

Electronic Submissions Gateway: Next Generation eCTD v4.0 Two-Way Communication

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A GATHERING OF GLOBAL PERSPECTIVES



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eCTD v4.0 Agenda

- Project Status
- Enhancements
- Two-way communication process & questions
- ICH & FDA websites

eCTD v4.0 Project Status

- ICH Step 4 (Adoption of Harmonised Guideline)
 - Implementation of the eCTD v4.0 requirements using the Health Level Seven (HL7) Regulated Product Submission (RPS) standard
- FDA Implementation Package
 - Posted and includes;
 - Implementation Guide
 - Code List (Spreadsheet and Genericcode Files)
 - XML Samples
- Regional Implementation Planning

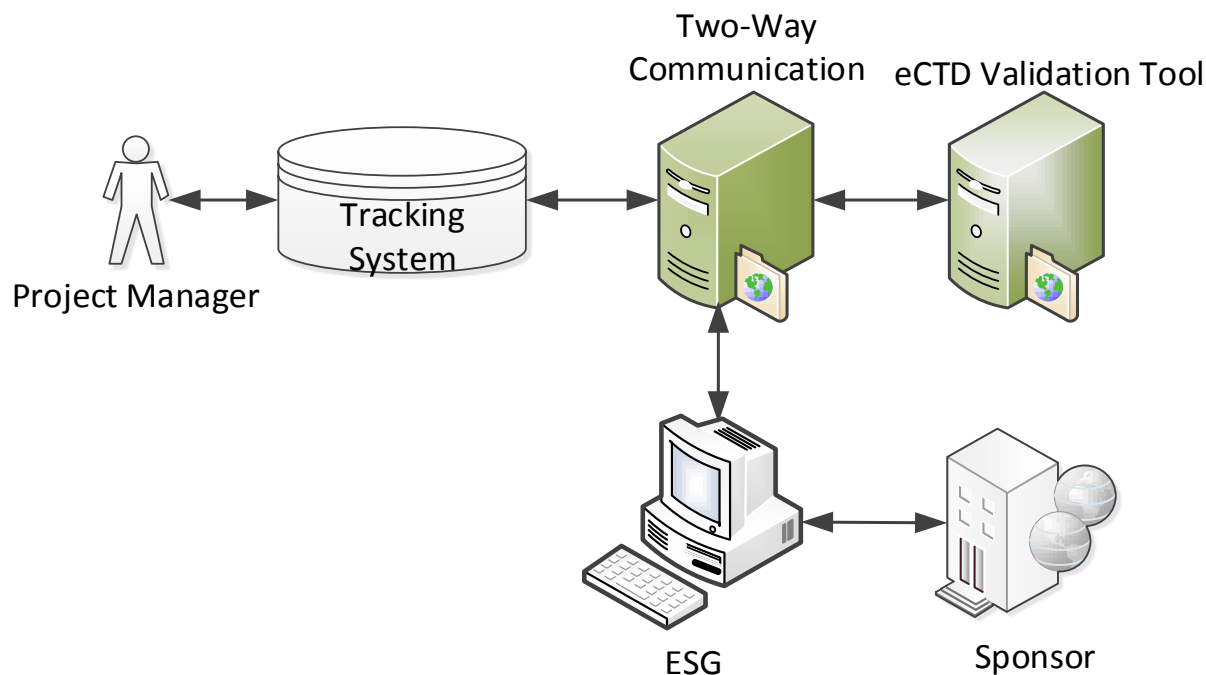


eCTD v4.0 Enhancements

- ***Enhanced control of dossier***
 - Keyword/attribute modifications
 - Enhanced Life-cycle control: one-to-one, one-to-many, many-to-one
 - Simple reuse of previously submitted documents
 - Document Ordering: explicitly define display order for documents in a specific section
 - New eCTD v4 Keyword “Group Title”
 - Sponsors can use group titles based on M4 Granularity Document where “One or multiple documents can be submitted”
- ***Enhanced identification of information contained within a submission:*** Designated in the document metadata
- ***Message flexibility***
 - Message is managed through the use of controlled vocabularies
 - For example, headings are a controlled vocabulary and would not require modification of the standard
- ***Support for two-way communication (Regional)***
 - The regulatory authority can use eCTD v4.0 to send correspondence to the submitter

Two-Way Communication High-Level Process

- Ability to send *structured* electronic regulatory correspondence to the submitter via the Electronic Submissions Gateway (ESG)
- Based on electronic Common Technical Document (eCTD) v4.0 exchange standard
- Submitters that submit their applications in eCTD v4.0 or have transition their applications to eCTD v4.0 will receive FDA correspondence electronically



Two-Way Communication Process Steps By Actor



**CDER or
CBER PM**

Once the CDER or CBER PM has selected the correspondence and entered the information into the Center Tracking System, the Center Tracking System determines if the correspondence should be sent electronically or manually. For all manual correspondence, the process continues as it does today. CDER electronic correspondence is sent to the CDER Document Room and CBER electronic correspondence is sent to the CBER Review Office.



**CDER Document
Room or CBER
Review Office**

The CDER Document Room or CBER Review Office reviews the correspondence for quality and completeness. After reviewing and finalizing the correspondence, the Document Room or Review Office submits the correspondence for distribution. The Center Tracking System forwards the correspondence to the Two-Way Communication system



**Two-Way
Communication
and eCTD
Validation Tool**

Two-Way Communication System creates a folder in EDR to store the correspondence files. It creates an XML file and attaches the correspondence files. The eCTD Validation Tool validates the XML file. Then Two-Way Communication creates a zip file containing the XML file and attachments and sends the zip file to the ESG



**Electronic
Submissions
Gateway (ESG)**

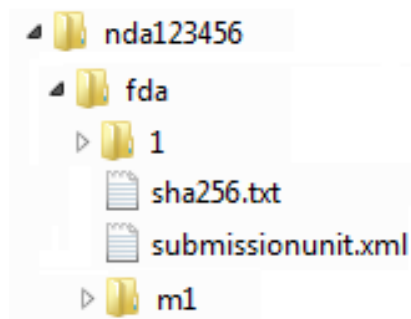
The ESG distributes the zip file to the designated ESG account using either the recipient's WebTrader or AS2 account. After transmitting the zip file, the ESG sends an email notification to the recipient and the Two-Way Communication system sends an email notification to the PM and either the Document Room or the Review Office

FDA eCTD v4.0 Correspondence

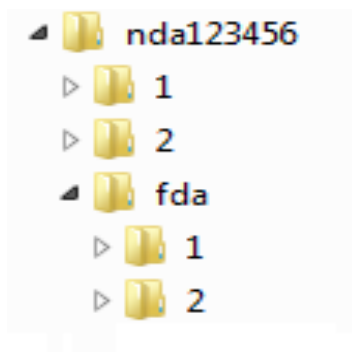
- Current thinking on the eCTD v4.0 FDA message
 - Application Type & Number
 - Submission (Regulatory Activity)
 - Submission Type
 - Regulatory Status & Effective Date, for status change correspondence
 - RPM Contact Information
 - Submission Unit
 - Submission Unit Type = “Correspondence”
 - FDA Sequence Number
 - Categorization, examples are;
 - Acknowledgement
 - Meeting Request Granted
 - Information Request / Advice
 - Complete Response
 - Context of Use & Document
 - Using “m1.25 fda to industry correspondence”

FDA eCTD v4.0 Correspondence Submission Unit Folder

- USFDA eCTD v4.0 Module 1 Implementation Guide v1.0
 - 4.1.2 Submission Unit Contents from USFDA



- USFDA eCTD v4.0 Module 1 Implementation Guide v1.0
 - 4.1.3 Comprehensive Folder Structure



FDA eCTD v4.0 Correspondence Questions

- Does this replace email between the FDA PM and industry?
- How will FDA ensure that sponsors have received the FDA correspondence?
- What happens if the sponsor has a validation issue with the FDA correspondence?
- Does the FDA and the sponsor need to coordinate the use of sequence numbers?
- Will FDA file attachments be in the PDF format? If yes, will they follow the PDF specifications?

FDA eCTD v4.0 Correspondence Questions

- Has FDA worked with other ICH regions?
- Will industry have the ability to grant temporary access to the ESG account used to receive FDA correspondence?
- Can FDA notify the industry regulatory contact that a FDA correspondence has been sent?
- What are the plans for testing two-way communication?

eCTD v4.0 Websites

- ICH webpage (<http://estri.ich.org/new-eCTD/index.htm>)
 - ICH Implementation Package
 - Implementation Guide
 - Code List (Spreadsheet and Genericode Files)
 - Schema Files
 - Links to regional web pages

- FDA webpage
 (<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm309911.htm>)
 - FDA Regional Implementation Package
 - Implementation Guide
 - Code List (Spreadsheet and Genericode Files)
 - XML Samples