

M8 VENDOR GROUP MEETING

Meeting Date: July 17, 2024

AGENDA

Discussion Topics:

- Objectives
- Group Communications
- Discussion Topics
- Next Steps

1. DISCUSSION

Communications: It was noted that there were issues with the communications with the ICH Secretariat:

- ICH did not answer some emails from interested people.
- No response to the original email

We will work with the ICH Secretariat to ensure that the email communication between meetings is improved.

Participation: In order to participate in the eCTD Vendor group, Vendors must sign-up via the ICH Secretariat by sending your contact information to: ICHM8Vendors@ich.org

The next meeting invite will only be sent to individuals who have submitted their request via the ICH Secretariat. Individuals who join without pre-registration will not be admitted into the meeting.

2. QUESTIONS

#	Questions/Answers – [action items are included for M8 IWG]
1	Question: In the latest ICH eCTDv.4 implementation guide v1.6, section 9.1.2 (xml sample). The item root and identifier name are the same as previous version. Why is it not incremented in the latest version? Answer: We made the decision not to update XML samples in the IG unless edits were made that would result in the need to edit the sample. XML samples in the IG are to be considered exemplary but not strictly to be followed version to version. When new XML snippets are added they will use current OIDs as of the time of the update.
2	Question: Are there any plans to harmonize the timelines across the Regions? Answer: Every January and July we update the Implementation Status to communicate the implementation timeline for each region. Because there are many factors each region must take into account when planning their implementation, including regulatory requirements, we do not anticipate the ability to harmonize timelines across regions. The July 2024 updates will be published in the next week or two and updated timelines will be available.

#	Questions/Answers – [action items are included for M8 IWG]
3	Question: Do we have any Regionally provided tools to validate eCTD v4.0? Answer: FDA, for informational purposes, posts the validation tool that is used by the Agency. JP PMDA confirmed that they provide a validation tool for public use for eCTD v4.0.
4	Question: Is there a forum that we can post questions as the vendors review the ICH specifications? Answer: Emails can be sent to the ICHM8Vendors@ich.org email to ask questions and they will be discussed during these calls.
5	Question: Forward Compatibility: CoUs in section M4 or M5 require keywords that came from STFs in ICH 3.2 sequences. So, with Forward Compatibility, for regions that did not accept or process STFs with ICH 3.2, you cannot replace content from 3.2 without breaking context groups. This means, all content needs to be suspended and re-added. Correct? Answer: We will take this question back to M8. [Action Item]
6	Question: What regions don't allow forward capability? Answer: We will take this question back to M8. [Action Item]
7	Question: Could we look at harmonising CV across the globe in the future? Answer: We will take this question back to M8. [Action Item]
8	Question: Can we submit a sample submission to any Authority who can technically validate our submission (ICH - countries)? Answer: Technical and Production Pilots are available and posted on the Implementation Status updates on the ICH eCTD v4.0 webpage. FDA plans to provide this type of support once the agency begins accepting eCTD v4.
9	Question: Are any recommendations available for Sender defined keyword code value format, on top of information defined in the ICH spec? It gives impression it can be literally anything. Answer: The codes format can be anything, as we have had requests from some vendors not to be prescriptive, and others that they be human readable. We will take this question back to M8. [Action Item]
10	Question: Can you harmonize the FORMAT (text, xml, excel, etc) of CVs that can simplify implementation? Answer: Genericcode and Excel files are provided for Controlled Vocabulary to comply with ICH processes. We will take this question back to M8 to determine where the variation maybe happening. [Action Item]
11	Question: How does eCTD v4.0 support the integration of new electronic submission types, such as the electronic Application Form (eAF) and electronic Product Information (ePI)? Answer: This is already being addressed in eCTD v3.2.2 (as optional use). eCTD v4.0 (like v3.2.2) is agnostic to file formats and will continue to support multiple file formats. Since the eAF and ePI are only applicable at the regional level, integration would be handled at that level as well. In the future, if these new materials are adopted by ICH, then ICH M8 will discuss making updates to the ICH eCTD v4 CV and/or ICH eCTD v4 IG to support requirements.
12	Question: Should we conduct outreach to any other vendor groups? Answer: Consider posting on the IRISS Forum. [Action Item]
13	Question: Is there a preference on meeting cadence? Answer: Quarterly with ad-hoc meetings as necessary. Our next meeting is scheduled in 2 months on September 11, 2024.
14	Question: Can we have an agenda prior the meeting? Answer: Any topics planned can be sent to the participants, but the agenda is open for individuals to raise during the meeting. Our next meeting will happen one week after our M8 teleconference to finalize the agenda. We will send out the agenda to the group shortly before the next meeting.

Future Meeting Agenda Topics:

1. ICHv1.6 Upgrade discussion (questions should be sent to M8)
2. Follow-up on “Harmonization Topics”
 - a. Forward Compatibility
 - b. Controlled Vocabulary
 - c. Outreach to IRISS Forum