

M8 VENDOR GROUP MEETING

Meeting Date: July 2, 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
- Open Q&A
- Next Steps

1. DISCUSSION

Discussion included an update on recent issues related to mailbox management, upcoming updates to the ICH eCTD v4.0 webpage, including regional eCTD v4.0 implementation status updates, responses to new questions that were submitted after the previous meeting and a reminder on meeting scope for new joiners. 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: Further to a previous question and response, additional question: are Group Titles allowed in Modules 4 and 5 in addition to the study id_study title keyword? Answer: Yes but they should not be used instead of Document Type Keywords.
2	Question: Further to a previous question and response, additional scenario: can the lifecycle 'replace' operation be used on a document placed in a higher section in eCTD v4.0 which was previously submitted in a lower section in DTD v3.2, if that lower section is no longer available for use? Answer: No, using the 'Replace' operator in this way would trigger an eCTD4-025 error. Content should be suspended and added as new.
3	Question: Further to a previous question and response, clarification question: must documents be replaced without keywords in a higher section of an eCTD v4.0 submission, when the keywords associated with a document submitted in DTD v3.2 sequences are no longer needed? Answer: Reminder: If no content changes are being made there is no need to resubmit for eCTD v4.0. If content is changing, keywords that are valid for the CoU should be used. Please follow the ICH CV and IG for guidance on the valid use of keywords and CoU.
4	Question: Further to a previous discussion, clarification question: what is the business requirement driving the SMART hyperlinking functionality? As a potential alternative, would it

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	be possible for the viewing tool at the agency to determine when the target of a link has been replaced/deleted and provide options? Answer: The potential alternative mirrors what M8 is proposing. eCTD carries the information required to track lifecycle of documents and submissions but it is up to each vendor to decide how to present this information to their respective users.
5	Question: Do eCTD4-072 and JP-eCTD4-141 prohibit the use of multiple keywords of the same type being assigned to a single CoU or rather keywords of the same value? Answer: Per eCTD4-072: On each Context of Use element, a valid Keyword Type shall only be used once.
6	Question: A question was received during the meeting that related to CoUs such as 5.3.1.1 for example, where COU and Document Type must support granular study reports containing multiple, different document types, whilst retaining priority numbers. Should Document Type be an attribute of Document and not the CoU to manage this? Answer: It is worth noting that documents should be re-usable across submissions. Having Document Type or Priority Number at the document level could cause issues. M8 will consider and provide a formal response.

Next meetings (invitations will be submitted)

- October 2025 - TBD

Future Meeting Agenda Topics:

1. New Topics/Questions from Vendors
2. Smart Hyperlinking
3. M4Q(2) updates

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