

M8 VENDOR GROUP MEETING

Meeting Date: October 9, 2024

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:

- Objectives
- Group Communications
- Discussion Topics
- Open Q&A
- Next Steps

1. DISCUSSION

Discussion included responses to questions about eCTD v4.0 Implementation: Forward Compatibility, Controlled Vocabulary, and Grouped Submissions. 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 have repeating sections? Answer: There are multiple conditions that factor into repeating sections. The technical specifications will identify which headings allow more than one document (e.g., M4 Granularity document); and the Controlled Vocabulary lists the Keywords allowed for each CoU code, which indicates when a section can be repeated. Regions may specify headings that are not repeatable (even when it is technically possible).
2	Question: When submitting a Forward Compatibility submission for the first time that the complete representation of the v3.2.2 structure (i.e., baseline transition) and are any modifications allowed? Answer: Forward Compatibility allows ongoing life cycle or document reuse to occur. Once v4.0 is submitted, no v3.2.2 submissions are allowed. Only content that needs to be life cycled will use forward compatibility (i.e., the entire application does not need to be resubmitted). References to documents previously submitted can be sent using forward compatibility.
3	Question: Is it recommended that a priority number get inherited by the replaced or suspended ContextOfUse? Answer: There are no recommendations that the priority number is assigned the same value when replacing content. The priority number may be reassigned to the replacement CoU, may be incremented, or reordered within the context group as necessary. The ICH Implementation guide does not prescribe the assignment of priority numbers. Regions may have specific rules for duplicate priority numbers, so that may need to be taken into consideration

#	Questions and Answers – [action items are included for M8 IWG]
4	Question: For suspended CoUs and the content is resubmitted, can the same priority number be used when resubmitting content? Answer: Yes
5	Question: Can you reactive a CoU, does the priority number need the updateMode? Answer: Action item taken to discuss with ICH M8 Post Meeting response: A 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.
6	Question: If there is a new mandatory keyword assigned for a CoU, how is life cycle maintained in future sequences? Answer: When new keywords are required, a new context group will be created. Context Group rules will apply in this scenario. Previous context groups will be suspended.
7	Question: Are there valid use cases when only the priority number is being updated? Answer: A change to the priority number cannot be done as a stand-alone operation. Content must be submitted to indicate the changes in order to use updateMode.
8	Question: Can you update a keyword definition if there are no uses of the keyword in the sequence? Answer: Keyword Definition updates can happen in any sequence whether or not content updates are included along with the keyword definition value. The changes will be applied across the application for these types of updates.
9	Question: Will the keyword definition update be applied to all submissions? Answer: The changes will be applied to all references to the keyword definition across the application. If the update is within a Grouped Submission, the keyword definition change will need to be made to all applications in the group.

Next meetings (invitations will be submitted)

- January 29, 2025
- April 9, 2025
- 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](#).