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Center for Drug Evaluation and Research

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eCTD v4.0 Implementation Update

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Agenda

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

ICH Activities

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

Regional Implementation Information

Region	Technical Pilot[1]	Implementation Dates[2]	Implementation Documents
ANVISA, Brazil	4Q 2024 (Planned)	1Q 2025 (Production Pilot) 2025 (Voluntary)	TBD
EC, Europe	2024 CAPs (Planned)	2025 (Voluntary for CAPs) 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	2024 (Planned)	2025 (Voluntary) 2027 (Mandatory)	Health Canada, Canada regional implementation page
MFDS, Republic of Korea	TBD	2025 (Voluntary) 2029 (Mandatory)	TBD
	2Q 2021	2022 (Voluntary)	

FDA Activities

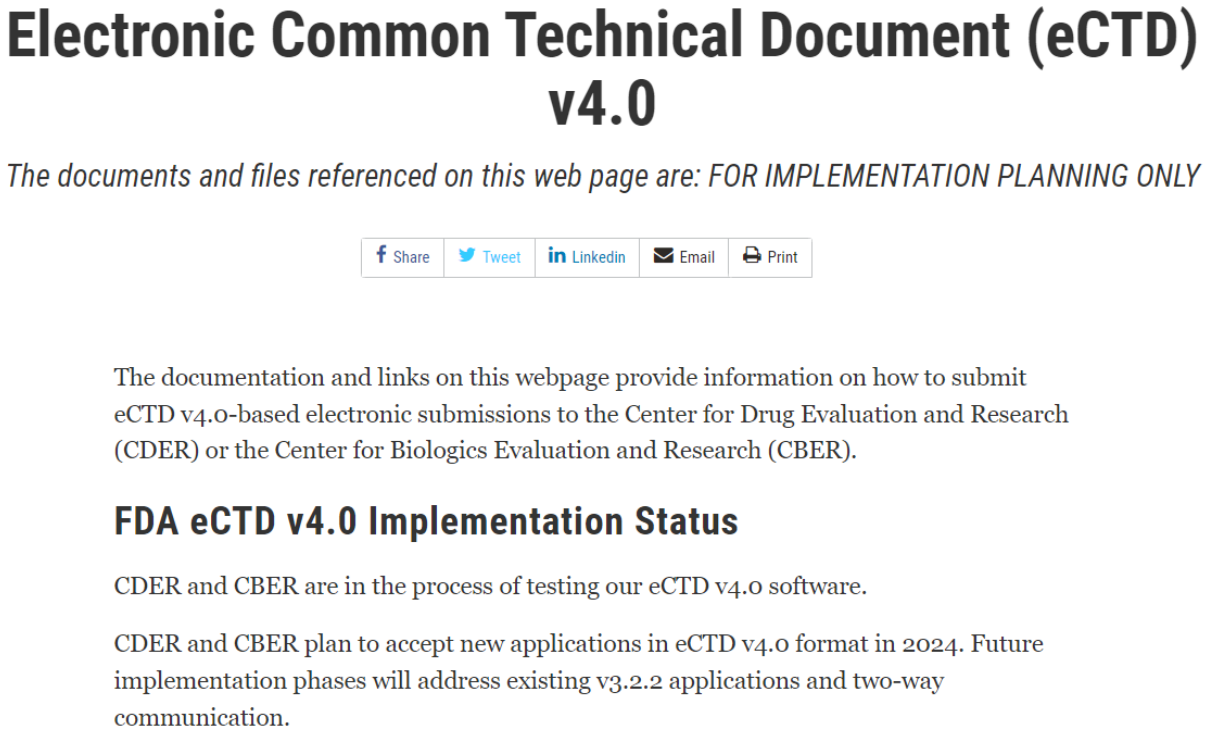
FDA Activities

- 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

FDA Implementation Strategy

- Initial release/acceptance for new applications in eCTD v4.0
  - Allows for development of eCTD v4.0 applications across regions
  - Perform testing with industry in 2023
  - Begin accepting new applications in eCTD v4.0 in FY24 Q3
- Future phases
  - Transition of current applications (Forward Compatibility)
  - Two-way communication



Electronic Common Technical Document (eCTD) v4.0

The documents and files referenced on this web page are: FOR IMPLEMENTATION PLANNING ONLY

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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 in the process of testing our eCTD v4.0 software.

CDER and CBER plan to accept new applications in eCTD v4.0 format in 2024. Future implementation phases will address existing v3.2.2 applications and two-way communication.

Technical Pilot

Technical Pilot

- The objective of this testing is to determine if the implementation satisfies the requirements in the technical specification and make any changes prior to accepting eCTD v4.0 submissions in the production environment.
- Duration (June 2022 – April 30, 2023)
- Technical Pilot Scope
  - Submission Scope
    - Original eCTD v4.0 applications and subsequent submissions (e.g., amendments, supplements)
    - Grouped eCTD v4.0 submissions
  - Enhancement Scope
    - Life-cycle (one-to-one, one-to-many, many-to-one)
    - Document reuse
    - Document ordering
    - Keyword modifications
    - “Group Title” Keyword

Technical Feedback on eCTD v4.0 Samples

Opportunity to obtain technical feedback on sample eCTD v4.0 submissions

- Exists today for eCTD v3.2.2
  - Find information about it here: https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/submit-ectd-or-standardized-data-sample-fda
- CDER plans to expand to include v4.0
  - Will commence when FDA begins accepting voluntary eCTD v4.0 submissions or possibly earlier. Check above link to updates.
- FDA CDER eSub team performs technical validation on the sample submission and reports back on validation errors and other technical issues

eCTD v4.0 Update – 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

eCTD V4.0 Websites

- 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 Requests & Questions
    - Q&A document

- 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
  - Link to ICH eCTD v4.0 webpage