

M8 eCTD Vendor Group

April 9, 2025

Welcome to the M8 eCTD Vendor Group



■ Agenda

- Discussion Topics
- Next Steps

Note: For new vendors, please see Appendix for the background information for this Vendor Group (e.g., group objectives and communication logistics for the group)

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

Discussion Topics

TODAY'S TOPICS

- M8 Announcements
- Vendor Questions
- Smart Hyperlinking
- Open Questions

FUTURE TOPICS

- M4Q (R2) Updates

M8 Announcements

M8 Announcements

- eCTD v4.0 Webpage

- Implementation Status Updates (posted on January 17, 2025)
 - Includes updates of Regional Implementation Timelines for eCTD v4.0
- Meeting Notes from October 9, 2024 (posted on February 14, 2025)
- eCTD FAQ (posted on February 14, 2025)
- M8 Vendor Group Questions (posted on March 20, 2025)
- eCTD v4.0 Q&A v1.9 (posted on March 24, 2025)

Question about Reactivation

- **Question:** Can you reactive a CoU, does the priority number need the updateMode?
- **Answer:** Action item taken to discuss with ICH M8
- **2024-10-09 Post Meeting response:** A Context of Use (CoU) cannot be reactivated simply by updating the status code. The content must be resubmitted with a new Context of Use. An available priority number would be assigned to the new CoU.

Interim Vendor Group Questions

- Questions are posted here: [Vendor Group Question \(kiosk\)](#) and direct link: [M8VendorGroup_Questions_2025_0314.pdf](#)
 - Any follow-up questions?

Sender-defined Keywords – Keyword Definition

codeSystem

We have a question regarding **Sender-defined Code Lists** in eCTD 4.0, specifically on the Code Systems.

Question : In a Keyword Definition, is it possible to change the Code System value for a sender-defined keyword?

For example, in the below XML the value in question is **bold**. If in a future sequence, the displayName for this keyword is updated (via updateMode=R,) can the codeSystem indicated for the display name update be different then what was initially defined, as long as the keyword.item@code remains the same (vernpharm in the below example)?

```
<referencedBy>
  <keywordDefinition>
    <code code="ich_keyword_type_3" codeSystem="2.16.840.1.113883.3.989.2.2.1.5.4"/>
    <statusCode code="active"/>
    <value>
      <item code="vernpharm" codeSystem="mySenderCode">
        <displayName value="VernPharm Inc"/>
      </item>
    </value>
  </keywordDefinition>
</referencedBy>
```

Our understanding is that the Code System for Sender-defined Keywords **cannot be updated** via updateMode.

Response: The sender-defined codeSystem cannot be updated using updateMode. If there is a new code system, the application will need new KeywordDefinitions and CoU lifecycle will be broken in order to use the new Keywords. Note – the keyword code is always checked against the codeSystem identifier

Code List Versioning – Support Dates

The applicant submits a Submission Unit with multiple CoU elements that use code “ich_document_type_4”, where two different Health Authority codesystem OIDs are used (namely, one CoU references the OID ending in “.3” and another CoU references OID ending in “.4.”

Here is the example in XML:

```
80      </documentReference>
81    </derivedFrom>
82    <referencedBy typeCode="REFR">
83      <keyword>
84        <code code="ich_document_type_4" codeSystem="2.16.840.1.113883.3.989.2.2.1.3.3"/>
85      </keyword>
86    </referencedBy>
87    <referencedBy typeCode="REFR">
88      <keyword>
89        <code code="jp_adam_20" codeSystem="2.16.840.1.113883.3.989.5.1.3.3.1.15.9"/>
90      </keyword>
91    </referencedBy>
92  </contextOfUse>
93 </component>
```

Here is an example

Codesystem ending in ".3"
for ich_document_type_4

```
105      </documentReference>
106    </derivedFrom>
107    <referencedBy typeCode="REFR">
108      <keyword>
109        <code code="ich_document_type_4" codeSystem="2.16.840.1.113883.3.989.2.2.1.3.4"/>
110      </keyword>
111    </referencedBy>
112    <referencedBy typeCode="REFR">
113      <keyword>
114        <code code="STDYID_TITLEXYZ" codeSystem="2.16.840.1.113883.9999.2"/>
115      </keyword>
116    </referencedBy>
117    <referencedBy typeCode="REFR">
118      <keyword>
119        <code code="Site_ID_code" codeSystem="2.16.840.1.113883.9999.2"/>
120      </keyword>
121    </referencedBy>
122  </contextOfUse>
123 </component>
```

Codesystem ending in ".4"
for ich_document_type_4

/PORP_IN000001UV/controlActProcess/subject/submissionUnit/component/contextOfUse/referencedBy/keyword/code/@codeSystem

length: 23,429 lines: 595

Ln: 109 Col: 111 Pos: 4,095

Code List Versioning – Support dates

- **Question:** Is it valid to submit a Submission Unit where a unique Code value is used in more than one Context of Use, but the Health Authority-defined Code System OIDs are different?
- **Answer:** The Region/Regulator will determine what code lists will be supported in their implementation. Regions may accept more than one version of the Controlled Vocabulary (CV), but they may limit the variation within one submissionunit.xml file.

Note – Technically the receiving system should be able to handle any valid codeSystem (which may be across CV versions).

Code List Versioning – Support dates

- **Question:** Given that the ICH specification says “The code lists have an ICH Support period. The ICH Support period has a start date and an end date. A code list may have one or more active versions at any given time”, our assumption is that the above case is possible and valid. Could you help confirm if our understanding is in alignment with what is expected from applicants?
- **Answer:** The ICH Support Dates in the ICH CV are indicated to allow the Region/Regulator to have adequate time to adopt the new CV version in their implementation. ICH M8 will determine when a CV version is no longer supported -- i.e., all Regions have adopted the newer CV version(s).

Table 6: Sample Code List

Code System			ICH Support Period	
Type	Code Set Name	Code System OID	Start Date	End Date
ICH	ICH Code List 1	2.16.840.1.113883.3.989.2.2.1.X.1	n/a	n/a
		2.16.840.1.113883.3.989.2.2.1.X.2	2020-01-01	2022-01-01
		2.16.840.1.113883.3.989.2.2.1.X.3	2021-06-01	
		2.16.840.1.113883.3.989.2.2.1.X.4	2023-01-01	

The following sub-sections describe how to interpret the ICH Support Period – i.e., whether or not the code list is valid or retired from use as well as the lifecycle of the codes.

Smart Hyperlinking

Smart Hyperlinking - Requirements

- M8 is considering adding a requirement to automatically hyperlink to the latest version of the document.
- Example: If a document in M2 (sent in SN2) contains a hyperlink to a document in M3 (also sent in SN2, but has an update in SN3 – i.e., it has been life cycled (with replace operation)).
 - Option 1: We are thinking an automated warning could be helpful when the eCTD viewer tool attempts to open a document that is not the latest lifecycle version. It could give the user an option to go directly to the “active” (i.e., “latest”) version of the document(s).
 - Option 2: [Are there any other recommended options?](#)

Smart Hyperlinking

- This feature is desired for eCTD in general. **Can this be agnostic of eCTD version?**
- **Should we include additional guidance in the M8 documents to ensure consistent implementation of this requirement across vendors?**
 - Note: Information about hyperlinking is currently provided in the [M8 SSF](#) (Specification for Submission Formats for eCTD) document
- **Next Steps:** Please send comments via email to: ICHM8Vendors@ich.org prior to June 3, 2025

Open Discussion

Additional Topics or Questions

- Are there any additional topics and/or questions for today's discussion? Or that should be addressed at future vendor group meetings?

Next Steps

Next Steps

- Meeting Schedule:
 - July 2, 2025
 - Smart Hyperlinking
 - October 2025 - TBD
- Future Agenda Topics
 - M4Q (R2) Updates
 - Others?

Appendix: Information for New Vendors

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.