

ECTD v4.0 Implementation Update

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SBIA REdl– June 5-9, 2023



Learning Objectives

- Understand fundamental eCTD v4.0 concepts
- Discuss FDA eCTD v4.0 implementation strategy
- Prepare for eCTD v4.0

eCTD v4.0 Goals



Excerpt from [ICH eCTD v4.0 Implementation Guide](#)

- The goal of upgrading to eCTD v4.0 is to facilitate the processing and review of electronic regulatory submissions.....key business drivers:
 - ⊖ Document Reuse – ability to submit a document once to a Regulatory Authority and refer to the document by its unique identifier in future submissions
 - ⊖ Document and Metadata life cycle – ability to manage versions of documents and/or metadata
 - ⊖ Management of Context Groups – ability to group documents together based on nature of their use (e.g., components of clinical study reports)

eCTD v4.0 Concepts

Harmonized Submission Unit and Document Reuse



- Harmonized submission unit
 - ⊖ All content from Module 1 through Module 5 contained in one exchange message

eCTD v4.0	eCTD v.3.2.2
Submissionunit.xml (M1-M5 and study information)	Usregional.xml (M1) Index.xml (M2-M5) Stf.xml files (Studies)

- Document reuse
 - ⊖ Once a document has been submitted, the document may be reused by referencing its unique identifier (ID) from the same or different submission unit (sequence).
 - ⊖ Allows reuse of meta-data (e.g., document title, location)

Context of Use (COU)

- Placement of a document within a TOC* heading/section
- Provides information regarding the usage of a document and its life cycle (e.g., content may be replaced)
- **Keyword** gives additional information to the **CoU**
 - ⊖ Keywords replace the eCTD v3.2.2 attributes and valid values
- Example:

COU X

3.2.S.2 Manufacture (**name 1, manufacturer 1**)

COU and Keyword Combinations (Context Group)



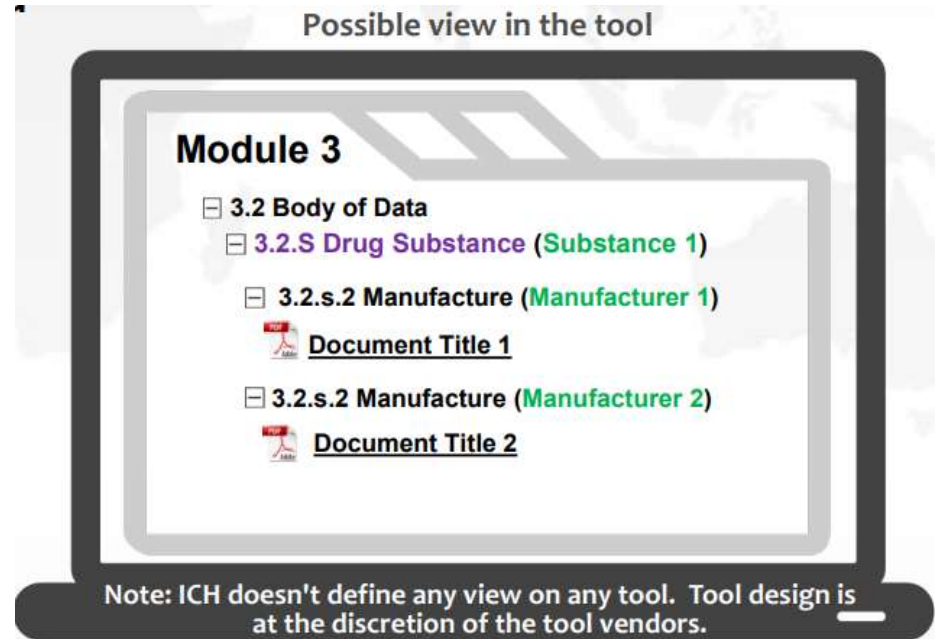
The combination of **CoU** and **keyword(s)** defines the context of the submission contents. If any one of them is different, the context is considered different.

COU X

3.2.S.2 Manufacture
Substance 1 manufacturer 1

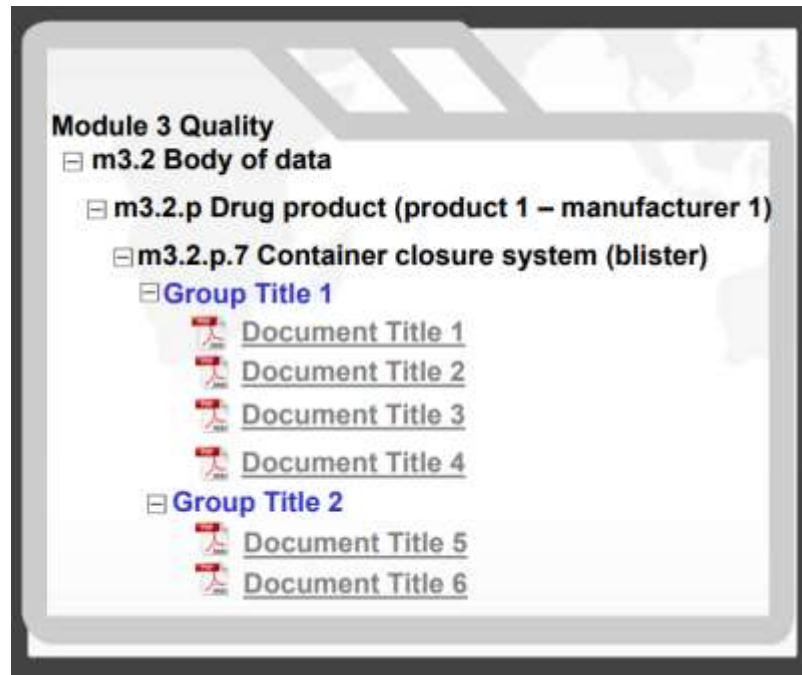
COU Y

3.2.S.2 Manufacture
Substance 1 manufacturer 2



Group Title

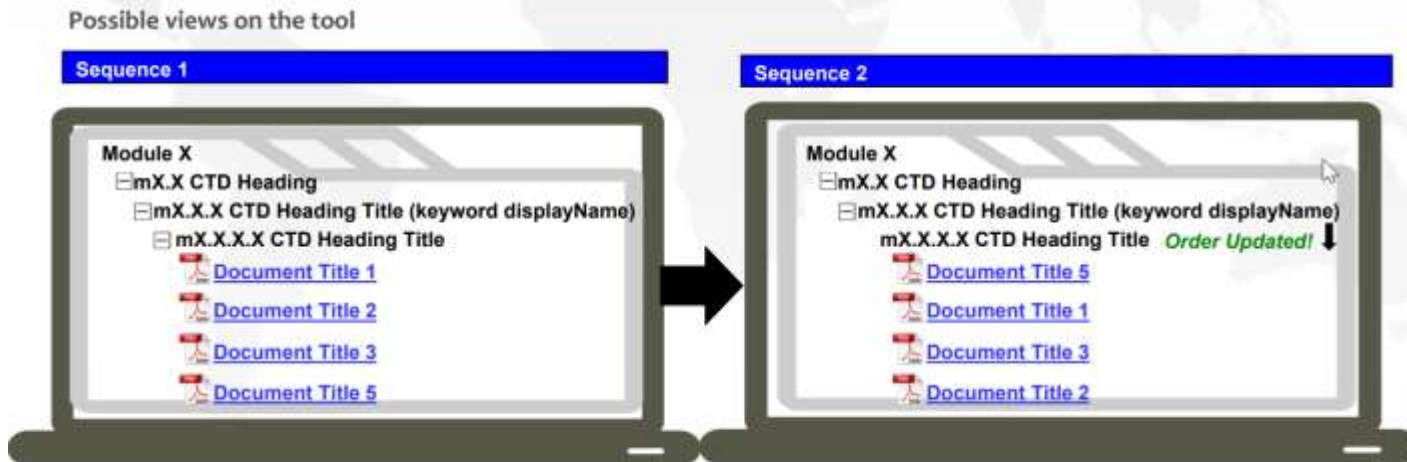
- Uses Group Title Keyword
- Applied to lowest level of Context of Use or Context Group to further organize content under a CTD heading when multiple documents are allowed
- The sender assigns the group title to specify how the content should appear together



Priority Number

Sets the order of documents within a CTD section

- Explicitly defines display order of documents under a Context of Use (CoU) or Context Group
- Sender may reorder submission content or insert submission content into a specific order within the existing content over time



Document Identifier

Every document assigned a unique identifier

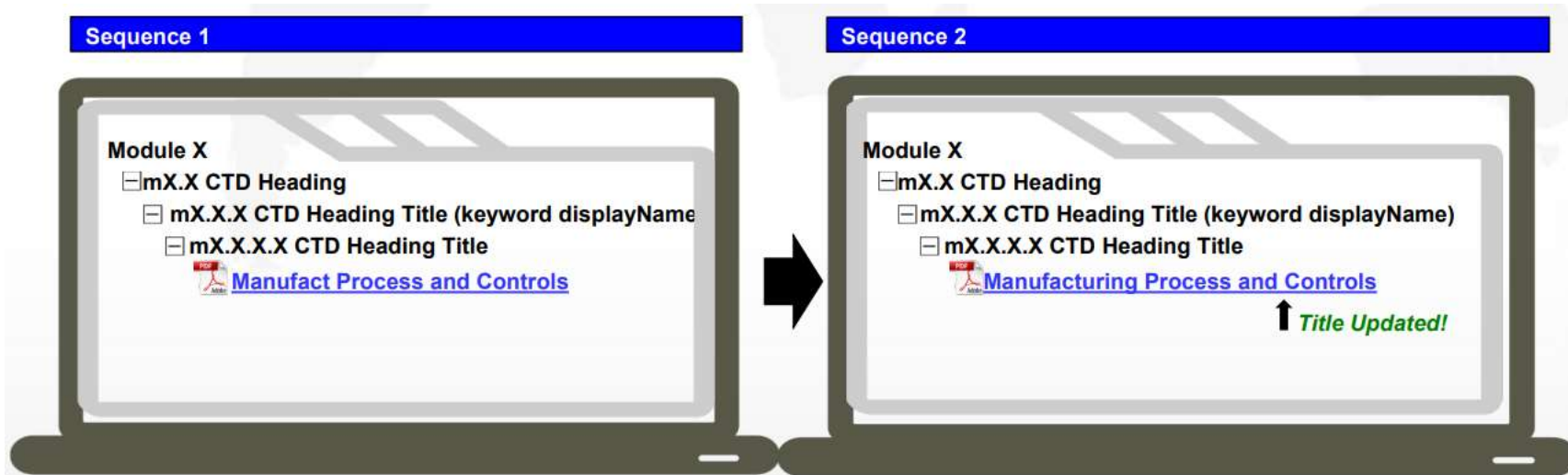
- Unique identifier approach means documents can be referenced/reused more effectively without resubmitting the physical file
 - ⊖ Across a Submission Unit (sequence)
 - ⊖ Across regulatory activities with an application
 - ⊖ Across different applications
- Used to reference the document in a context of use or context group
- Reuse document metadata (e.g., document title, location)

Update Document Information



- Update document title

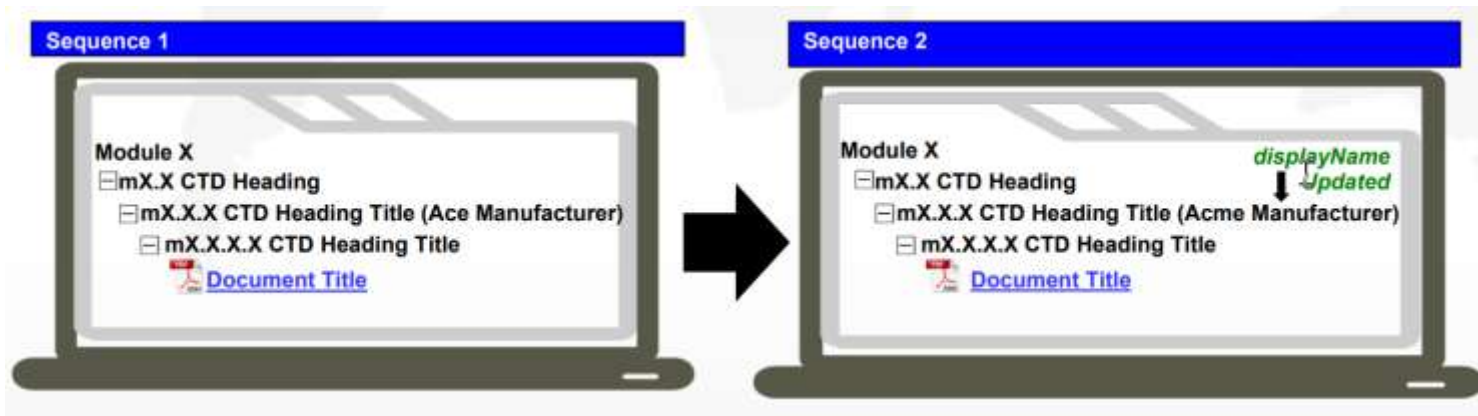
⇒ e.g., fix typo



Note: ICH doesn't define any view on any tool. Tool's design is at the discretion of the tool vendors.

Update Display Name Values

- Update display name values in eCTD headings without need to life cycle content



Document Life cycle

- Document Life cycle

- Replace:

- One to One

- Many to One

- One to Many





Challenge Question #1

An eCTD v4.0 sequence contains a harmonized submission unit message called submissionunit.xml

- A. True
- B. False

Challenge Question #2

eCTD v4.0 document life cycle functionality allows

- A. One to one
- B. One to many
- C. Many to one
- D. All of the above



FDA eCTD v4.0 Implementation Strategy

ICH Activities

- ICH eCTD v4.0 Implementation Package
 - ⊖ V1.5 May 2022
- Q&A Change Requests
 - ⊖ V1.7 June 2022
- Regional Implementation Information posted on ICH eCTD v4.0 webpage
 - ⊖ Regional planned Technical Pilots & Implementation Dates
 - ⊖ Links to regional Implementation Documents

ich.org/page/ich-electronic-common-technical-document-ectd-v40

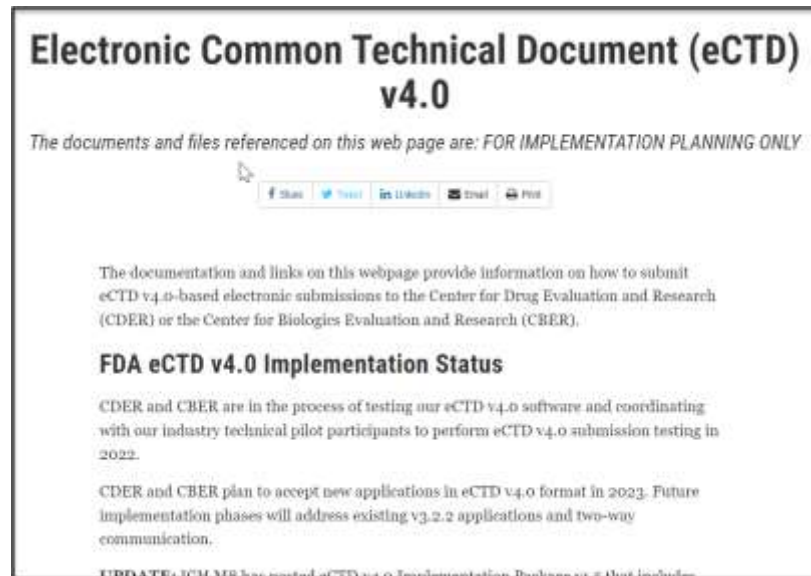
Step 4 Implementation Package
To download the package, click here.

This Implementation Package comprises multiple documents and files. Note that these documents need to be used in conjunction with the Regional/Module 1 documents provided on each of the regional consultation pages (see links below).

Document	File Name	Version Number
ICH eCTD v4.0 Implementation Package History	eCTD v4_0_Implementation_Package_History_v1_5.pdf	V1.5
ICH eCTD v4.0 Implementation Guide	ICH_eCTDv4_0_ImplementationGuide_v1_5.pdf	V1.5
ICH Code List for eCTD v4.0	ICH_eCTDv4_0_CVv5.xlsx	V5.0
M8 Genericcode Schema and Files	Genericcode	-
Schema Files for eCTD v4.0	ICH_eCTD_v4_SchemaFiles	-

FDA Activities

- eCTD v4.0 Technical Conformance Guide and FDA eCTD v4.0 Module 1 Implementation Package
 - ⊖ Posted February 2020 for public comment
 - ⊖ Posted updates on September 2022
- Specifications for eCTD v4.0 Validation Criteria (October 2022)
- eCTD v4.0 Comprehensive Table of Contents Headings and Hierarchy (June 2021)
- Software updates and testing
 - ⊖ Currently testing eCTD v4.0 vendor software
 - ⊖ eCTD v4.0 Technical Pilot



FDA Implementation Strategy



- Initial release/acceptance for new applications in eCTD v4.0
 - ⇒ Technical Pilot (completed)
 - ⇒ Small group
 - ⇒ Accept sample submissions for technical feedback
 - ⇒ Open to all (planned for late 2023)
 - ⇒ Begin accepting new applications in eCTD v4.0 in 2024
- Future phases
 - ⇒ Transition of current applications
 - ⇒ Two-way communication

eCTD v4.0 Webpages

- ICH eCTD v4.0 Webpage (<https://www.ich.org/page/ich-electronic-common-technical-document-ectd-v40>)
 - ⇒ ICH eCTD v4.0 Implementation Package
 - ⇒ Supplemental Documents for eCTD v4.0 Implementation Package
 - ⇒ Regional Implementation Information & Regional Links
 - ⇒ Change Control (Process, Change Request & Questions)
- FDA eCTD v4.0 Webpage (<https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/electronic-common-technical-document-ectd-v40>)
 - ⇒ FDA eCTD v4.0 M1 Implementation Package
 - ⇒ eCTD v4.0 Technical Conformance Guide, CTOC, Validations
 - ⇒ Link to ICH eCTD v4.0 webpage

Prepare for eCTD v4.0

How to Prepare for eCTD v4.0

- Discuss eCTD v4.0 development plans with your vendor and/or IT organization
 - ⇒ Understanding the specifications
 - ⇒ Is there a plan for transitioning to eCTD v4.0?
 - ⇒ Send questions to ICH or FDA
- Become familiar with eCTD v4.0 concepts and enhancements
 - ⇒ ICH Supplemental Documents for eCTD v4.0
 - Support Documentation and Orientation Material for eCTD v4.0 Implementation Package
 - ⇒ FDA eCTD v4.0 Technical Conformance Guide
- Know where to find the eCTD v4.0 information
- Submit an eCTD v4.0 sample submission for technical feedback
 - ⇒ Information will be posted on the eCTD Sample Submission Process webpage later this year (<https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/submit-ectd-or-standardized-data-sample-fda>)

Poll Question #1



My company plans to submit an eCTD v4.0 test submission in:

- A. 2023
- B. 2024
- C. Already submitted
- D. No plans at this time

Summary

- eCTD v4.0 builds upon the success of v3.2.2
 - ⇒ Enhanced document replacement
 - ⇒ Harmonized submission unit (backbone) file
 - ⇒ Utilization of controlled vocabularies
 - ⇒ Ability to rename documents and context groups
- eCTD v4.0 is ready to implement
 - ⇒ Regulators are actively working on their regional implementations
- FDA has published regional specifications, completed pilot testing, and working toward acceptance of eCTD v4.0 submissions in 2024
- FDA eCTD website (www.fda.gov/ectd) contains all regional eCTD v4.0 specifications and links to ICH specifications

Questions?

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