Recommended Contents of a Sample eCTD v4.0 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.

A single eCTD v4.0 sample should include the following items and those items must comply with FDA and ICH specifications:

At a minimum Module 1 information should be included, but information in Modules 2-5 is recommended 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.	
Submissions adhere to the **PDF Specifications –** pay close attention to:	
Bookmarks	
PDF document open properties	
Proper page rotation/page	
Display PDF file and folder	
Names	
Hypertext links adhere to the **eCTD Guidance**	
keywords are used correctly	
Controlled Vocabulary terms are used correctly	
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, CDISC, Document Reuse)	
	The appropriate FDA form (e.g., 356h, 1571, or 3938)	
Module 2	Include at least one context of use	
Module 3	Include at least one context of use 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**. Include the following data context of uses:	
	data definition context of use (define.xml file)	
	a study report context of use	
	a dataset context of use (.xpt file)	
	To check non-standardized study information, submit at least one context of use to 4.2.1, 4.2.2, 4.2.3.3, 4.2.3.5, 4.2.3.6, or 4.2.3.7. Refer to the **ICH Implementation Guide** and the **controlled vocabulary**	
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. the **ICH Implementation Guide**, the **controlled vocabulary**, and the **Specifications for eCTD v4.0 Validation Criteria**. Include the following data context of uses:	
	at least one data definition context of use (define.xml file)	
	a study report context of use	
	at least one dataset context of use (.xpt file)	

	Include at least one annotated case report form (blank case report form). FDA does not use 5.3.7. Instead CRFs should be linked into the appropriate study tagging file. Refer to the **ICH Implementation Guide** and the **controlled vocabulary**	
	To check non-standardized study information, submit at least one context of use to 5.3.1.3, 5.3.1.4, 5.3.2, 5.3.3.5, 5.3.5.3, 5.3.5.4, or 5.3.6. Refer to the **ICH Implementation Guide** and the **controlled vocabulary**	

Document Reuse:

Document reuse may be used for submissions where previously submitted information needs to be submitted to multiple applications. It's possible to reference documents across different application type for example IND, NDA, BLA, ANDA, or MF.

The sample should contain two eCTD applications using two different sample application numbers. Refer to the eCTD sample submission recommendations for more specific content recommendation for each Module 1-5.	
One eCTD Application	
At a minimum Module 1 information should be included and the files which will be referenced, but information in Modules 2-5 is recommended to be included	
A second eCTD application	
At a minimum Module 1 information should be included and the files which reference the first eCTD application, but information in Modules 2-5 is recommended to be included	
For information and examples on document reuse, refer to the ICH eCTDv4.0 Implementation Guide, section 9.2.17 Considerations for the Document Element (eCTD Submission Standards for eCTD v4.0 and Regional M1)	

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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