

FDA Module 1 Electronic Common Technical Document (eCTD) v4.0 Forward Compatibility XML Samples History v1.0

VERSION HISTORY

Date	Version	ICH IG/CV Conformance	FDA IG/CV Conformance	Notes
2026-05	1.0	ICH eCTD v4.0 Implementation Package v1.6	USFDA eCTD v4.0 Implementation Package v1.7	

The following tables list the files included in the FDA Module 1 Electronic Common Technical Document (eCTD) v4.0 Forward Compatibility Samples and notes for the changes made in this version of the package.

XML SAMPLE FILES

Folder Name	Folder Contents	Release Notes
Document Reuse	BLA 700001 Sequence 0001 – Content establishes the sequence.	
	BLA 700001 Sequence 2 – Document reuse from within application (document from 0001) and across applications (document from BLA 700002 SN 0001).	
	BLA 700001 Sequence 2 – Content establishes the sequence.	
Life Cycle Content ¹	NDA 700003 Sequence 0001 – Establishes initial set of content for life cycle and keywords	
	NDA 700003 Sequence 2 – One-to-one replace of content from 0001. Withdraw content from 0001.	

¹ Life cycle content also appears in other XML samples as secondary objectives.

Folder Name	Folder Contents	Release Notes
Study Data Content	IND 700004 Sequence 0001 – Establishes initial study data content in Module 4.	
	IND 700004 Sequence 2 – Life cycle of Module 4 study with one-to-one replace of study report. Establishes matching keywords from v3.2.2 study information.	