

eCTD v4.0 Implementation Package v1.5

The following tables list the files included in the eCTD v4.0 Implementation Package v1.5.

MAIN IMPLEMENTATION DOCUMENTS

Document Title	Document Version	File Name	File Format	Release Notes
ICH eCTD v4.0 Implementation Guide	v1.5	ICH_eCTDv4_0_ImplementationGuide_v1_5.pdf	Adobe Acrobat (PDF)	Changes to the following areas: Unique identifiers (00660), CoU Priority Numbers (00670), Document Reference (00690), Context of Use Code (00700), and Transition Mapping Message (00710). <i>Note: The Transition Mapping Message has been removed and replaced with a Forward Compatibility approach.</i>
ICH eCTD v4.0 Controlled Vocabulary	V5.0	ICH_eCTDv4_0_CVv5_0.xlsx	Excel	Changes to the following areas: Errors in CoU mappings (00650 and 00680),), update to Keyword Definition Type for site id (00640) and update with XML Types for Forward Compatibility (00710).
ICH eCTD v3.2.2 Transition Mapping Message Controlled Vocabulary	v3.0	ICH_eCTDv3_2_2TMM_CVv3.xlsx	Excel	Removed from Implementation Package v1.5

ICH ECTD v4.0 SCHEMA FILES

Document Title	Document Version	File Name	File Format	Release Notes
coreschemas (folder)				
HL7 datatype R1 schema	R1	datatypes-rX-cs.xsd	XSD	RPS R2 (2015 Normative Edition)
HL7 datatype R2 schema	R2	hl7-r2_datatypes.xsd	XSD	RPS R2 (2015 Normative Edition)
HL7 Infrastructure Root schema	R2	infrastructureRoot-r2.xsd	XSD	RPS R2 (2015 Normative Edition)
HL7 Narrative Block schema	N/A	NarrativeBlock.xsd	XSD	RPS R2 (2015 Normative Edition)
HL Vocabulary R2 schema	R2	voc-r2.xsd	XSD	RPS R2 (2015 Normative Edition)

Document Title	Document Version	File Name	File Format	Release Notes
multicacheschemas (folder)				
RPS Interaction Schema	N/A	PORP_IN000001UV.xsd	XSD	RPS R2 (2015 Normative Edition)
RPS Message Type Schema	R1	PORP_MT000001UV01.xsd	XSD	RPS R2 (2015 Normative Edition)
RPS Transmission Schema	R2	MCCI_MT000100UV02.xsd	XSD	RPS R2 (2015 Normative Edition)
RPS Control Act Schema	R2	MCAI_MT700201UV02.xsd	XSD	RPS R2 (2015 Normative Edition)
Common Message Elements Schema - MT150007UV	N/A	COCT_MT150007UV.xsd	XSD	RPS R2 (2015 Normative Edition)
Common Message Elements Schema - MT150000UV02	R2	COCT_MT150000UV02.xsd	XSD	RPS R2 (2015 Normative Edition)

Document Title	Document Version	File Name	File Format	Release Notes
Common Message Elements Schema - MT150003UV03	R3	COCT_MT150003UV03.xsd	XSD	RPS R2 (2015 Normative Edition)
Common Message Elements Schema - MT710000UV07	R7	COCT_MT710000UV07.xsd	XSD	RPS R2 (2015 Normative Edition)
Common Message Elements Schema - MT960000UV05	R5	COCT_MT960000UV05.xsd	XSD	RPS R2 (2015 Normative Edition)
Common Message Elements Schema - MT030203UV07	R7	COCT_MT030203UV07.xsd	XSD	RPS R2 (2015 Normative Edition)
Common Message Elements Schema – MT040203UV09	R9	COCT_MT040203UV09.xsd	XSD	RPS R2 (2015 Normative Edition)
Common Message Elements Schema – MT070000UV01	R1	COCT_MT070000UV01.xsd	XSD	RPS R2 (2015 Normative Edition)
Common Message Elements Schema – MT090100UV01	R1	COCT_MT090100UV01.xsd	XSD	RPS R2 (2015 Normative Edition)
Common Message Elements Schema – MT090108UV	N/A	COCT_MT090108UV.xsd	XSD	RPS R2 (2015 Normative Edition)
Common Message Elements Schema – MT090300UV01	R1	COCT_MT090300UV01.xsd	XSD	RPS R2 (2015 Normative Edition)

Document Title	Document Version	File Name	File Format	Release Notes
Common Message Elements Schema – MT090303UV01	R1	COCT_MT090303UV01.xsd	XSD	RPS R2 (2015 Normative Edition)

GENERICODE FILES (CONTAINED IN ROOT DIRECTORY OF THE PACKAGE)

Document Title	Document Version	File Name	File Format	Release Notes
ICH M8 Codelist Set for Genericode	v4.0	ICH M8 Codelist Set.gc_v4.xml	XML	Updated with new Forward Compatibility OID
ICH M8 OID Listing	v5.0	ICH M8 OID Listing_eCTDv4_v5.xlsx	Excel	Updated with new Forward Compatibility OID
eCTD v4.0				
Genericode schema	v1.0	genericode.xsd	XSD	Initial schema file for implementation.
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.
ICH Context of Use CV	v4.0	M8 CL1 ich-cou.gc_v4.xml	Genericode (XML)	Updated to correct errors in CoU mappings (00650 and 00680).
ICH Document Type keyword CV	v3.0	M8 CL3 ich-document.gc_v3.xml	Genericode (XML)	Added CDISC values in version 1.4.
ICH Duration CV	v1.0	M8 CL4 ich-duration.gc_v1.xml	Genericode (XML)	Initial genericode file.
ICH Keyword Definition Type CV	v3.0	M8 CL5 ich-keyword-definition-type.gc_v3.xml	Genericode (XML)	Updated mappings in Keyword Definition Type (00640)
ICH Route of Administration CV	v1.0	M8 CL6 ich-route-of-administration.gc_v1.xml	Genericode (XML)	Initial genericode file.
ICH Species for Non-clinical studies	v1.0	M8 CL7 ich-species-for-non-clinical-study.gc_v1.xml	Genericode (XML)	Initial genericode file.

Document Title	Document Version	File Name	File Format	Release Notes
ICH Type of Control CV	v1.0	M8 CL10 ich-type-of-control.gc_v1.xml	Genericcode (XML)	Initial genericcode file.
ICH XML Type	v1.0	M8 ich-xml-types-fc.gc_v1.xml	Genericcode (XML)	Initial genericcode file. Added with Forward Compatibility content.
Context of Use Status CV	v1.0	M8 context-of-use-status.gc_v1.xml	Genericcode (XML)	Initial genericcode file.
Study Group Order CV	v1.0	M8 CL12 ich-study-group-order.gc_v1.xml	Genericcode (XML)	Initial genericcode file.
eCTD v3.2.2 Transition Mapping Message (TMM)				
Genericcode schema	v1.0	genericcode.xsd	XSD	Removed from Implementation Package v1.5
ICH M2 Code List stylesheet	v1.0	ICH_M2_Codelist.xml	XSL	Removed from Implementation Package v1.5
ICH Logo	v1.0	ich-logo.png	PNG	Removed from Implementation Package v1.5
ICH Context of Use TMM CV	v1.0	M8 CL1 ich-cou-tmm.gc_v1.xml	Genericcode (XML)	Removed from Implementation Package v1.5
ICH Document Type keyword TMM CV	v3.0	M8 CL3 ich-document-tmm.gc_v3.xml	Genericcode (XML)	Removed from Implementation Package v1.5
ICH Duration TMM CV	v1.0	M8 CL4 ich-duration-tmm.gc_v1.xml	Genericcode (XML)	Removed from Implementation Package v1.5
ICH Keyword Definition Type TMM CV	v2.0	M8 CL5 ich-keyword-definition-type-tmm.gc_v2.xml	Genericcode (XML)	Removed from Implementation Package v1.5
ICH Route of Administration TMM CV	v1.0	M8 CL6 ich-route-of-administration-tmm.gc_v1.xml	Genericcode (XML)	Removed from Implementation Package v1.5
ICH Species for Non-clinical studies TMM CV	v1.0	M8 CL7 ich-species-for-non-clinical-study-tmm.gc_v1.xml	Genericcode (XML)	Removed from Implementation Package v1.5

Document Title	Document Version	File Name	File Format	Release Notes
ICH Submission CV	v1.0	M8 CL8 ich-submission-type-tmm.gc_v1.xml	Genericcode (XML)	Removed from Implementation Package v1.5
ICH Submission Unit CV	v1.0	M8 CL9 ich-submission-unit-type-tmm.gc_v1.xml	Genericcode (XML)	Removed from Implementation Package v1.5
ICH Type of Control TMM CV	v1.0	M8 CL10 ich-type-of-control-tmm.gc_v1.xml	Genericcode (XML)	Removed from Implementation Package v1.5
Context of Use TMM CV	v1.0	M8 context-of-use-status-tmm.gc_v1.xml	Genericcode (XML)	Removed from Implementation Package v1.5
XML Type TMM CV	v2.0	M8 xml-types-tmm.gc_v2.xml	Genericcode (XML)	Removed from Implementation Package v1.5