

M8 VENDOR GROUP MEETING

Meeting Date: January 28, 2026

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
- Submitted Vendor Questions & Responses
- Open Q&A
- Next Steps

1. M8 ANNOUNCEMENTS

Discussion included upcoming updates to the ICH eCTD v4.0 webpage, including regional eCTD v4.0 implementation status updates to be posted in February and notes and slides from the last meeting held in July 2025. The slides should be consulted for specific responses.

2. SUBMITTED QUESTIONS AND RESPONSES

#	Questions and Answers – [action items are included for M8 IWG]
1	Question: Related to Forward Compatibility and Sequence Numbering Answer: In v4.0 a sequence number should be chosen which continues the same numbering scheme previously used for v3.2.2, as long as it is a whole number. No further questions or comments received
2	Question: Related to Document Re-use Answer: An alternative approach would be to store the document ID element along with any other metadata deemed relevant in a single lookup table. However, solutions should be implemented as vendors choose within their own system to meet the requirements of the specifications. Vendor Follow-up Question: Is the Document ID consistent across all applications? Answer: M8 confirmed this was the case. Vendor Follow-up Question: Is re-use only possible across applications within the same regulator? Answer: M8 confirmed that Document ID should be viewed as unique per region.
3	Question: Related to Forward Compatibility and Optional Keywords Answer: It is acceptable to transition files under 3.2.A without keywords. However, there is no need to resubmit v3.2.2 content when transitioning to v4.0 if the content has not changed. Complications would arise from submitting an updated document where the attributes don't match the keywords. No further questions or comments received

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4	Question: Related to Document Type and Priority Number Answer: eCTD v4 is set up to allow the submitter to include multiple documents under one study and further organize these documents into groupings with Document Type Keywords. The priority number defines the display order of the document within a group of documents at the same hierarchical level. Documents are established with only basic metadata to provide maximum flexibility to be used again under different COUs via document re-use. Examples were provided. Vendor Follow-up Question: Do priority numbers need to be sequential across Document Type keywords, or can they be repeated under different Document Type keywords? Answer: M8 confirmed that content would be ordered by priority number within a Document Type keyword and so didn't need to be sequential with other instances and could be re-used.
5	Question: Related to Forward Compatibility and Node Extensions Answer: Conversion steps and representative xml examples were provided for two scenarios related to carrying forward v3.2.2. Node Extension values when no dedicated v4.0 keyword exists: A Group Title keyword providing the value from a single v3.2.2 node extension and from multiple node extensions (from the same heading or nested) in v3.2.2. Vendor Follow-up Question: Is a simple space used as the concatenation delimiter? Answer: M8 confirmed. (See follow-up in Open Discussion)
6	Question: Related to Forward Compatibility and Study_Id & Study Title Answer: The approach referred to as Option 1 in the submitted question was confirmed as the correct approach to use. No further questions or comments received
7	Question: Related to M4Q(R2) Changes Answer: eCTD v3.2.2 will not be updated or incorporate any of the changes described in the M4Q(R2) guideline. eCTD v4.0 ICH Context of Use codes will be updated to reflect the M4Q(R2) changes once the guidance is finalized. No further questions or comments received

3. OPEN DISCUSSION

#	Questions and Answers – [action items are included for M8 IWG]
1	Question: Related to Contact lifecycle across regulatory activities Submission xml element represents regulatory activity and its id determines whether the whole submission unit is about a new regulatory activity or a continuation of an existing one. So, I'm interested in the following scenario: Seq 1 – New Submission1 with Contact1 Seq 2 – New Submission2 (different submission id than in seq1) with same Contact1 (same contact id as in seq1) Is this allowed or should be treated as an error? Is contact and its lifecycle (updates) defined within the scope of a single regulatory activity? Answer: M8 representatives suggested that the same contact details should be able to be re-used across activities. Vendor Follow-up Question: If this is the case, why should the details need to be re-entered. This is confusing from a validation perspective – why should the details have to be rendered in

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	full, with all fields repeated? If a typing mistake was made, for example, it would lead to an error. Answer: M8 will discuss within the EWG and revert.
2	Question: Is there a maximum number of node extensions that can be concatenated as per the examples provided in answer to the question above? Raised due to multiple concatenations, for different regions, for example, could become very complex and make it difficult to see delimiters. Answer: M8 (EC, Europe) stated that there was no upper limit defined and no practical examples of complexities yet. That being said, advice had always been to limit the use of node extensions, albeit, in practice, they were used widely. An upper limit had probably not been envisaged as advice had always been not to use expansively. Vendor Follow-up Question: Should submitters be mindful of ordering, given that systems could have issues identifying critical keywords? Answer: M8 suggested that vendors could run a test concatenating 100 node extensions, for example, and share the results. M8 (EC, Europe) stated that they would be happy to take this issue and look into it further in their next pilot phase. Vendor Follow-up Question: Could this cause an issue with the 512-character limit? Answer: M8 (EC, Europe) will check and revert. Vendor Follow-up Question: Is the character limit published or referenced in documentation? Answer: Yes. It is referenced in US-eCTD-501. M8 reminded and requested that participants submit any further questions to the Vendor Group Mailbox. Management of this mailbox has been revised so M8 hope to be more agile in responding moving forward. New participants were referred to the slide contained in the meeting deck appendix.

Next meetings (invitations will be submitted)

- April 2026 - TBD

Future Meeting Agenda Topics:

1. New Topics/Questions from Vendors

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