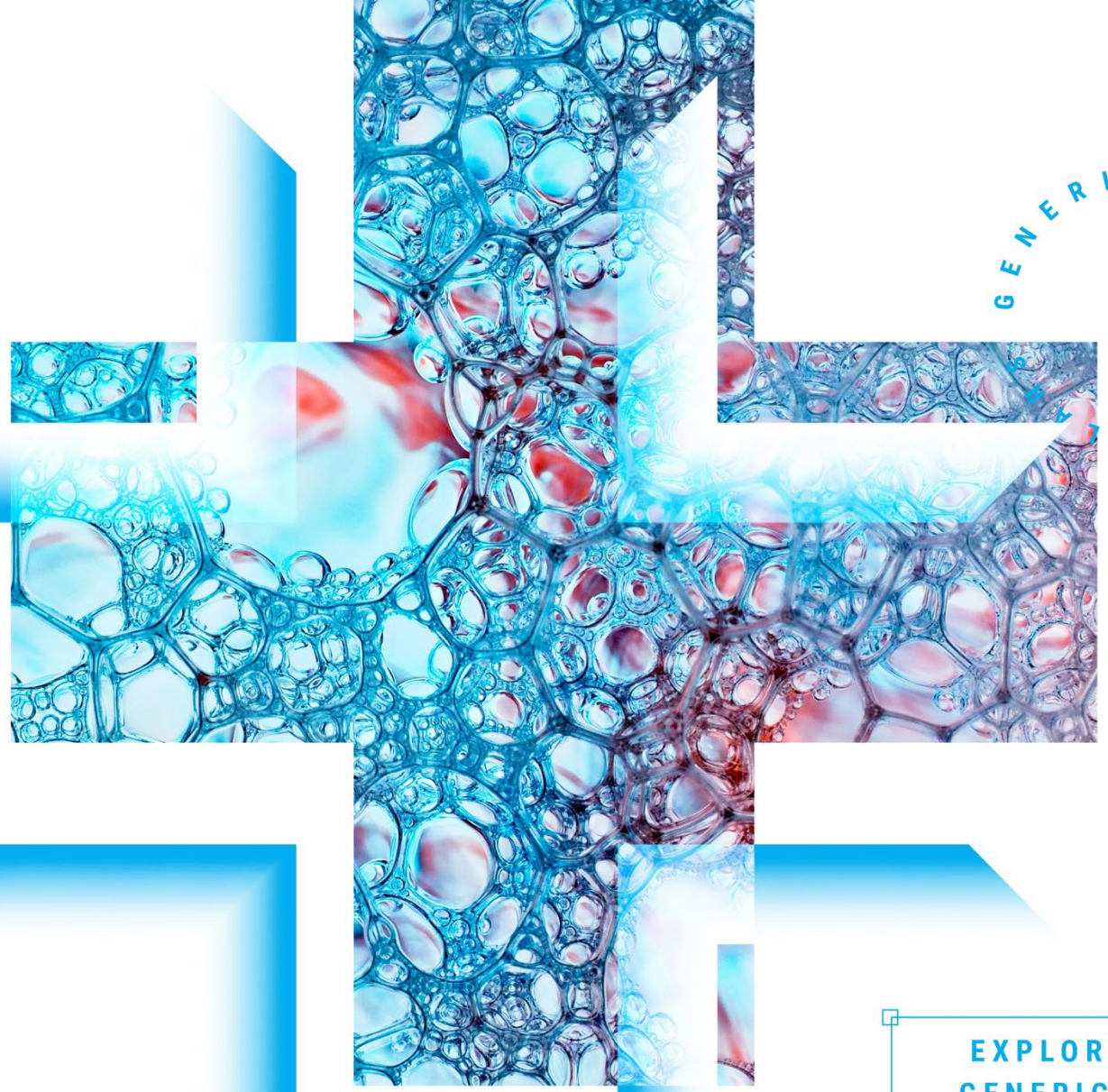

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eCTD v4.0 Implementation Update

Jonathan Resnick
CDER/OSP/OBI

October 21, 2024

Agenda

- ICH Activities
- FDA Activities
- FDA Implementation Strategy
- Technical Feedback on eCTD v4.0 Samples
- How to Prepare
- Resources

ICH Activities

ICH Activities

- ICH eCTD v4.0 Implementation Guide
  - V1.6 May 2024
- ICH eCTD v4.0 Controlled Vocabulary Package
  - V1.0 May 2024
- Q&A Change Requests
  - V1.8 May 2024
- eCTD Tool Vendor Group Established
  - Sign up on ICH web page
- Regional Implementation Information posted on ICH eCTD v4.0 webpage *(fig. 1)*
  - Technical pilots & implementation ates
  - Links to regional implementation documents

Region	Technical Pilot[1]	Implementation Dates[2]	Implementation Documents
ANVISA, Brazil	4Q 2025 (Planned)	1Q 2026 (Production Pilot[2]) 2026 (Voluntary)	TBD
EC, Europe	2024 CAPs (Planned)	2025 (Voluntary for CAPs[2]) 2026 (Voluntary for MRP/DCP/NP) 2027 (Mandatory for CAPs) TBC (Mandatory for MRP/DCP/NP)	EC, Europe regional implementation page
FDA, United States	2022 - 2Q 2023 (Completed)	2024 (Voluntary) 2029 (Mandatory)	FDA, United States regional implementation page
Health Canada, Canada	2025 (Planned)	2026 (Voluntary) 2028 (Mandatory)	Health Canada, Canada regional implementation page
MFDS, Republic of Korea	TBD	2027 (Voluntary) TBD (Mandatory)	TBD
MHLW/PMDA, Japan	2Q 2021 (Completed)	2022 (Voluntary) 2026 (Mandatory)	MHLW/PMDA, Japan regional implementation page
Swissmedic, Switzerland	2025 (Planned)	2026 (Voluntary) 2029 (Mandatory)	Swissmedic, Switzerland regional implementation page
TGA, Australia	4Q 2025 (Planned)	2026 (Voluntary) TBD (Mandatory)	TGA Implementation of ICH eCTD v4.0 Specification

Fig 1 – Snippet of Regional Implementation Information

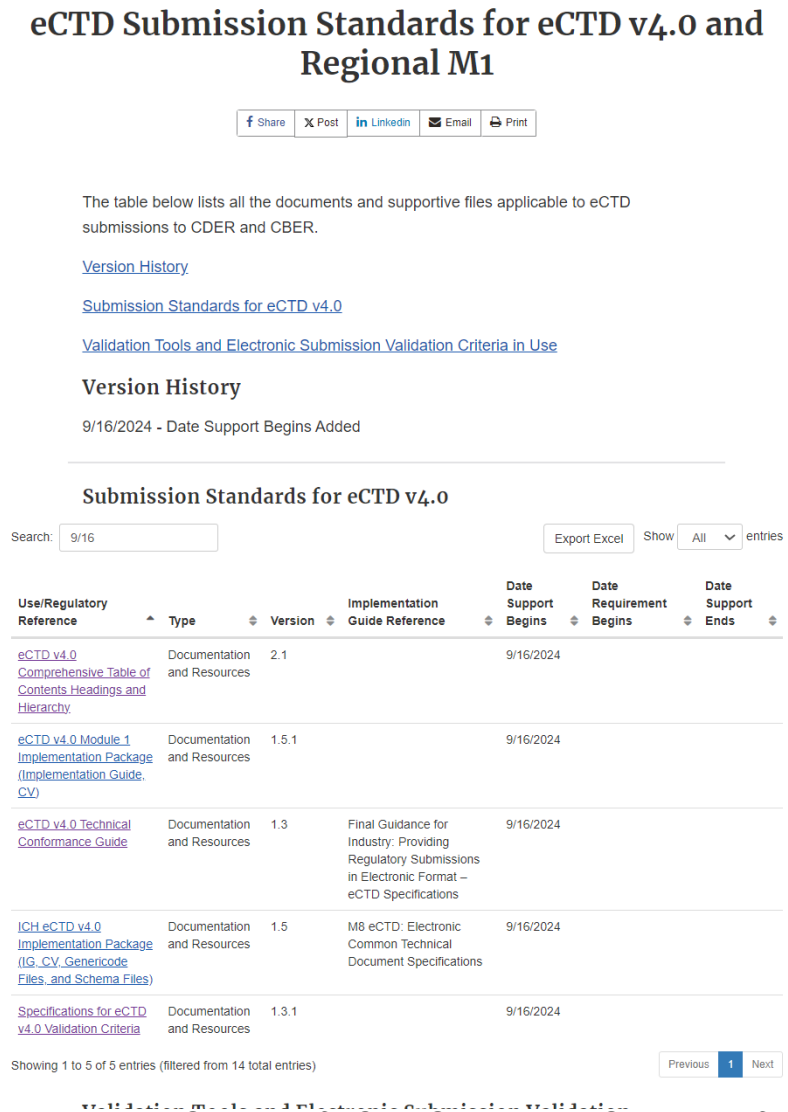
FDA Activities

FDA Activities

- CDER/CBER Supporting eCTD v4.0 as of September 16, 2024
  - Federal Register Notice – published 9/16/24
  - For a listing of eCTD v4.0 Implementation Guides, Specifications, Validations, Technical Conformance Guide, and Supportive Files, refer to the eCTD Submission Standards for eCTD v4.0 and Regional M1

(fig. 2)

- eCTD Guidance – Revision 8
  - Updated hyperlinks
  - Added references to eCTD v4.0
- FDA Data Standards Catalog
  - Added eCTD v4.0
- FDA Study Data Technical Conformance Guide
  - Added eCTD v4.0 related references



eCTD Submission Standards for eCTD v4.0 and Regional M1

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The table below lists all the documents and supportive files applicable to eCTD submissions to CDER and CBER.

Version History

Submission Standards for eCTD v4.0

Validation Tools and Electronic Submission Validation Criteria in Use

Version History

9/16/2024 - Date Support Begins Added

Submission Standards for eCTD v4.0

Search: 9/16 Export Excel Show All entries

Use/Regulatory Reference	Type	Version	Implementation Guide Reference	Date Support Begins	Date Requirement Begins	Date Support Ends
eCTD v4.0 Comprehensive Table of Contents Headings and Hierarchy	Documentation and Resources	2.1		9/16/2024		
eCTD v4.0 Module 1 Implementation Package (Implementation Guide, CV)	Documentation and Resources	1.5.1		9/16/2024		
eCTD v4.0 Technical Conformance Guide	Documentation and Resources	1.3	Final Guidance for Industry: Providing Regulatory Submissions in Electronic Format – eCTD Specifications	9/16/2024		
ICH eCTD v4.0 Implementation Package (IG, CV, Genericode Files, and Schema Files)	Documentation and Resources	1.5	M8 eCTD: Electronic Common Technical Document Specifications	9/16/2024		
Specifications for eCTD v4.0 Validation Criteria	Documentation and Resources	1.3.1		9/16/2024		

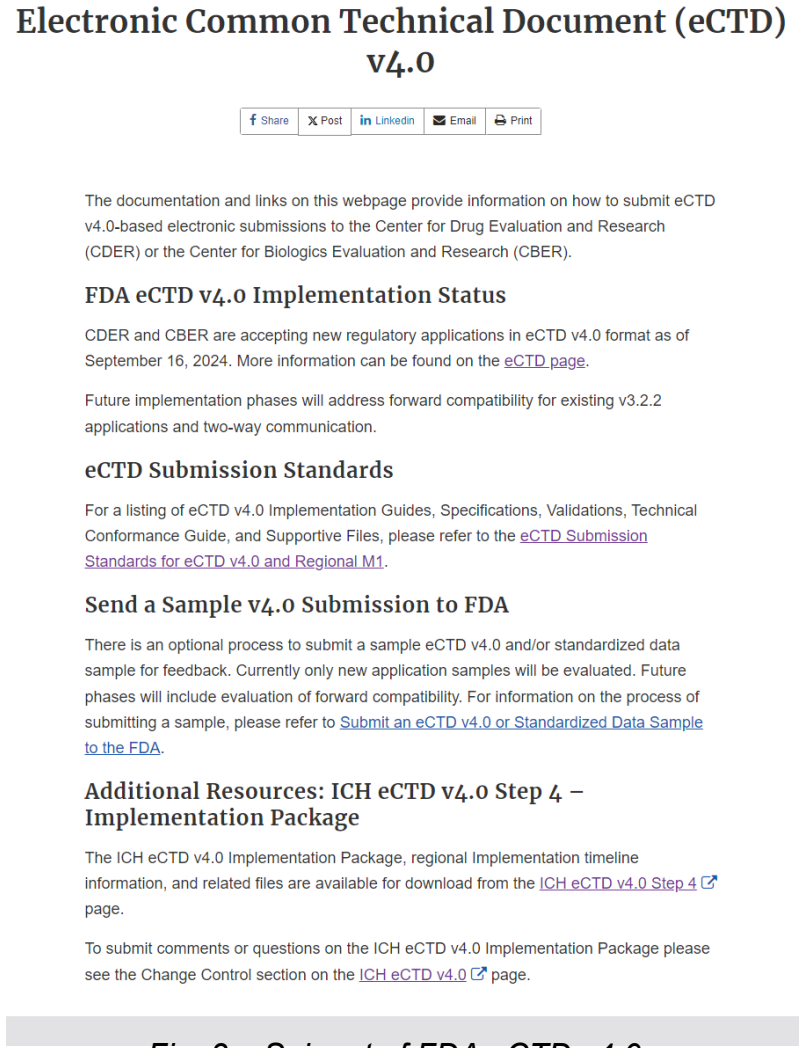
Showing 1 to 5 of 5 entries (filtered from 14 total entries) Previous 1 Next

Fig. 2 – Snippet of eCTD Submission Standards for eCTD v4.0 and Regional M1

FDA Implementation Strategy

FDA Implementation Strategy

- Initial release/acceptance for new applications in eCTD v4.0 *(fig. 3)*
  - Allows for development of eCTD v4.0 applications across regions
  - CDER/CBER support started 9/16/24
  - Sample submissions can be sent to CDER ESUB for technical feedback
- Future phases
  - Transition of current applications (Forward Compatibility)
  - Two-way communication



Electronic Common Technical Document (eCTD) v4.0

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The documentation and links on this webpage provide information on how to submit eCTD v4.0-based electronic submissions to the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER).

FDA eCTD v4.0 Implementation Status

CDER and CBER are accepting new regulatory applications in eCTD v4.0 format as of September 16, 2024. More information can be found on the eCTD page.

Future implementation phases will address forward compatibility for existing v3.2.2 applications and two-way communication.

eCTD Submission Standards

For a listing of eCTD v4.0 Implementation Guides, Specifications, Validations, Technical Conformance Guide, and Supportive Files, please refer to the eCTD Submission Standards for eCTD v4.0 and Regional M1.

Send a Sample v4.0 Submission to FDA

There is an optional process to submit a sample eCTD v4.0 and/or standardized data sample for feedback. Currently only new application samples will be evaluated. Future phases will include evaluation of forward compatibility. For information on the process of submitting a sample, please refer to Submit an eCTD v4.0 or Standardized Data Sample to the FDA.

Additional Resources: ICH eCTD v4.0 Step 4 – Implementation Package

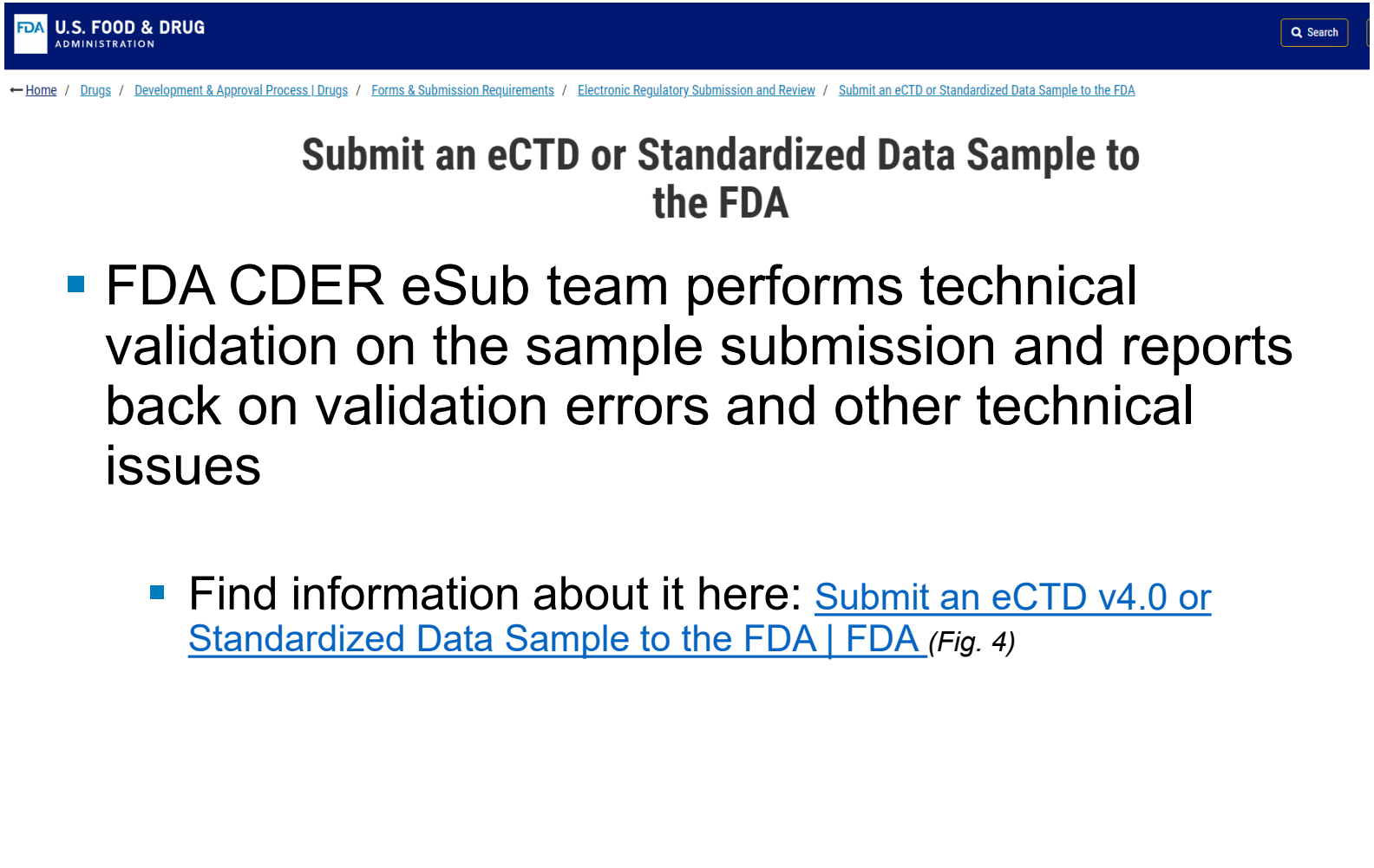
The ICH eCTD v4.0 Implementation Package, regional Implementation timeline information, and related files are available for download from the ICH eCTD v4.0 Step 4 page.

To submit comments or questions on the ICH eCTD v4.0 Implementation Package please see the Change Control section on the ICH eCTD v4.0 page.

Fig. 3 – Snippet of FDA eCTD v4.0 web page

Technical Feedback on eCTD v4.0 Samples

Technical Feedback on eCTD v4.0 Samples



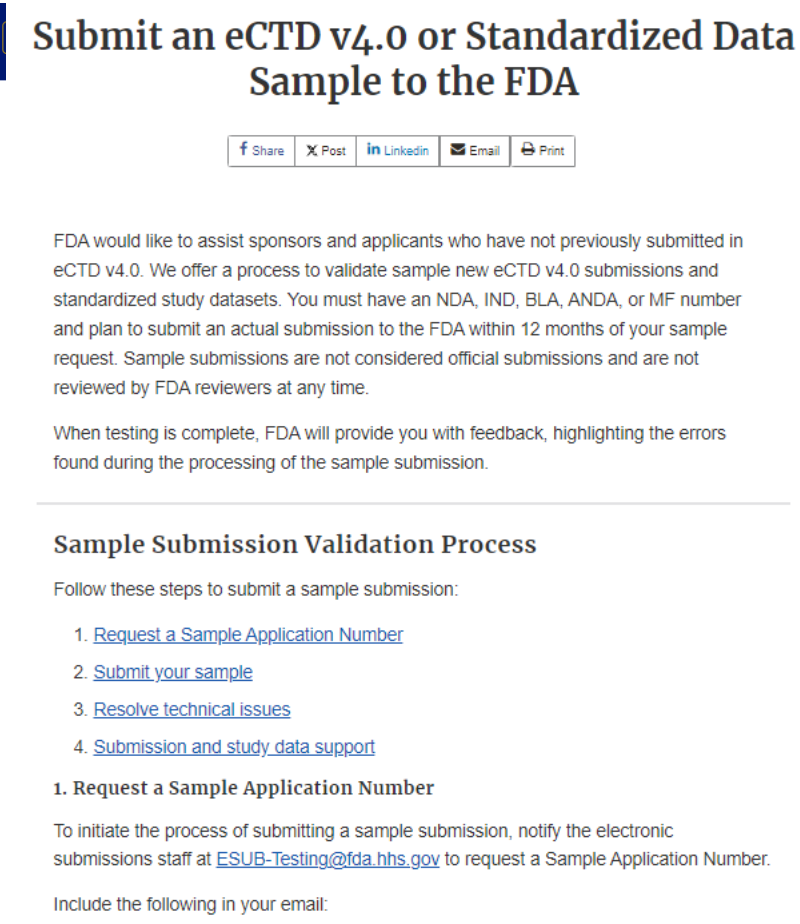


Fig. 4 – Snippet of FDA eCTD sample web page

How to Prepare

How to Prepare

- 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 for eCTD v4.0 Implementation Package - Explains contents enclosed in the Implementation Package. The target audience is business and technical personnel who build and/or review the eCTD v4.0 XML Messages.
    - Orientation Material for eCTD v4.0 Implementation Package - Provides an outline of eCTD v4.0 concepts from business perspective. The target audience is business personnel and management involved in any aspect of eCTD submission design and preparation.
  - FDA eCTD v4.0 Technical Conformance Guide
- Know where to find the eCTD v4.0 information

Resources

- ICH eCTD v4.0 Materials (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

- FDA eCTD v4.0 Regional Implementation Information

  (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
  - Link to ICH eCTD v4.0 webpage

- FDA Related Guidance and Specifications
  - eCTD Guidance – Revision 8 (https://www.fda.gov/media/135373/download)
  - FDA Data Standards Catalog (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/data-standards-catalog)
  - FDA Study Data Technical Conformance Guide (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/study-data-technical-conformance-guide-technical-specifications-document)

Thank You.

- Questions?