhs.gov or CBER at esubprep@fda.hhs.gov

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