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## ICH electronic Common Technical Document - eCTD v4.0

### ICH eCTD v4.0 Step 4 page

#### Background

The ICH M2 EWG has previously developed a list of requirements for input into the Health Level Seven (HL7) Regulated Product Submissions (RPS) Project. The list of requirements was last updated on November 11, 2010, and a link is available below on this page to use as a reference.

The ICH M8 EWG/IWG was formed in November 2010 to assume responsibility for the continued development of the next major version of the eCTD.

At the December 2015 ICH meeting, the ICH Assembly endorsed the *Step 4* ICH eCTD v4.0 Implementation Package v1.0 and related files.

The Package has been updated in response to the change requests and/or discussion within the EWG after its initial release. As of May 2024, the Implementation Guide and Controlled Vocabulary documents were split into two different packages to enable Controlled Vocabulary Versioning.

See the Implementation Guide Package History document or the eCTD v4.0 Controlled Vocabulary ReadMe file for a detailed revision history. The latest version of the eCTD v4.0 Implementation Guide (v1.6) and eCTD v4.0 Controlled Vocabulary Package (v1.0.2) documents were endorsed by the ICH Assembly in May 2024.

#### ICH Step 4: Adoption of ICH Harmonised Guideline

ICH *Step 4* is an ICH step where the ICH Assembly agrees that there is sufficient consensus on the Guideline.

#### Step 4 Implementation Documents

##### ICH eCTD v4.0 Implementation Guide Package

To download the package, [click here](#).

This Implementation Guide Package contains the Implementation Guide and the schema files.

*Note that these documents need to be used in conjunction with the Regional/Module 1 documents provided on each of the regional consultation pages (see links below).*

Document	File Name	Version Number	Description
ICH eCTD v4.0 Implementation Guide History	eCTD v4_0_Implementation_Package_History_v1_6.pdf	V1.6	History of the documents contained in the package.

ICH eCTD v4.0 Implementation Guide	ICH_eCTDv4_0_ImplementationGuide_v1_6.pdf	V1.6	Instructions portions of t specification
Schema Files for eCTD v4.0 Message	ICH_eCTD_v4_SchemaFiles	-	Folder conta of schema fil

### ICH eCTD v4.0 Controlled Vocabulary Package

To download the package, [click here](#).

This Controlled Vocabulary Package contains the eCTD v4.0 Code List and associated Genericcode files.

*Note that these documents need to be used in conjunction with the Regional/Module 1 documents provided on each of the regional consultation pages (see links below).*

Document	File Name	Version Number	Description
ICH eCTD v4.0 Controlled Vocabulary Package ReadMe file	ReadMe_eCTDv4_0_CV_Package_v1.0.2.pdf	V1.0.2	History of the contained Vocabulary pa
ICH Code List for eCTD v4.0	ICH_eCTDv4_0_CV_v6.xlsx	V6.0	Harmonized cc
M8 Genericcode Schema and Files	Genericcode	-	Folder contain controlled voca

### Supplemental Documents for eCTD v4.0 Implementation Package

The following documents are to facilitate understanding of the Implementation Package:

- [Support Documentation for eCTD v4.0 Implementation Package](#) - This document explains the contents enclosed in the Implementation Package (listed above) as an overview of the eCTD v4.0 implementation. The target audience is business and technical personnel who build and/or review the eCTD v4.0 XML Messages.
- [Orientation Material for eCTD v4.0 Implementation Package](#) - This document provides an outline of eCTD v4.0 concept from business perspective. The target audience is business personnel and management involved in any aspect of eCTD submission design and preparation.
- [eCTD FAQs](#) - This document provides frequently asked questions about the eCTD implementation. The target audience is anyone interested in the ongoing implementation of eCTD v4.0

### Schema Files for eCTD v4.0 message

The Implementation Package above contains the schema files for eCTD v4.0 *Step 4*. Implementers should use the included schema files.

Extract the zip file to a convenient location. The folder/file structure found in the zip file is important. When referencing these schema files with software tools, the 2 folders ("coreschemas" and "schema") along with the schema files within those folders should be maintained.

## ICH Step 5: Implementation

Once *Step 4* is reached, the harmonised Guideline moves to the final step of the process and is implemented by each of the Regulatory Members in their respective regions. The harmonised Guideline is implemented according to the same national/regional procedures that apply to other regional, scientific or regulatory Guidelines and requirements.

## Call for Vendor Participation

If you are an eCTD v4.0 Tool Vendor and would like to join the eCTD Tool Vendor Group to discuss eCTD v4.0 implementation, please send the following information listed below to [ICHM8Vendors@ich.org](mailto:ICHM8Vendors@ich.org):

- First Name;
- Last Name;
- Email;
- Company Name;

Please note that your information will be shared as needed with Representatives of ICH Members and Observers involved with ICH eCTD activities.

Reference links below for "Regional Implementation Information".

## Regional Implementation Information

Region	Technical Pilot <sup>1</sup>	Implementation Dates <sup>2</sup>	Implementation Documents
ANVISA, Brazil	4Q 2026 (Planned)	2027 (Voluntary) TBD (Mandatory)	TBD
EC, Europe	2024 CAPs (MAA completed)  2026 CAPs (Forward compatibility - planned start Q1)  2026 non-CAPs (MAA - planned start Q2)  2026 non-CAPs (Forward compatibility - planned)	2025 (Voluntary for CAPs <sup>2</sup> )  2026 (Voluntary for MRP/DCP/NP)  2027 (Mandatory for CAPs)  TBC (Mandatory for MRP/DCP/NP)	<a href="#">EC, Europe regional implementation page</a>

FDA, United States	2022 - 2Q 2023 (Completed)  2026 Forward Compatibility (Planned)	2024 (Voluntary)  2029 (Mandatory)	<a href="#">FDA, United States regional implementat</a>
Health Canada, Canada	2026 - 2027 (Planned)	2027 (Voluntary)  2029 (Mandatory)	<a href="#">Health Canada, Canada regional impleme</a>
MFDS, Republic of Korea	TBD	2027 (Voluntary)  TBD (Mandatory)	TBD
MHLW/PMDA, Japan	2Q 2021 (Completed)	2022 (Voluntary)  2026 (Mandatory)	<a href="#">MHLW/PMDA, Japan regional implemente</a>
Swissmedic, Switzerland	2026 (Planned)	2027 (Voluntary)  2030 (Mandatory)	<a href="#">Swissmedic, Switzerland regional implem</a>
TGA, Australia	2028 (Planned)	2029 (Voluntary)  TBD (Mandatory)	<a href="#">TGA Implementation of ICH eCTD v4.0 S</a>

<sup>1</sup> A Technical pilot includes industry parties (participation may be limited in some regions) who will submit sample/test submissions. The objective of this testing is to determine if the implementation satisfies the requirements in the technical specification, and make any changes prior to accepting eCTD v4.0 submissions in the production environment.

<sup>2</sup> A Production pilot includes industry parties (participation may be limited in some regions) who will submit submissions to the regulator for regulatory review. The objective of this testing is to ensure that the production environment is ready for a full release, and to accept the production volume of submissions.

Voluntary dates indicate when eCTD v4.0 submissions are accepted into the production environment after all pilots are complete.

Mandatory dates indicate when all submissions are required to be in the eCTD v4.0 format.

TBD = Dates and/or materials are not yet known or not ready for public release, respectively.

*This information will be updated biannually based on the progress of ongoing implementation activities.*

## [Updated in March 2026]

### Change Control

- The M8 IWG has implemented a [Change Control Process](#). (PDF document)
- A request for change may be submitted by use of [this form](#). (zipped MS Word document)
- Results of change requests are published in a [Q&A document](#) (Excel spreadsheet) [Q&A version 1.9: Updated in March 2025]

