

FDA Module 1 Electronic Common Technical Document (eCTD) v4.0 XML Samples History v3.0

VERSION HISTORY

Date	Version	ICH IG/CV Conformance	FDA IG/CV Conformance	Notes
2024-10	3.0	ICH eCTD v4.0 Implementation Package v1.5	USFDA eCTD v4.0 Implementation Package v1.5.1	This version of the samples replaces those in the USFDA eCTD v4.0 Implementation Package v1.5.1.

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

XML SAMPLE FILES

Folder Name	Folder Contents	Release Notes
Life Cycle Content ¹	NDA111886 Sequence 1 – Establishes initial set of content for life cycle and keywords	Added IG Conformance note; Updated Message Header; Updated CV OIDs; and updated Contact Party elements.
	NDA111886 Sequence 2 – Life cycle of contents from many to one. Document Title updated for a SN1 Context of Use. Study title keyword update to correct typo.	Added IG Conformance note; Updated Message Header; Updated CV OIDs; and updated Contact Party elements.
Grouped Submission	NDA111111 Sequence 1 – Establishes initial set of content for life cycle and keywords	Added IG Conformance note; Updated Message Header; Updated CV OIDs; and updated Contact Party elements.
	NDA111111 Sequence 2 – Life cycle of contents from many to one	Added IG Conformance note; Updated Message Header; Updated CV OIDs; and updated Contact Party elements.
	NDA111111 Sequence 3 – Life cycle of contents from one to one and additional content	Added IG Conformance note; Updated Message Header; Updated CV OIDs; and updated Contact Party elements.
	NDA111111 Sequence 6 – Grouped Submission with applications NDA222222 Sequence 4 and NDA333333 Sequence 3	Added IG Conformance note; Updated Message Header; Updated CV OIDs; Updated NDA222222 to SN4; and updated Contact Party elements.

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

Folder Name	Folder Contents	Release Notes
	NDA222222 Sequence 1 Initial submission unit to establish keywords	Added IG Conformance note; Updated Message Header; Updated CV OIDs; and updated Contact Party elements.
	NDA222222 Sequence 2 – Includes one to many replacement	Added IG Conformance note; Updated Message Header; Updated CV OIDs; and updated Contact Party elements.
	NDA222222 Sequence 3 – Additional content added	Added IG Conformance note; Updated Message Header; Updated CV OIDs; and updated Contact Party elements.
	NDA333333 Sequence 1 – Establishes initial set of content for life cycle and keywords; Document Reuse from 11111 and 22222	Added IG Conformance note; Updated Message Header; Updated CV OIDs; and updated Contact Party elements.
	NDA333333 Sequence 2 – Document Reuse and added manufacturer keywords	Added IG Conformance note; Updated Message Header; Updated CV OIDs; and updated Contact Party elements.
Study Data	NDA111888 Sequence 1 – Initial study data content	Updated Scenario notes to indicated document reuse elements; Added IG Conformance note; Updated document titles; Updated Message Header; and updated Contact Party elements.
Promotional Materials	NDA111113 Sequence 1 – Promotional Material	Updated Message Header; Added IG Conformance note; Updated Promotional Material type for Clean version of Print Ad CoU; and updated CV OIDs.
Document Reuse	NDA111889 Sequence 1 – Reuse of Study Data content from NDA 111888	Sequence 2 Folder removed from the Document Reuse Folder. Updated Scenario notes to indicated document reuse elements; Added IG Conformance note; Updated CoU document type for ADAM data; Updated CV OIDs; and updated Contact Party elements.
Withdraw Content	NDA111889 Sequence 2 – Withdraw of entire Sequence 1	Sequence 1 Folder removed from the Withdraw Contents Folder (see Document Reuse Folder for the initial submission unit); Added IG Conformance note; and updated CV OIDs.
	NDA111777 Sequence 1 – Content establishes the sequence	Updated Scenario notes to indicated withdraw with life cycle. Added IG Conformance note; Updated Submission Unit type; Updated Message Header; and updated Contact Party elements.

Folder Name	Folder Contents	Release Notes
Withdraw Content (continued)	NDA111777 Sequence 2 – Content from added (in error)	Updated Scenario notes to indicated withdraw with life cycle. Added IG Conformance note; Updated Submission Unit type; Updated Message Header; Added IG Conformance note; Updated CV OIDs; and updated Contact Party elements. Updated folder contents to include 356h file.
	NDA111777 Sequence 3 Content added in error is withdrawn from Sequence 2 Content life cycled with suspend and life cycle to revert to Sequence 1 content	Updated Scenario notes to indicated withdraw with life cycle. Added IG Conformance note; Updated Submission Unit type; Updated Message Header; and updated Contact Party elements.