

M8 eCTD Vendor Group

January 28, 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
- Open Discussion

FUTURE TOPICS

- M4Q (R2) Updates

M8 Announcements



M8 Announcements

- eCTD v4.0 Webpage
 - Implementation Status to be updated in February
 - Includes updates of Regional Implementation Timelines for eCTD v4.0
 - Notes and slides from last meeting (July 2, 2025) posted



Submitted Questions



Forward Compatibility / Sequence Numbering

- **Question:**

For cases of forwards compatibility and setting sequence IDs. It is fairly common for US applications to contain sequence IDs for ad-promo submissions to start with 50XX and safety submissions to start with 30XX and all other submissions to follow the typically 00XX pattern.

However when transitioning an application from eCTD 3.2 to eCTD 4.0 what is the expectation of sponsors who have applications that contain sequences where some start with 50XX, 30XX and 00XX. From the guidance documents it is expected that sequence ID should be incremented by a single digit. When going from 3.2 to 4.0 in the above example would the first sequence number follow the last previously highest submitted sequence ID (50XX) or would it be acceptable to start from the last known 00XX or would it be acceptable to start at 1 or would it be acceptable to continue this pattern in future submissions under the application given 50XX and 30XX already follow the pattern of sequence IDs for eCTD 4.0?

- **Answer:**

When transitioning to v4.0, you may use a sequence number which continues the same numbering scheme previously employed for your v3.2.2 submissions, provided that it is a whole number (e.g. 2, 5002).



Document Reuse Implementation

- **Question:**

As per the regional and ICH guidelines, a document submitted to agency need not be physically submitted again. Once a document has been submitted, eCTD v4.0 will allow for this document to be reused in the same context in a different submission unit, submission or application, reused in a different context in the same submission unit or application, or reused in a different context in a different submission unit or application. This is accomplished by assigning each document with a unique ID that can be referenced anywhere in the Regulatory Authority's environment.

The document id is referenced when user selects document reuse (without title change)

Any viewer tool needs to parse each of the sequences to identify the source document details using the ID alone. The same search to be extended to other applications if the document id is not matched within the application.

This results in performance issues to locate the reused document details.

Q: Is there any attribute that can be added along with the document reference element for identifying the source document?

- **Answer:**

An alternative approach would be to store the document ID element along with any other metadata deemed relevant in a single lookup table. (Please note while ICH provides specifications, it is up to the vendor to determine how best to implement them in their tool.)



Forward Compatibility / Optional Keywords

- **Question:**

Keyword mapping for 3.2.a and its sub nodes are totally different between previous versions and v4.0. So, during transition the files under 3.2.a are added without keywords.

3.2.A Appendices

3.2.A.1 Facilities and Equipment [facility (O)]

3.2.A.2 Adventitious agents safety evaluation [component (O)]

3.2.A.3 Novel excipients [excipient (O)]

Q: Is it ok to transition these files without keywords?

- **Answer:**

Yes, but note that there is no need to resubmit v3.2.2 content when transitioning to v4.0 if the content has not changed. Please note if an updated document is submitted where the attributes don't match the keywords, this will result in both documents being displayed (e.g., if a document was submitted under 3.2.a.1 with the 'name' and 'manufacturer' attributes in v3.2.2 and an updated document was submitted in v4.0 either without keywords or with the optional 'facility' keyword). If it would not be desired to display both documents, the v3.2.2 document would need to be suspended with the replacement submitted as new in v4.0.



Document Type / Priority Number

- **Question:**

Regarding Study Report Granularity. Certain CoUs, like ich_5.3.1.1 assume their usage for Study Reports, and the same granularity level as Study Report. At the same time, CoU has a Document Type field, meaning the user can select a single document type for that CoU. Issue is under each Study Report (CoU) there is likely to be multiple documents of different types.

It can be solved by repeating the same CoU for each time we need to mention a different Document Type. However this results in priority numbers reset on each CoU occurrence, which may lead to conflicts in the output, as well as repeating info of Study Report level, when it is already specified.

Logically Document Type should be an attribute of Document and not the CoU. Please advise or share any recommendations on how it should be used in the industry.

- **Answer:**

eCTD v4 is set up to allow the submitter to include multiple documents under one study and further organize these documents into groupings with Document Type Keywords. The priority number defines the display order of the document within a group of documents at the same hierarchical level. Documents are established with only basic metadata to provide maximum flexibility to be used again under different CoUs via document re-use. We use excerpts from the USFDA regional XML samples to illustrate how 3 documents are referenced under a single study.

Adding ts.xpt to STDYID_TITLE_1 under 5.3.1.1

```
<!-- Start - Context of Use - Reference to document in m5/111888-001/SDTM/ts.xpt -->
▼<component>
  <priorityNumber value="1000"/>
  ▼<contextOfUse>
    <id root="76dc2c45-7269-4072-9c6c-354f057f220f"/>
    <code code="ich_5.3.1.1" codeSystem="2.16.840.1.113883.3.989.2.2.1.1.4"/>
    <statusCode code="active"/>
    ▼<derivedFrom>
      ▼<documentReference>
        <id root="c28ca6be-3935-492a-a135-2e6a39584e12"/>
      </documentReference>
    </derivedFrom>
    ▼<referencedBy typeCode="REFR">
      ▼<keyword>
        <code code="ich_document_type_71" codeSystem="2.16.840.1.113883.3.989.2.2.1.3.3"/>
      </keyword>
    </referencedBy>
    ▼<referencedBy typeCode="REFR">
      ▼<keyword>
        <code code="STDYID_TITLE_1" codeSystem="2.16.840.1.113883.9999.2"/>
      </keyword>
    </referencedBy>
  </contextOfUse>
</component>
<!-- End - Context of Use -->
```

Heading: 5.3.1.1

Study: STDYID_TITLE_1

Doc Type Keyword: 71

Priority Number: 1000

Document: ts.xpt

Adding dm.xpt to STDYID_TITLE_1 under 5.3.1.1

```
<!-- Start - Context of Use - Reference to document in m5/111888-001/SDTM/dm.xpt -->
▼<component>
  <priorityNumber value="2000"/>
  ▼<contextOfUse>
    <id root="4c2be8a5-b893-4b1a-9eb7-941be2a14c89"/>
    <code code="ich_5.3.1.1" codeSystem="2.16.840.1.113883.3.989.2.2.1.1.4"/>
    <statusCode code="active"/>
    ▼<derivedFrom>
      ▼<documentReference>
        <id root="b1a8975c-ccc8-4f6c-bf2f-9fa72ab1a601"/>
        </documentReference>
      </derivedFrom>
      ▼<referencedBy typeCode="REFR">
        ▼<keyword>
          <code code="ich_document_type_71" codeSystem="2.16.840.1.113883.3.989.2.2.1.3.3"/>
          </keyword>
        </referencedBy>
        ▼<referencedBy typeCode="REFR">
          ▼<keyword>
            <code code="STDYID_TITLE_1" codeSystem="2.16.840.1.113883.9999.2"/>
            </keyword>
          </referencedBy>
        </contextOfUse>
      </component>
    <!-- End - Context of Use -->
```

Heading: 5.3.1.1

Study: STDYID_TITLE_1

Doc Type Keyword: 71

Priority Number: 2000

Document: dm.xpt

Adding adsl.xpt to STDYID_TITLE_1 under 5.3.1.1

```
<!-- Start - Context of Use - Reference to document in m5/111888-001/ADaM/adsl.xpt -->
▼<component>
  <priorityNumber value="3000"/>
  ▼<contextOfUse>
    <id root="efd4c31e-6850-462e-8027-7afd923be5b2"/>
    <code code="ich_5.3.1.1" codeSystem="2.16.840.1.113883.3.989.2.2.1.1.4"/>
    <statusCode code="active"/>
    ▼<derivedFrom>
      ▼<documentReference>
        <id root="33a10bd2-49a4-4db0-b60c-4102e39b907d"/>
        </documentReference>
      </derivedFrom>
      ▼<referencedBy typeCode="REFR">
        ▼<keyword>
          <code code="ich_document_type_73" codeSystem="2.16.840.1.113883.3.989.2.2.1.3.3"/>
          </keyword>
        </referencedBy>
        ▼<referencedBy typeCode="REFR">
          ▼<keyword>
            <code code="STDYID_TITLE_1" codeSystem="2.16.840.1.113883.9999.2"/>
            </keyword>
          </referencedBy>
        </contextOfUse>
      </component>
    <!-- End - Context of Use -->
```

Heading: 5.3.1.1

Study: STDYID_TITLE_1

Doc Type Keyword: 73

Priority Number: 3000

Document: adsl.xpt

eCTD Viewer Tool Display

Module 5 - Clinical Study Reports

- M5 - Clinical Study Reports
 - └─ ■ 5.3.1.1 - Study Reports of Controlled Clinical Studies
 - └─ ■ Study: ID_ABC123_\$ClinicalXYZ
 - └─ ■ SDTM Data
 - └─ ■ Trial Summary (ts.xpt)
 - └─ ■ Demographics (dm.xpt)
 - └─ ■ SDTM Define.xml (define.xml)
 - └─ ■ ADaM Data
 - └─ ■ Subject Level Analysis Dataset (adsl.xpt)
 - └─ ■ ADaM Define.xml (define.xml)

Heading: 5.3.1.1

Study: STDYID_TITLE_1

Doc Type Keyword: 71

Priority Number: 1000

Document: ts.xpt

Heading: 5.3.1.1

Study: STDYID_TITLE_1

Doc Type Keyword: 71

Priority Number: 2000

Document: dm.xpt

Heading: 5.3.1.1

Study: STDYID_TITLE_1

Doc Type Keyword: 73

Priority Number: 3000

Document: adsl.xpt



Forward Compatibility / Node Extensions

- **Question:**

We understand the **Group Title** keyword is a mechanism to carry forward **v3.2.2 Node Extension** values when no dedicated v4.0 keyword (like **StudyId_StudyTitle**) exists.

To ensure our implementation is valid, could you please provide a representative XML snippet from a sample Submission Unit that clearly illustrates the following two scenarios:

- **Single Node Extension:** A Group Title keyword providing the value from a single v3.2.2 node extension.
- **Multiple Node Extensions:** A single Group Title keyword definition containing the concatenated values from multiple node extensions (from the same heading or nested) in v3.2.2.

While the functional logic is documented, a concrete XML example of these fallback cases would be helpful towards our development and validation.



Single Node Extension (1)

Forward compatibility steps for a single extension

Conversion Steps:

1. **Identify Node Extension Title elements**
2. **Map to Group Title:** The exact string must be used as the value of the displayName attribute for the corresponding Group Title keyword in v4.0.
3. **Identify Location:** The document is under the same CTD heading

Single Node Extension (2)

Node extension to replace in eCTD 3.2.2(2)

```
<m2-common-technical-document-summaries>
<m2-3-quality-overall-summary>
<m2-3-r-regional-information>
<node-extension>
<title>special-summary</title>
<leaf ID= "a123456" operation = "new" xlink:type = "simple" xlink:href = "m2/23-qos/extraquality-sum.pdf"
  |checksum-type="md5" checksum = "7490d74c3d5e442ad57daa155253eb16">
  <title>Extra Quality Summary </title>
</leaf>
</node-extension>
</m2-3-r-regional-information>
</m2-3-quality-overall-summary>
</m2-common-technical-document-summaries>
```

Single Node Extension (3)

ECTD 4.0 Keyword Definition

```
<referencedBy>
  <keywordDefinition>
    <code code="ich_keyword_type_9" codeSystem="2.16.840.1.113883.3.989.2.2.1.5.2"/>
    <statusCode code="active"/>
    <value>
      <item code="GT001" codeSystem="2.16.840.1.113883.3">
        <displayName value="special-summary"/>
      </item>
    </value>
  </keywordDefinition>
</referencedBy>
```

ECTD 4.0 CoU replacement

```
<contextOfUse>
  <id root="[New UUID]"/>
  <code code="ich_2.3.r" codeSystem="2.16.840.1.113883.3.989.2.2.1.1.1"/>
  <statusCode code="active"/>

  <replacementOf typeCode="RPLC">
    <relatedContextOfUse>
      <id root="2.16.840.1.113883.3.989.2.2.1.13.1" extension="0000.ich#a123456"/>
    </relatedContextOfUse>
  </replacementOf>

  <derivedFrom>
    <documentReference>
      <id root="[New Document UUID]"/>
    </documentReference>
  </derivedFrom>

  <referencedBy typeCode="REFR">
    <keyword>
      <code code="GT001" codeSystem="2.16.840.1.113883.3"/>
    </keyword>
  </referencedBy>
</contextOfUse>
```



Multiple Node Extensions (1)

Forward compatibility steps for a multiple node extensions (1)

Conversion Steps:

1. Identify Node Extension Title elements
2. Map to Group Title. The exact concatenated string must be used as the value of the `displayName` attribute for the corresponding Group Title keyword in v4.0.
3. Identify Location under the same CTD heading

Multiple Node Extensions (2)

Node extension to replace in eCTD 3.2.2(2)

```
<m2-common-technical-document-summaries>
  <m2-3-quality-overall-summary>
    <m2-3-r-regional-information>
      <node-extension>
        <title>Summary Type: Manufacturing Changes</title>
      <node-extension>
        <title>Change Number: 2025-001</title>
      <leaf ID="a123456"
        operation="new"
        xlink:href="m2/23-qos/extra-quality-sum.pdf"
        checksum="7490d74c3d5e442ad57daa155253eb16"
        checksum-type="md5">
        <title>Extra Quality Summary</title>
      </leaf>
    </node-extension>
  </m2-3-r-regional-information>
</m2-3-quality-overall-summary>
</m2-common-technical-document-summaries>
```

Multiple Node Extensions (3)

ECTD 4.0 Keyword Definition

```
<keywordDefinition>
  <code code="ich_keyword_type_9" codeSystem="2.16.840.1.113883.3.989.2.2.1.5.2"/>
  <statusCode code="active"/>
  <value>
    <item code="GT001" codeSystem="2.16.840.1.113883.3">
      <displayName value="Summary Type: Manufacturing Changes Change Number: 2025-001"/>
    </item>
  </value>
</keywordDefinition>
```

ECTD 4.0 CoU replacement

```
<component>
  <priorityNumber value="1000"/>
  <contextOfUse>
    <id root="f5e3d7a8-1c3b-4d5f-9a7e-0b2c4f6a8e9d"/>
    <code code="ich_2.3.r" codeSystem="2.16.840.1.113883.3.989.2.2.1.1.1"/>
    <statusCode code="active"/>
    <replacementOf typeCode="RPLC">
      <relatedContextOfUse>
        <id root="2.16.840.1.113883.3.989.2.2.1.13.1" extension="0000.ich#a123456"/>
      </relatedContextOfUse>
    </replacementOf>
    <derivedFrom>
      <documentReference>
        <id root="a0b1c2d3-e4f5-6789-a0b1-c2d3e4f56789"/>
      </documentReference>
    </derivedFrom>
    <referencedBy typeCode="REFR">
      <keyword>
        <code code="GT001" codeSystem="2.16.840.1.113883.3"/>
      </keyword>
    </referencedBy>
  </contextOfUse>
</component>
```

Forward Compatibility / Study Id_Study Title

■ Question:

Our Current Understanding:

- For Forward Compatibility of v3.2.2 STF XML to Study Id Study Title Keyword Definition v4.0: The link between the legacy 3.2.2 attribute values and the new v4.0 Keyword Definition is established solely via the [keywordDefinition.value.item@displayName](#) attribute. This value must match the concatenated string of the legacy v3.2.2 Study ID and Study Title (separated by _\$)
- **Code Attribute:** The [keywordDefinition.value.item@code](#) in v4.0 acts as the internal "source of truth" and identifier for the v4.0 lifecycle. Consequently, this code does **not** need to match the legacy v3.2.2 values. It can be a new sender-defined value, such as *STD301* or *CSTY_001*.

Could you please confirm if the following mapping approach (Option 1) is compliant?

- **Legacy v3.2.2 Input from STF XML (study-identifier):**
 - <title>: Phase 3 Efficacy Study
 - <study-id>: VIR-301

Option 1: Proposed Approach

- **eCTD v4.0 Keyword Definition (ich_keyword_type_8):**
 - [value.item@code](#): **STUDY301** (New sender-defined value)
 - [value.item.displayName](#): **VIR-301_\$Phase 3 Efficacy Study** (Matches legacy concatenation)

Option 2: Alternative Approach

- **eCTD v4.0 Keyword Definition (ich_keyword_type_8):**
 - [value.item@code](#): **VIR-301_\$Phase 3 Efficacy Study** (*item@code that matches the legacy string concatenation*)
 - [value.item.displayName](#): **VIR-301_\$Phase 3 Efficacy Study** (Matches legacy concatenation)



Forward Compatibility / Study Id_Study Title (2)

- **Question Continued:**

In Option 1, will the eCTD Viewer correctly map the study to the legacy v3.2.2 content based strictly on the Display Name, ignoring the fact that the Item Code (*STUDY301*) does not match the legacy Study ID?

Or, is it required that the *item@code* also match the legacy string/concatenation (*as shown in Option 2*)?

We believe relying on the Display Name for the legacy match (while using a stable, immutable sender-defined value for the Code) is the correct implementation to ensure robust lifecycle management in v4.0, but we seek your official confirmation

- **Answer:**

Yes, your understanding is correct; option 1 is the correct approach to use.



M4Q(R2)

- **Question:**

The current ICH eCTD v3.2 dtd does not reflect the changes to Modules 2 and 3 mentioned in the M4Q(R2) Draft Guideline, so could you please confirm whether the changes described in the 'M4Q(R2) Draft Guideline' has any impact to the ICH eCTD v3.2 dtd and eCTD v4.0 ICH Context of Use.

- **Answer:**

The eCTD v3.2.2 standard will not be incorporating any of the changes described in the M4Q(R2) guideline. The eCTD v4.0 ICH Context of Use codes will be updated to reflect the M4Q(R2) changes once the guidance has been finalized.



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:
 - April 2026 - 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.