

M8 eCTD Vendor Group

October 9, 2024

Welcome to the M8 eCTD Vendor Group



■ Agenda

- Objectives
- Group Communications
- Discussion Topics
- Next Steps

Important Note: This information is based on the information and circumstances provided at the date of publication and may change as new developments arise

eCTD Vendor Group Objectives

- Objectives:
 - To create an ongoing forum to raise eCTD v4.0 implementation questions – e.g., specification details, etc.
 - To understand the current availability of eCTD v4.0 Tools available to Regulated Industry

eCTD Vendor Group Communications

- Please feel free to raise topics *before, during* or *after* the meetings
 - Agendas will be drafted to address any **ongoing** or **new** topics
 - Topics may include:
 - How to use this eCTD Vendor forum
 - Clarifications on Implementation specifications
 - Implementation status across regions
 - New requirements
- We aim to discuss implementation questions in general
 - Questions should focus on the specifications and not how specific tools are implemented
 - If you have a region-specific question, please contact the region directly
- The vendor group is solely intended to facilitate collaborative discussion on the eCTD v4.0 Implementation Specification and timelines.
 - This is not an opportunity to share product offerings

How to Communicate with M8

EMAIL: ICHM8VENDORS@ICH.ORG



- All correspondence related to the *eCTD Vendor Group activities* should be sent to the designated email.

Examples include:

- Feedback related to eCTD v4.0 topics in the eCTD Vendor Group
- Suggestions for future topics

EMAIL: ADMIN@ICH.ORG



- Official *Change Requests* to the ICH eCTD v4.0 Implementation and Controlled Vocabulary specifications
- These request will result in a change request at the specification level and be included in the next version of the eCTD v4.0 Q&A document.

Discussion Topics

- Questions about eCTD v4.0 Implementation
 - Forward Compatibility
 - Controlled Vocabulary
 - Grouped Submissions
- M8 Resources
 - [eCTD v4.0 Webpage](#)
 - Includes information about eCTD v4.0 Specifications and Implementation Status
 - Previous Vendor Group Materials are now posted on the [eCTD v4.0 webpage \(Kiosk\)](#)
- Future Topics
 - Smart Hyperlinking
 - M4Q (R2) Updates

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

[ESTRI Home page](#)

M8 Vendor Meeting 1 - Minutes and Presentation

-  [Minutes of Meeting](#)
-  [Presentation](#)

Forward Compatibility

- ***Question:** CoUs in section M4 or M5 require keywords that came from STFs in ICH 3.2 sequences. So, with Forward Compatibility, for regions that did not accept or process STFs with ICH 3.2, you cannot replace content from 3.2 without breaking context groups. This means, all content needs to be suspended and re-added. Correct?*
- **Answer:**
 - **We currently have the following guidance in the ICH IG (Section 9.2.9.2.1):** “For forward compatibility, when replacing v3.2.2 content keywords must match the attributes, node extensions, file-tags, property or categories previously submitted in v3.2.2. All existing values shall be provided regardless of keyword type – i.e., now part of a controlled vocabulary or a keyword definition. If a node-extension was previously allowed, the group title keyword definition should be used to send the same value. If multiple node extensions were provided on the same heading or nested, the values should be concatenated into one group title keyword definition. In addition, refer to Regional/Module 1 Implementation Guide for Module 1 Context of Use vocabulary that may be replacements for node-extensions.”
 - **We will add the node-extensions to the ICH IG Table 9: “Attribute Mappings”** to be clear how this should be used; The Group title should be used to provide the v3.2.2 node extension as noted above only when an equivalent keyword does not exist.
 - Regions planning on implementing Forward Compatibility: [Europe](#), [US](#), [Canada](#), [Switzerland](#) and [Australia](#)

Controlled Vocabulary

- **Question:** Could we look at harmonising CV across the globe in the future?
- **Answer:** Updates to Controlled Vocabulary in Module 2 – 5 should be Change Requests; Module 1 Regional content will not be harmonised as it is not within the scope of ICH

Controlled Vocabulary

- **Question:** Are any recommendations available for Sender defined keyword code value format, on top of information defined in the ICH spec?
- **Answer:** As the *keywordDefinition.value.item@code* is sender defined, we are not providing specific requirements for this attribute. Some regions may limit the number of characters for this attribute, but they are within 180-256 characters. The samples in the ICH IG are for illustration only and should not be considered prescriptive.

Controlled Vocabulary

- **Question:** Can you harmonize the file format (text, xml, excel, etc) of CVs that can simplify implementation?
- **Answer:** Regions are using the Genericode and/or CV Spreadsheets (.xlsx) file formats to provide regional controlled vocabulary

Grouped Submissions

- Grouped Submissions are an “excluded business process” in the ICH Implementation due to the regional variations
- Given the variation in regulatory processes and definition of a “grouped submission”, this will not be harmonised across regions.
- For eCTD v4.0, the following regions will implement **Grouped submissions as defined by the Region:** EC, Europe; FDA, United States; Health Canada, Canada; and Swissmedic, Switzerland

Current ICH IG Text regarding Grouped Submissions

- Section 4.8 – Excluded Business Processes
 - “*Grouped Submission* – may be handled differently across the regions due to the variation in regulatory processes.”
- Section 6.5.1 – Keyword Definitions (in Sender-defined Values section)
 - “*Note to Implementers:* There may be business scenarios that require the management of sender-defined vocabulary across applications (e.g., grouped submissions). It is recommended that keyword definitions be managed across applications to optimise their future use in each relevant Application as Context of Use keywords. Refer to Regional/Module 1 Implementation Guides for additional information.”
- Section 9.2.18.6.1
 - “At this time, keywords should only be defined for an application. However, the same keyword definitions (code and value pair) may be resubmitted across applications to allow for specific regional business scenarios (e.g., grouped submissions).”



Additional Topics or Questions

- Are there any additional topics and/or questions for today's discussion? Or future vendor group meetings?
- Any updates you would like to receive when we meet again in 2025?

Next Steps

- Meeting Schedule:
 - January 29, 2025
 - April 9, 2025
 - July 2, 2025
 - October 2025 - TBD
- Future Agenda Topics
 - Smart Hyperlinking
 - M4Q (R2) Updates