eCTD v4.0 Controlled Vocabulary (CV) Package v1.0 Read Me

1. PACKAGE REVISION HISTORY

Version	Date	Comments
1.0	May 2024	Initial Version. As of eCTD v4.0 Implementation Package v1.6, the Controlled Vocabulary files will be maintained in this separate package. (00750) Note: the eCTD v4.0 Implementation Package v1.5 contains active Code Lists. This version includes the addition of new Document Type keywords. (00740)

This package contains the information for the controlled vocabulary files needed to implement eCTD v4.0.

2. INVENTORY OF CONTROLLED VOCABULARY FILES

This package includes a spreadsheet and genericode files with the controlled vocabulary inventory:

| Artifact | Description | CV Spreadsheet | Genericode Files | |
			Support Files	Code Lists
ICH eCTD v4.0 CV – Index tab	Includes the history of the controlled vocabulary (also found in Section 4 below) in Excel.	✓	N/A	N/A
ICH M8 Controlled Vocabulary.gc	Includes the OIDs and Version listing for code lists in the current package in Genericode Format. **Note:** This was previously named "ICH M8 Codelist Set.gc"	N/A	✓	N/A
ICH M8 OID Listing_eCTD v4	Includes the OIDs and Version listing for code lists in the current package in Excel format	N/A	✓	N/A
genericode	The schema file for the code lists	N/A	✓	N/A
ICH_M2_Codelist	The stylesheet for the code list for human-readable version	N/A	✓	N/A
ich-logo.png	The image file used by the stylesheet	N/A	✓	N/A

Artifact	Description	CV Spreadsheet	Genericode Files	
			Support Files	Code Lists
ICH Context of Use	Current code list of the ICH Context of Use codes	✓	N/A	✓
ICH Context of Use Status	Current code list of the ICH Context of Use Status codes	✓	N/A	✓
ICH Document Types	Current code list of the ICH Document Type codes	✓	N/A	✓
ICH Duration	Current code list of the ICH Duration codes	✓	N/A	✓
ICH Keyword Definition Types	Current code list of the ICH Keyword Definition Types	✓	N/A	✓
ICH Route of Administration	Current code list of the ICH Route of Administration	✓	N/A	✓
ICH Species	Current code list of the ICH Species	✓	N/A	✓
ICH Type of Control	Current code list of the ICH Type of Control	✓	N/A	✓
ICH Study Group Order	Current code list of the ICH Study Group Order	✓	N/A	✓
ICH XML Types	Current code of ICH XML Types	✓	N/A	✓

Note: The human-readable and machine-readable code lists contain the same information.

3. CURRENT REVISION HISTORY

The following table provides the current revision history for the package. Release notes below include this version's changes only.

The following tables list the files included in the eCTD v4.0 CV Package v1.0.

CODE LIST SPREADSHEET

Document Title	Document Version	File Name	File Format	Release Notes
Support Files				
ICH eCTD v4.0 CV v6	V6.0	ICH_eCTDv4_0_CV_v6.xlsx	XLSX	Updated with CV versioning and updates to Document Type Keywords.

GENERICODE FILES

Document Title	Document Version	File Name	File Format	Release Notes
Support Files				
ICH M8 Controlled Vocabulary for Genericode	V1.0	ICH M8 Controlled Vocabulary.gc_v1.xml	XML	Updated with new OIDs for eCTD v4.0 . This replaces the previous ICH M8 Codelist Set.gc.
ICH M8 OID Listing	V6.0	ICH M8 OID Listing_eCTDv4_v6.xlsx	Excel	Updated with CV versioning information. Added OID for Controlled Vocabulary package.
Genericode schema	v2.0	genericode.xsd	XSD	Updated with CV versioning information.
ICH M2 Code List stylesheet	v1.0	ICH_M2_Codelist.xsl	XSL	Initial codelist stylesheet for genericode files.
ICH Logo	v1.0	ich-logo.png	PNG	ICH logo for genericode files.
Code List				
ICH Context of Use CV	v5.0	M8 CL1 ich-cou.gc_v5xml	Genericode (XML)	Added controlled vocabulary versioning
ICH Document Type keyword CV	v4.0	M8 CL3 ich-document.gc_v4.xml	Genericode (XML)	Added 23 Document types to be used as study tags; Removed 1 document type, Study Data Standardization Plan; Added controlled vocabulary versioning
ICH Duration CV	v2.0	M8 CL4 ich-duration.gc_v2.xml	Genericode (XML)	Added controlled vocabulary versioning
ICH Keyword Definition Type CV	v4.0	M8 CL5 ich-keyword-definition-type.gc_v4.xml	Genericode (XML)	Added controlled vocabulary versioning
ICH Route of Administration CV	v2.0	M8 CL6 ich-route-of-administration.gc_v2.xml	Genericode (XML)	Added controlled vocabulary versioning
ICH Species for Non-clinical studies	v2.0	M8 CL7 ich-species-for-non-clinical-study.gc_v2.xml	Genericode (XML)	Added controlled vocabulary versioning

Document Title	Document Version	File Name	File Format	Release Notes
ICH Type of Control CV	v2.0	M8 CL10 ich-type-of-control.gc_v2.xml	Genericode (XML)	Added controlled vocabulary versioning
ICH XML Type	v2.0	M8 ich-xml-types-fc.gc_v2.xml	Genericode (XML)	Added controlled vocabulary versioning
Context of Use Status CV	v2.0	M8 context-of-use-status.gc_v2.xml	Genericode (XML)	Added controlled vocabulary versioning
Study Group Order CV	v2.0	M8 CL12 ich-study-group-order.gc_v2.xml	Genericode (XML)	Added controlled vocabulary versioning