

M8 VENDOR GROUP MEETING

Meeting Date: April 9, 2025

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

AGENDA

Discussion Topics:

- M8 Announcements
- Vendor Questions
- Smart Hyperlinking
- Open Q&A
- Next Steps

1. DISCUSSION

Discussion included recent updates to the ICH eCTD v4.0 webpage, review of ICH M8 response to an outstanding vendor group question about reactivation from the previous meeting, and responses to new questions that were submitted after the previous meeting. Smart hyperlinking was discussed: M8 is considering adding a requirement to automatically hyperlink to the latest version of a document and described a scenario to the group, requesting feedback on options. The slides should be consulted for specific responses to those topics.

2. OPEN DISCUSSION/Q&A

#	Questions and Answers – [action items are included for M8 IWG]
1	Question: Can you reactivate a CoU, does the priority number need the updateMode? Answer: A Context of Use (CoU) cannot be reactivated simply by updating the status code. The content must be resubmitted with a new CoU. An available priority number would be assigned to the new CoU
2	Question: In a Keyword Definition, is it possible to change the Code System value for a sender-defined keyword? Answer: 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.
3	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.
4	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.

Questions and Answers – [action items are included for M8 IWG]

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).

Next meetings (invitations will be submitted)

- July 2, 2025
- October 2025 - TBD

Future Meeting Agenda Topics:

1. New Topics/Questions from Vendors
2. Smart Hyperlinking

Reminder: Any clarifications and/or recommended changes to the implementation specifications can be submitted as [change requests](#).