

M8 VENDOR GROUP MEETING

Meeting Date: April 22, 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
- Upcoming changes to the IG and CV packages
- Open Discussion
- Next Steps

1. M8 ANNOUNCEMENTS

Discussion included March-2026 updates to the ICH eCTD v4.0 webpage, including regional eCTD v4.0 implementation status updates posted and notes and slides from the last meeting held on Jan 28, 2026. 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: 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: Seq1 - New Submission1 with Contact1 Seq2 - New Submission2 (different submission id than in seq1) with same Contact1 (same contact id as in seq1) Is this allowed or should it be treated as an error? Is contact and its lifecycle (updates) defined within the scope of a single regulatory activity? Answer: The handling of contact information is handled at the regional level. Please refer to the regional authority's IG to determine requirements when submitting. No further questions or comments received.
2	Question: Can documents submitted in eCTD 3.2.2 in a Dossier X be reused in an eCTD v4.0 sequence for Application Y, even if the Dossier X has not yet transitioned to eCTD v4.0? Answer: Yes, this is possible. It is detailed in the ICH guidance in the following chapters: 8.1 Considerations for Forward Compatibility -> 8.1.1 Uniquely Linking to v3.2.2 Leaf 9.2.17.1 Document reuse -> Document Reuse using Forward Compatibility.

#	Questions and Answers – [action items are included for M8 IWG]
	No further questions or comments received.
3	Question: Is there a maximum number of node extensions that can be concatenated? Answer: An upper limit will be assessed during the EU forward compatibility pilot if possible. A potential recommendation would be when concatenating a large number of extensions, to introduce a new context of use (CoU). No further questions or comments received.
4	Question: A follow-up email received after last meeting discussion on forward compatibility nested node extensions The email presented – “Following up on the Forward Compatibility nested node extension discussion with the vendor group, a node extension delimiter is probably needed because the concatenation of multiple titles might end up in the same string.” Both provided examples would result in eCTD v4.0 keyword: 'HPCN-001 Comparative BA and BE', but it is important to distinguish the different node-extension values. Instead of using a space we recommend defining a different delimiter, such as “_”: With this approach, the eCTD v4.0 keyword would be different for provided examples (contained in meeting slides). Answer: • Using only spaces as delimiters makes it impossible to determine whether concatenation involves 2 or 3 different levels • Using the underscore dollar sign (_\$) delimiter clearly shows the number of levels in the concatenation No further questions or comments received

3. UPCOMING CHANGES TO THE IG AND CV PACKAGES

#	Upcoming changes to the IG and CV packages
1	Discussion included upcoming updates to the eCTD version 4.0 Implementation Guide (IG) version 1.7 and Controlled Vocabulary (CV) version 1.03. CV ▪ Removed ich_2 Heading (m2 common technical document summaries) IG ▪ Node Extensions ◦ Added to Attribute Mappings table to provide clarity on use ◦ Added use of _\$ to be used when nesting ▪ Added Clarity to Validation related to suspension of v3.2.2 Leaf Reference ◦ Content must be previously submitted and have a status code of “active” ◦ Can no longer be updated once assigned status code of “suspended” ▪ New Message Header Validation ◦ Message Header requires both valid ICH and Regional IG OID values ▪ New updateMode Validation ◦ Updates to the text@integrityCheckAlgorithm, text.integrityCheck, and reference@value attributes are ignored when using updateMode = “R” Further questions submitted via chat:

Upcoming changes to the IG and CV packages

Question: Is there a timeframe for the publication of the IG and CV?

Answer: Hoping to accomplish this before the end of April

- Documents will be circulated for M8 EWG sign-off this week or next week
- Goal: Submit to ICH Secretariat for approval and posting by the end of April 2026

4. OPEN DISCUSSION

Additional Questions and Answers

The participants were asked if they had any other questions or additional topics that anyone would like to discuss.

Other questions submitted via chat:

1 Question: Can you share about the FDA pilot and how industry can be involved?

Answer:

- FDA started the “Forward Compatibility” pilot earlier this week with a kickoff meeting
- Pilot is conducted through PDUFA VII (Prescription Drug User Fee Act) user fee commitments
- Announcement went out through PhRMA and BIO trade groups
- Pilot kicked off on Monday of this week (April 20, 2026)
- The pilot is not for vendors, only for industry submitters actually sending in submissions

2 Question: If any other parties were still interested in joining, could they join the pilot at this point?

Answer: They should contact eSub Testing (esub-testing@fda.hhs.gov).

3 Question: When can we expect actual mandatory date for eCTD v4.0 for generics ANDA?

Answer:

- The implementation table currently says no earlier than 2029
- This assumes forward compatibility testing goes well and full implementation into production by the beginning of 2027 to allow for the 2-year time period
- FDA wants to ensure everything is in production and stable before updating guidance with the required date
- FDA is aiming for 2029 as stated on the ICH implementation table
- Participants should check the table for region-specific information

M8 reminded and requested that participants submit any further questions to the Vendor Group Mailbox (ICHM8Vendors@ich.org).

Next meetings (invitations will be submitted)

- **Summer or early fall 2026 – TBD** (Decision on timing (before or after summer vacation period) will depend on volume of questions received)

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](#).