

M8 eCTD Vendor Group

July 2, 2025

Welcome to the M8 eCTD Vendor Group



■ Agenda

- Discussion Topics
- Next Steps

Note: For new vendors, please see Appendix for the background information for this Vendor Group (e.g., group objectives and communication logistics for the group)

Important Note: This information is based on the information and circumstances provided at the date of publication and may change as new developments arise



Discussion Topics

TODAY'S TOPICS

- M8 Announcements
- Submitted Vendor Questions
- Open Questions

FUTURE TOPICS

- M4Q (R2) Updates

M8 Announcements



M8 Announcements

- Vendor Group Mailbox
 - Forwarding of communications has resumed
- eCTD v4.0 Webpage
 - Implementation Status to be updated in July
 - Includes updates of Regional Implementation Timelines for eCTD v4.0
 - Note and slides from last meeting sent to Secretariat for posting



Vendor Group Questions



Group Title Question

Hi ICH Team

We wanted to follow up on a question we previously asked that was answered in the ICH Vendor meeting w.r.t the Group Title keyword. In the attached document an answer was provided w.r.t when to use the Group Title keyword.

We've heard from sponsors that there is still some ambiguity around its use.

The group title keyword is outlined as an acceptable keyword across many CTD headings based on the ICH_eCTDv4_0_CV_v6 CV listing document. From the previous response however it makes it seem like Group Title should not be used in Module 4 and 5 as 'the Group title should only be used for keyword definitions that have not been specified.'

Is there a full list of headings where previously node-extensions were acceptable but have now been replaced by a keyword, in which case the Group Title keyword should not be used? Or perhaps we misunderstood the response and Group Title is in fact allowed in module 4 and 5 in addition to the study id_study title keyword?

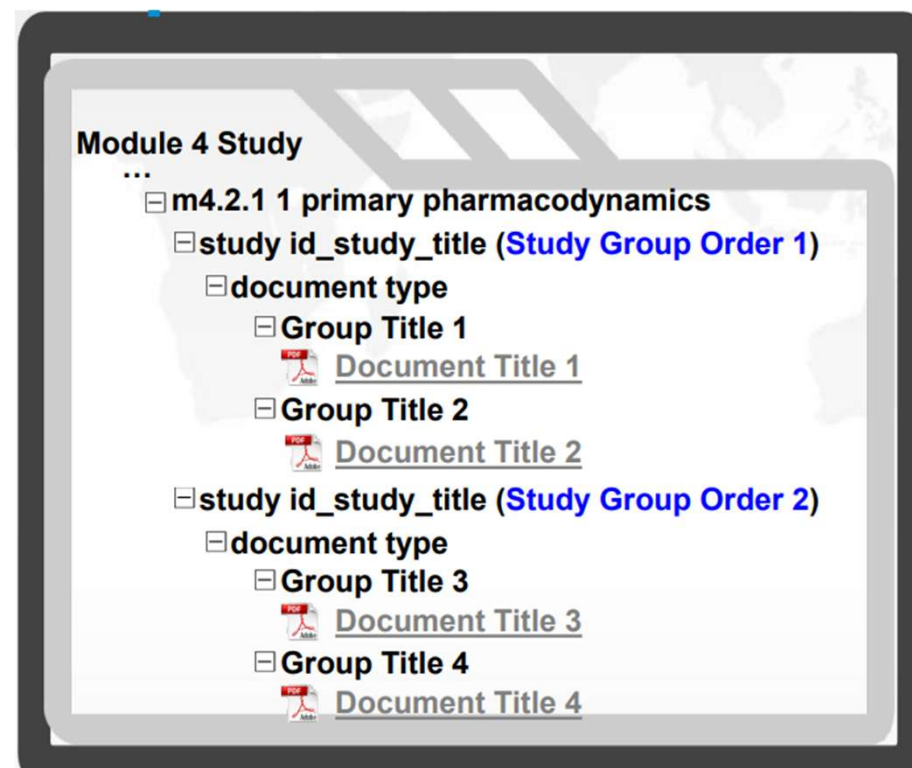
Appreciate the help and guidance.

Thanks

Jordan

Group Title Answer

- Yes, Group Title Keywords can be used in modules 4 and 5, but should not be used instead of Document Type Keywords (listed in the ICH CV package)
- See example in [ICH orientation materials](#) under Study Group Order section



Life-Cycle Question

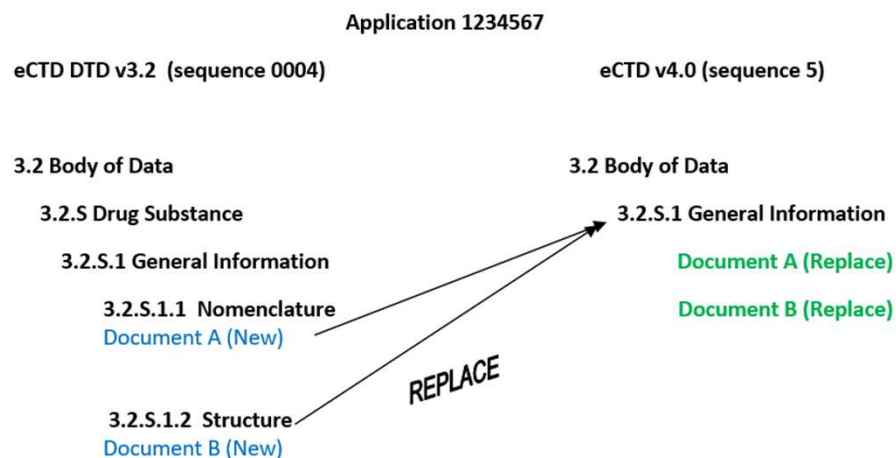
We seek further clarity on few eCTD v4.0 scenarios which were discussed in the previous vendor meeting discussions and currently documented in the ICH official website (M8 Vendor Group Questions).

- a) Can we infer from the below 'Answer' for 'Question 4' that life cycle 'replace' is allowed directly on a higher section in eCTD v4.0 on a document which was earlier submitted in the lowest section in dtd v3.2 ? (i.e., can any leafs under lower subheadings in v3.2 be replaced on a higher heading in v4.0 ?)

- 4 **Question:** 4. ICH Context of Use Code ich_3.2.s.1 does not have any lower level codes associated with it. In 3.2 there were additional XML elements m3-2-s-1-1-nomenclature, m3-2-s-1-2-structure, and m3-2-s-1-3-general-properties defined in the DTD. Can you please confirm that these are no longer required and all of the document previously associated with this section can be submitted under the heading ich_3.2.s.1 in eCTD 4.0?
- Answer:** Yes, we confirm – those headings are no longer available for use in v4.0. Forward compatibility will follow the same rules for context group life cycle. Any leafs under subheadings (3.2.s.1.1, 3.2.s.1.2, 3.2.s.1.3) will break life cycle and content will need to be submitted at 3.2.s.1 or higher with any relevant v4.0 keywords.

Life-Cycle Question Continued

- The below snapshot represents our understanding – Could you please confirm whether our understanding is correct.





Life-Cycle Answer

- No, using “Replace” in the way shown will trigger an eCTD4-025 error (see below)
- The proper way to do this would be to:
 - Suspend the content under the previous headings
 - Submit the replacement document as new under the supported heading
- eCTD4-025 = Context of Use and Related Context of Use referenced must have the same Context of Use code and Keyword code combination (or matching v3.2.2 equivalents)

Keywords Question

- b) Does the 'Answer' to 'Question 6' below (esp. underlined in brown) indicate that documents must be replaced in higher section (eCTD v4.0 submission) without keywords when the keywords associated with a document submitted in the earlier dtd v3.2 sequences are no longer needed in 4.0?

6 **Question:** Following up on forward compatibility. In the m4 granularity index (https://www.ema.europa.eu/en/documents/scientific-guideline/ich-guideline-m4-r4-common-technical-document-ctd-registration-pharmaceuticals-human-use-organisation-ctd-step-5_en.pdf) in reference to the manufacturer keyword there is a paragraph explaining the use of 'all' as metadata for manufacturers.

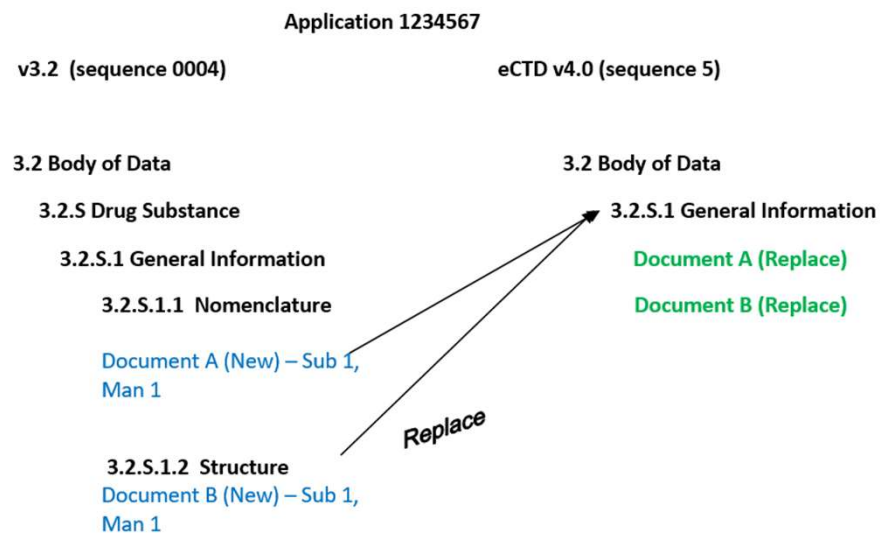
The "manufacturer" keyword was designed to facilitate lifecycle management where there might be different manufacturers (e.g., using a different drug substance route of synthesis (chemical entity) or manufacturing process (biologic)). If the applicant determines that there is no need to have multiple 3.2.S or 3.2.P sections (e.g., where few 3.2.S.x topics have manufacturer/site/process-specific documents (either now or likely in the future)) then the use of this keyword is not recommended; there is no benefit of a general umbrella term such as "all" or "applicant" or "not specified". The value for the "manufacturer" keyword might be a firm's name, the first word or abbreviation of a long company name, a site name, or simply words that differentiate different routes or processes. Use a term that is less likely to change during the life of the application.

My question: for forward compatibility purposes since 3.2 and 4.0 metadata must match. If sponsors have used "all" or "applicant" or "not specified" is the expectation that a keyword using the generic 'all' be defined to maintain forwards compatibility?

Answer: In general, to retain life cycle of content submitted in 3.2.2 that included attributes no longer recommended for use, keywords should be established in v4.0 to match the leaf attributes if they are allowed. Alternatively, life cycle can be broken to remove the keyword definition values no longer recommended or allowed. The cited guidance is for new v4.0 applications to not introduce these keyword definition values.

Keywords Question Continued

- The below snapshot represents our understanding – Could you please confirm whether our understanding is correct.





Keyword Answer

- You should include the keywords that are valid for the CoU. Please follow the ICH CV and IG for guidance on the valid use of keywords and CoU.
- Also, if you don't make any changes in the content there is no need to resubmit under eCTD v4.0.
- Please see our previous answer regarding life-cycle operations under different headings.



Smart Hyperlinking Question

Requirement

The high-level requirement is for tools to **identify, on an individual document basis, all documents in a sequence where a lifecycle operation is being performed and any links that were pointing to the previously submitted document.**

For example:

- **Sequence 1:** Documents A, B, C, D are submitted.
 - Document A links to Document B
 - Document B links to Document C
 - Document C links to Document D
 - Document D links to Document B
- **Sequence 2:** Document B is replaced/deleted.

Outcome: A validation rule should flag the following:

- Document A now has a broken link.
- Document D also has a broken link.

Links from the replaced document to documents still in the current view (e.g., Document B's link to Document C) are **not** flagged, as Document B is no longer relevant.



Smart Hyperlinking Question Continued

Potential Alternative

Would it be possible for the viewing tool at the agency to determine when the target of a link has been replaced/deleted? When the link is selected, it could be intercepted, and the user directed to the latest version, or a warning could be displayed that the document has since been replaced.

This approach might not fully meet the business requirement that drove this request. Could you please share the underlying business requirement so we can consider alternative solutions more effectively?



Smart Hyperlinking Answer

- Your potential alternative mirrors what we are already proposing.
- We don't know how each tool is representing life-cycle; this might be different in the solutions available. The eCTD is carrying information to enable tools to display the life-cycle information of documents and submissions.
- It is up to the vendor how to present this information to the users (pop-up window, colourful indicator, etc).



CoU Validations Question

eCTD4-072 and JP-eCTD4-141

Would you be able to clarify the rules mentioned in the subject line of this email. In general across Japan and ICH level rules the rule is defined as:

Multiple Keywords of the same type shall not be assigned to one Context of Use.

Does this also mean that the ICH Species keyword to be used for non-clinical studies can not exist multiple times in a context of use? Or is the rule referring to the actual value defined in the [controlActProcess.subject.submissionUnit.component.contextOfUse.referencedBy.keyword.code@code](#) cannot be duplicated on a CoU?



CoU Validations Answer

- Yes, multiple keywords of the same type are NOT allowed within a COU.
- Per eCTD4-072: On each Context of Use element, a valid Keyword Type shall only be used once.

Open Discussion



Additional Topics or Questions

- Are there any additional topics and/or questions for today's discussion? Or that should be addressed at future vendor group meetings?

Next Steps



Next Steps

- Meeting Schedule:
 - October 2025 - TBD
- Future Agenda Topics
 - Discuss any questions to Vendor Group mailbox

Appendix: Information for New Vendors



eCTD Vendor Group Objectives

- Objectives:
 - To create an ongoing forum to raise eCTD v4.0 implementation questions – e.g., specification details, etc.
 - To understand the current availability of eCTD v4.0 Tools available to Regulated Industry



eCTD Vendor Group Communications

- Please feel free to raise topics before, during or after the meetings
 - Agendas will be drafted to address any ongoing or new topics
 - Topics may include:
 - How to use this eCTD Vendor forum
 - Clarifications on Implementation specifications
 - Implementation status across regions
 - New requirements
- We aim to discuss implementation questions in general
 - Questions should focus on the specifications and not how specific tools are implemented
 - If you have a region-specific question, please contact the region directly
- The vendor group is solely intended to facilitate collaborative discussion on the eCTD v4.0 Implementation Specification and timelines.
 - This is not an opportunity to share product offerings

How to Communicate with M8

EMAIL: ICHM8VENDORS@ICH.ORG



- All correspondence related to the *eCTD Vendor Group activities* should be sent to the designated email.

Examples include:

- Feedback related to eCTD v4.0 topics in the eCTD Vendor Group
- Suggestions for future topics

EMAIL: ADMIN@ICH.ORG



- Official *Change Requests* to the ICH eCTD v4.0 Implementation and Controlled Vocabulary specifications
- These request will result in a change request at the specification level and be included in the next version of the eCTD v4.0 Q&A document.