

M8 eCTD Vendor Group

April 22, 2026

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
- Upcoming changes to the IG and CV packages
- Open Discussion

M8 Announcements



M8 Announcements

- eCTD v4.0 Webpage

- Implementation Status Table updated in March
 - Includes current regional implementation timelines for eCTD v4.0
- Notes and slides from last meeting (Jan 28, 2026) posted



Submitted Questions



Submission Contact Information

- **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 be treated as an error? Is contact and its lifecycle (updates) defined within the scope of a single regulatory activity?

- **Answer:**

The requirements pertaining to contact information are determined at the regional level. Please refer to the regional authority's IG for guidance on how contact information is to be submitted.

Document Reuse Across Applications

■ 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.

• Document Reuse

- Within the same application:
 - `sequenceNumber.xmlType.leafId` (e.g., 0000.ich#NLAS57D17EB601C9EDCA)
- Across applications
 - Application Identifier with a Regionally assigned Application Type and Number: `ApplicationTypeApplicationNumber.sequenceNumber.xmlType.leafId` (e.g., nda123456.0000.ich#NLAS57D17EB601C9EDCA)
 - Application Identifier with a Regionally assigned Application Type and Number for Regional Content: `ApplicationTypeApplicationNumber.sequenceNumber.xmlType.leafId` (e.g., nda123456.0000.us-regional#NLAS57D17EB601C9EDCA)
 - Application Identifier with a Unique identifier (e.g., UUID): `UUID.sequenceNumber.xmlType.leafId` (e.g., 5f0e8436-e1df-4031-90d3-413deff109e5.0000.ich#NLAS57D17EB601C9EDCA)

 **Note to Implementers** – Refer to Regional/Module 1 Implementation Guide for specific details on the expected values for Leaf Reference.

When referencing a document in another application with a unique identifier, it may be used for the application as depicted below in the `document.id@extension` value.

```
<component>
  <priorityNumber value="1000"/>
  <contextOfUse>
    <id root="612fa349-d70d-4184-99c1-3f7348e585e6"/>
    <code code="ich_3.2.p.1" codeSystem="2.16.840.1.113883.3.989.2.2.1.1.3"/>
    <statusCode code="active"/>
    <derivedFrom>
      <documentReference>
        <id root="2.16.840.1.113883.3.989.2.2.1.1.13.1" extension="5f0e8436-e1df-4031-90d3-413deff109e5.0000.ich#NLAS57D17EB601C9EDCA"/>
      </documentReference>
    </derivedFrom>
  </contextOfUse>
</component>
```

Refer to Regional/Module 1 Implementation Guide for assignment of application number and appropriate `id@extension` value as an OID or UUID.



Concatenated Node Extension Limit

- **Question:**

Is there a maximum number of node extensions that can be concatenated?

- **Answer:**

EU will attempt to assess this as part of their forward compatibility pilot. It is recommended to consider introducing a new CoU when presented with the need to concatenate several node extensions.

Node Extension Delimiter

■ Question:

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 both examples:

- Example 1: HPCN-001_\$Comparative BA and BE
- Example 2: HPCN-001_\$Comparative_\$BA and BE

Example 1

```
<node-extension>
  <title>HPCN-001</title>
  ...
  <node-extension>
    <title>Comparative BA and BE</title>
    ...
  </node-extension>
</node-extension>
```

Example 2

```
<node-extension>
  <title>HPCN-001</title>
  ...
  <node-extension>
    <title>Comparative</title>
    ...
  <node-extension>
    <title>BA and BE</title>
    ...
  </node-extension>
</node-extension>
```



Updates to the IG and CV Packages



Coming Soon: ICH eCTD v4.0 IG v1.7 and CV v1.03

■ IG

- Node Extensions
 - Added to Attribute Mappings table to provide clarity on use
 - Added prescribed use of _\$ delimiter 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”

■ CV

- Removed ich_2 Heading (m2 common technical document summaries)



Open Discussion



Additional Topics or Questions

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



Next Steps



Next Steps

- Meeting Schedule:
 - Summer/Fall 2026 – TBD
 - Dependent upon content
- 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.