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Overview of Structural Specifications and Validation of eCTD (v3.2.2): An Elucidation of the General Architecture of EU Module 1 and GCC Module 1

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Abstract

A comprehensive understanding of the eCTD structural specifications ensures compliance, accelerates the product approval process, and facilitates seamless interactions between pharmaceutical companies and regulatory authorities. This article provides an overview of the eCTD submission process and the scope of eCTD challenges and Module 1 (Region-Specific Administrative and Product Information). It also presents a concise summary of eCTD structural specifications, along with an illustration of the folder naming conventions and structure of Module 2. The article outlines the general architecture of EU Module 1 and GCC Module 1, demonstrating the envelope, directory/file structures, as well as file naming conventions and formats. Additionally, it explains the stages of eCTD validation and some of the Validator tools; it also includes three practical cases illustrating common validation errors. Furthermore, it demonstrates the transition to eCTD version 4.0 and its implementation timeline across the EMA, FDA, Health Canada, and PMDA (Japan).

Conclusion: Conducting eCTD structural specifications governs the electronic submission framework to ensure seamless regulatory compliance. Module 1 (EU, GCC) demands precise adherence to regional regulatory requirements. Vigilance in preparing the eCTD and its validation process plays a quintessential role in minimizing submission errors, achieving approval, and enabling quicker access to new products.

Keywords: electronic Common Technical Document (eCTD); The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH); Validation; Submission; Module; Specifications; European Union (EU) Module 1; Gulf Cooperation Council (GCC) Module 1

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1. Introduction

The structural specifications of eCTD are established by ICH and regional regulatory bodies. These specifications cover standardised submission content and folder organization, the XML backbone, controlled vocabularies, formatting for PDFs and files, checksums to verify file integrity, hyperlinking and granularity requirements, as well as lifecycle management processes. The primary purpose of an eCTD submission is regulatory harmonization and efficiency, as well as facilitating the data exchange. (1)

1.1 eCTD Submission Process

eCTD submission proceeds a structured sequence:

a) Dossier Planning: Determine the type of submission (such as NDA, ANDA, MAA, IND) and identify the necessary modules.

b) Dossier Content Preparation: Assemble documents using standardised templates and ensure they have the appropriate level of detail in each module.

c) Publishing: Convert documents into PDF format, add bookmarks, hyperlinks, metadata, and arrange them according to the eCTD structure.

d) Validation: Perform technical checks using validation tools approved by regulatory agencies.

e) Submission: Electronically submit sequences through agency / regulatory authority's portals.

f) Lifecycle Management: Continuously manage submissions by adding new sequences, updates, and variations. (2)

1.2 The Scope of eCTD Challenges

Pharmaceutical companies achieve regulatory success by ensuring data accuracy and consistency throughout the eCTD package, maintaining and developing the necessary technical infrastructure and expertise, and applying rigorous validation standards and tools. (2)

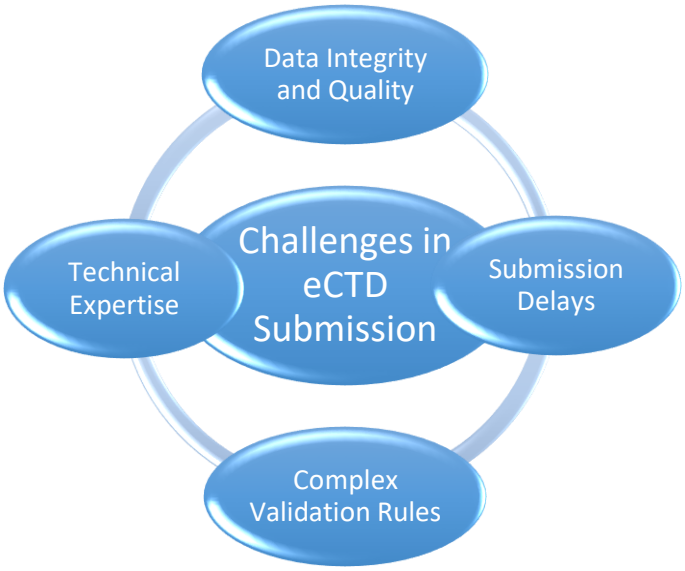

Figure 1. Challenges in eCTD Submission

1.3 Module 1 (Region-Specific Administrative and Product Information)

The eCTD is an XML-based format organized hierarchically into five principal modules. CTD Modules 2–5 content outlines (Overviews &Summaries, Quality, Nonclinical Study Reports, and Clinical Study Reports) are standardised worldwide according to ICH M4 guidelines. Module 1 (Region-Specific Administrative and Product Information) is specific to each region and requires customisation for each regulatory authority. The following is a list of some specific documents required by various agency/authorities:

a) FDA: Form FDA 356h, SPL product labels, and establishment registration.

b) EMA: Electronic Application Forms (eAF), SmPC, labeling, and Risk Management Plans (RMP).

c) PMDA: Japanese-language administrative documents, GMP certificates, and PMDA-specific cover letters.

d) Health Canada: HC-SC forms, electronic signatures, and additional bilingual content.

Every module is required to comply with proper XML metadata standards and lifecycle operations (new, replace, delete, append). Mistakes in module 1 often result in regulatory delays and can cause rejections. (3)

2. Overview of the eCTD Structure Specification (4,5)

2.1 Modular Organization of the eCTD: The layout of the electronic submission, including its organization and navigation, should align with the modular framework according to the ICH Common Technical Document.

2.2 XML-Based eCTD: The XML eCTD Document Type Definition (DTD) defines the overall structure of the submission. The XML backbone serves as the digital framework for the entire submission. It's a file that functions as an intelligent, hyperlinked table of contents. It does not include the actual documents, but it informs the regulatory agency's software about the identity of each file, its location, and its connection to the other parts of the submission, which manages metadata for the entire submission and each document within the submission. Metadata at the submission level includes information about submitting and receiving organization, manufacturer, publisher, ID, and kind of the submission, as well as associated data items.

2.3 Directory Structure The directory structure consists of directories and files, with a reasonable maximum number of entries allowed in each directory. File and directory names serve as identifiers. Although file names are not meant to include metadata, having meaningful names is beneficial (i.e., avoid random names). Any directory and file names added by the applicant to the eCTD submission should be clear, logical, and concise.

2.4 XML eCTD Instance: The instance is located within the submission sequence number directory. This directory must include at least two files and one or more directories. Among these files, one should be the instance itself, and another should be the MD5 checksum of that instance. The instance serves as the initial file for processing by an XML processor.

The goal is to have links from the instance's leaf elements to the files in the eCTD submission, rather than compiling the entire eCTD submission into a single XML document. Furthermore, the instance includes metadata at the leaf element level.

2.5 Checksums: The eCTD submission must include checksums for every individual file, as well as a checksum file for the eCTD XML instance. Initially, the Message-Digest Algorithm (MD5) should be employed for this task. Providing a checksum for each file offers several advantages, such as:

- Ensuring the integrity of each file by comparing the checksum submitted with the file and the computed checksum.
- Allowing verification that the file remains unchanged within the regulatory authority's historical archive.

This is particularly important when files are transferred between storage media. (4,5)

2.6 Lifecycle Management Using eCTD Sequences

eCTD lifecycle management guarantees that all modifications are monitored, documented, and properly liaised to health authorities.

A major advantage of the eCTD format is its ability to streamline lifecycle management. Every submission receives a unique "sequence number," allowing the cumulative dossier to develop over time with each new event:

a) 0000 – Original application

b) 0001, 0002, and so on – for any changes/variations, updates, and replies to inquiries.

This apparent sequencing enables regulatory authorities to easily follow a product's regulatory history. Applicants are responsible for maintaining version control, implementing archiving procedures, and ensuring their internal naming systems are consistent. (3,5)

2.7 File and Folder

a) File Extension: Every file must have exactly one file extension. This extension should be used to specify the file's format. For instance: study-report-1.pdf.

b) Folder and File Name Length: The maximum length for any folder or file name is 64 characters, including the file extension. Folder names should be in lowercase letters only. (4)

Table (1) and Figure (2) below illustrate the naming convention and structure of the Module 2 folder. (4)

Table 1. Module 2 Folder Naming Convention

Section in CTD	Description	Folder Name
2.2	Introduction	*22-intro*
2.3	Quality Overall Summary	*23-qos*
2.4	Nonclinical Overview	*24-nonclin-over*
2.5	Clinical Overview	*25-clin-over*
2.6	Nonclinical Written and Tabulated Summaries	*26-nonclin-sum*
2.7	Clinical Summary	*27-clin-sum*

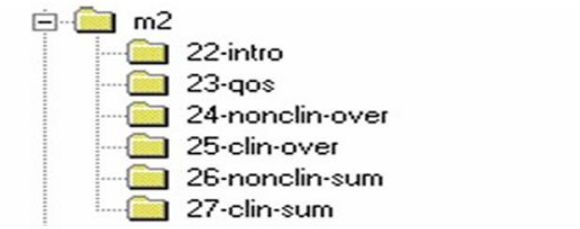

Figure 2. Representation of Module 2 Folder Structure

c) File Formats: Formats must remain accessible for at least as long as required by the regulatory process, which can be quite lengthy (for example, up to 50 years).

The typical formats that can be incorporated into an eCTD submission include:

- Narrative: Portable Document Format (PDF)
- Structured: Extensible Markup Language (XML)
- Graphics: Use PDF whenever feasible. If PDF is not suitable or possible, use Joint Photographic Experts Group (JPEG), Portable Network Graphics (PNG), Scalable Vector Graphics (SVG), or Graphics Interchange Format (GIF). (4)

2.8 PDF Publishing Standards

a) Portable Document Format (PDF) and Version: PDF is recognized as the standard format for documents outlined in the ICH specification.PDF Version: All ICH Regional Health Authorities are able to read and have agreed to accept PDF files saved as PDF version 1.4.

b) Font Type, Size, and Color: Times New Roman, 12-point font, the font used for this document, is appropriate in size for narrative text and should be used whenever possible. It is advised to use black for the font color. Blue is utilized for hyperlinks.

c) Page Size and Margins: The print area for pages should fit on a sheet of A4 (210 x 297 mm) and Letter (8.5" x 11") paper. A sufficient margin (at least 2.5 cm) on the left side of each page.

d) Hypertext Linking and Bookmarks: Hypertext links and bookmarks improve navigation through PDF documents. Generally, for documents that include a table of contents, bookmarks should be created for every item listed in the table of contents, encompassing all tables, figures, publications, other references, and appendices. Bookmarks should align with the hierarchy and sequence of the table of contents. It is advisable to limit the hierarchy to a maximum of four

levels. Including hypertext links within the document to connect annotations, related sections, references, appendices, tables, or figures that appear on different pages is beneficial and enhances navigation efficiency.

e) **Page Numbering:** Only the document's internal page numbers (1 through n) are required. There should be no additional page or volume numbers that continue across multiple documents. The first page of the document should be labeled as page 1, and all following pages, including appendices and attachments, that should be numbered sequentially using Arabic numerals (0-9 digits). Roman numerals should not be used for page numbering (such as on title pages or tables of contents), and no pages should be left without numbers (for example, the title page).

f) **Source of Electronic Document:** These documents should be created from electronic source files rather than scanned copies, except in cases where the original electronic file is not accessible or a signature is required. (4)

3. General Architecture of EU Module 1 (6)

The structure of EU Module 1 resembles that of eCTD Modules 2-5, featuring a directory structure and a backbone with associated leaves. The backbone must be a valid XML document conforming to the EU Regional Document Type Definition (DTD). This backbone file, named "eu-regional.xml," holds metadata about the leaves, including references to files within the directory structure. Furthermore, the EU Regional DTD specifies submission-level metadata encapsulated within an envelope. The root element, called "eu-backbone," which includes two elements: "eu-envelope" and "m1-eu."

3.1 Envelope

The "eu-envelope" element is intended for use with all types of submissions related to a specific medicinal product and is primarily used for initial processing at the EMA level. This envelope includes metadata at both the eCTD application and sequence levels.

For submissions under the Centralised Procedure, the "eu-envelope" element should contain a single "envelope" element with the country attribute set to 'EU-EMA'. For all other procedures, the "eu-envelope" element must include a separate "envelope" element for each Member State involved in the procedure.

3.2 Directory / File Structure

The EU Module 1 Specification outlines a recommended directory and file structure. Across all four procedures (MR, DCP, NP, and CP), the same high-level directory structure is being used. This uniformity is maintained even though files for the MP, DCP, and NP are usually country-specific, while files for the Centralised Procedure are usually language-specific. For the Centralised Procedure, the country subdirectory is always named either "ema" or "common". The folder named "common" should be reserved exclusively for documents that may apply to all EU countries, regardless of their current participation in the procedure.

3.3 Node Extensions

Node extensions serve as a method to add extra organizational details to the eCTD. They should be viewed as additional headings within the CTD structure and displayed accordingly when viewing the XML backbone. However, their use should be restricted to situations where it is essential.

There are certain rules for the use of node extensions in the EU:

a) Node extensions must not be used in areas where ICH-defined sub-headings already exist (for example, drug substance and drug product are all ICH-specified node extensions).

b) Node extensions should only be applied at the lowest level of the eCTD hierarchy (for instance, a node extension can be used at level 5.3.5.1 but not at level 5.3).

c) The primary purpose of node extensions is to group documents that consist of multiple leaf elements.

d) Node extensions must be preserved throughout the entire eCTD lifecycle.

e) Nesting of node extensions is permitted, as allowed by the eCTD DTD.

f) Content linked to a node extension can be stored in a separate subfolder within the submission; this is suggested for use in Module 5 studies, where study reports are split into multiple files. However, there is no mandatory requirement to create an additional subfolder.

3.4 Folder and File

a) File Naming Convention

The first part of a file name must be the country code, unless the document applies to all countries and all procedures. The second part should be the document type code. If needed, the third part should be the variable component.

For country-specific files, the general format is CC-FIXED-VAR.EXT. Here, CC represents the country code used in certain CTD modules, FIXED is a predefined part of the filename based on the CTD section, and VAR is an optional additional variable element. EXT stands for the file extension. Each part is separated by a hyphen, except for the dot before the file extension. Spaces are not allowed within any component, but hyphens may be used in the variable part to separate multiple words. The fixed components are strongly recommended. The variable component is optional and should be used when necessary to provide further detail about the file. If included, the variable part should be a meaningful combination of words, optionally separated by hyphens, and kept as concise and descriptive as possible to prevent exceeding maximum path length limits. File names must always be in lowercase.

b) Folder and File Name Path Length

The total length of the folder and file name path, beginning from the sequence number, must not exceed 180 characters for any file within any module. This is a requirement specific to the EU region and is recognized as being shorter than the overall path length agreed upon by ICH.

c) File Format

The preferred file format for content documents is PDF. All PDF files submitted within an eCTD, regardless of the module, should be versions 1.4, 1.5, 1.6, 1.7, PDF/A-1, or PDF/A-2.

3.5 Other Considerations:

a) Use of Electronic Signatures

Electronic signatures in the European Union are regulated by Regulation (EU) No 910/2014 of the European Parliament and Council. For Marketing Authorisation Applications (MAA) and post-authorisation submissions, most National Competent Authorities (NCAs) and the European Medicines Agency (EMA) do not require physical or digital signatures on cover letters or application forms.

b) Updating Backbone Attributes/Metadata

It is not possible to modify XML backbone attributes during the eCTD lifecycle by deleting existing documents and resubmitting them with updated attributes. The recommended approach is to keep the original entry as is and use the document content to provide the current information.

c) Demonstrating the Use of Related Sequence

In eCTD, this includes all the sequences that collectively represent the entire lifecycle of a specific regulatory activity. The Submission unit type element specifies the phase within the regulatory activity, for example, initial or response.

3.6 Universal Unique Identifier (UUID)

The UUID is used by authorities to help archive the sequence with the correct eCTD lifecycle. It is crucial that each eCTD lifecycle has a unique UUID. There is no restriction on using uppercase or lowercase letters in the UUID, but the chosen format must remain consistent throughout the entire lifecycle. Applicants should generate the UUID according to ISO/IEC 11578:1996 and ITU-T Rec X.667 | ISO/IEC 9834-8:2005 standards. The UUID is a hexadecimal number formatted as xxxxxxxx-xxxx-xxxx-xxxx-xxxxxxxxxxxx, consisting of 32 digits and 4 hyphens, where each 'x' is replaced by a number or letter. (6)

4. General Architecture of GCC Module 1 (7)

The ICH Common Technical Document (CTD) requires that Module 1 include region-specific administrative and product details. The architecture of GCC Module 1 resembles that of eCTD modules 2-5, featuring a directory structure along with a backbone and its leaves. The backbone must be a valid XML document that complies with the GCC Regional Document Type Definition (DTD). This backbone instance, known as the gc-regional.xml file, holds metadata for the leaves, including references to files within the directory structure. Furthermore, the GCC Regional DTD specifies metadata at the submission level through an envelope. The root element is "gc-backbone," which includes two elements: "gc-envelope" and "m1-gc."

4.1 Envelope

The "gc-envelope" element is intended for use with all kinds of submissions (such as initial applications, variations, renewals, and others) related to a specific medicinal product. It is mainly used for the initial elementary processing at the agency level. The envelope contains metadata related to the submission.

4.2 XML Catalogue

The "m1-gc" element of the GCC regional DTD is follows the same conceptual framework as the common part of the ICH eCTD DTD. It provides an XML catalogue with metadata at the leaf level, along with references to the file locations within a directory structure.

4.3 Directory / File Structure

The actual file and directory names should be written in lowercase, following the eCTD guidelines. The terms "VAR" and "EXT" indicate a variable part of the file name and a file extension, respectively. These are shown in uppercase only to distinguish the variable elements from the fixed parts of the name. "CC" stands for the country code, and "LL" represents the language code. These are added to a directory when a file is specific to a particular country. If the file applies to all GCC countries, the "CC" value will be "common."

4.4 File Naming Convention

The eCTD file naming rules are outlined in the ICH M2 eCTD Specification. File names consist of fixed and variable parts, separated by hyphens. Hyphens or spaces should not appear within any individual part. Fixed parts are obligatory, while the variable part is optional and can be used to provide additional detail about the file. If included, the variable part should be a meaningful combination of words without separators, kept concise and descriptive. File extensions should follow the specification and be applied as needed.

The file format is indicated by its extension. File names must always be lowercase, according to the ICH eCTD specification. Examples include: sa-cover.pdf (Saudi Arabia), ae-cover.pdf (UAE), bh-cover.pdf (Bahrain), kw-cover.pdf (Kuwait), qa-cover.pdf (Qatar), ye-cover.pdf (Yemen), sa-form.pdf (Saudi Arabia), and om-form.pdf (Oman).

4.5 Regional File Formats

The standard format is PDF, as outlined in the ICH eCTD Specification Document. Bookmarks and hyperlinks should be incorporated to facilitate navigation. XML is also acceptable for delivering structured data within Module 1, particularly for the application form and product information, provided the XML complies with the standards set in the electronic application forms. Documents should be created from electronic source files.

Signatures can be embedded as graphic images within the PDF if desired, though this is optional since the legally binding signature is on the physical paper copy. If higher resolution images are needed for mock-ups, formats such as JPEG, GIF, PNG, or SVG may be used selectively. Labeling texts can be submitted in XML format following the PIM Data Exchange Standard. (7)

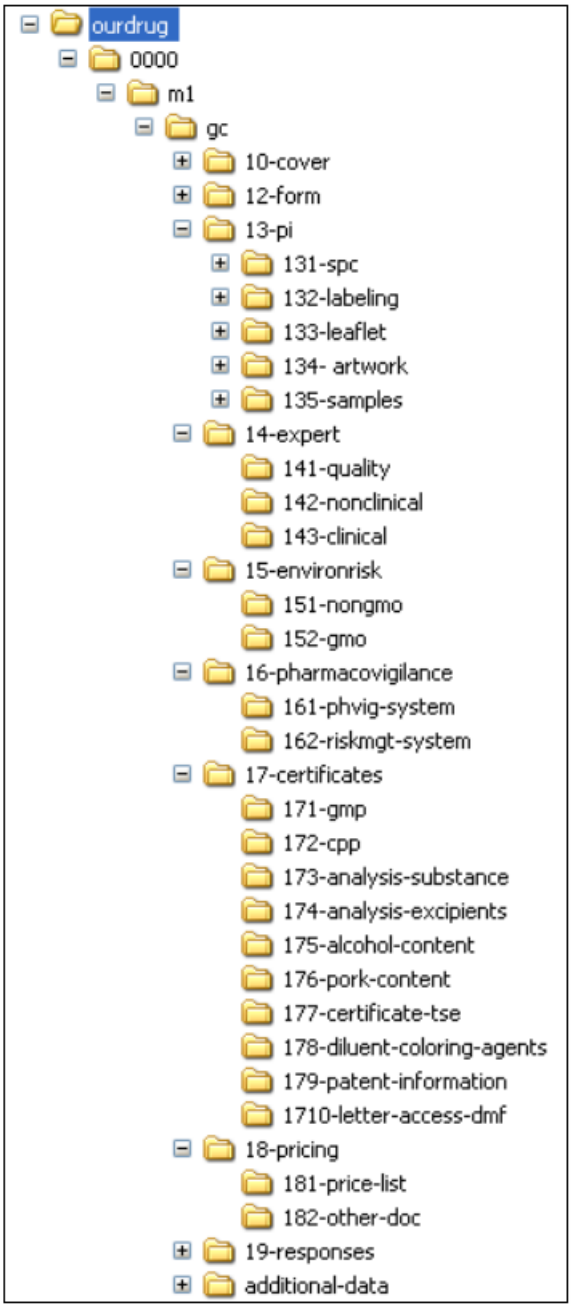

Figure 3. Representation of the Directory Structure for Gulf Cooperation Council (GCC) Module 1

5. eCTD Validation (8,9)

eCTD validation is a thorough procedure that ensures an Electronic Common Technical Document (eCTD) submission complies with all the technical, structural, and content standards set by regulatory authorities and ICH guidelines.

5.1 Prevalent eCTD Validation Error Categories

a) Mislead /incorrect mandatory files and folders.

b) Errors in file format and content.

c) Incorrect use of lifecycle operations.

d) PDF navigation issues.

e) Form and administrative mistakes (including meta-information)

5.2 Stages of eCTD Validation

a) **Technical validation** identifies errors that lead to instant gateway rejection, such as incorrect XML formatting, PDFs that do not meet standards, and checksum errors.

b) **Structural validation** checks that the submission is correctly arranged following eCTD module guidelines, including working hyperlinks and accurate cross-references between files.

c) **Content validation** extends beyond technical checks to confirm that the submission's content is precise, consistent throughout the modules, and fully meets regulatory criteria. (8,9)

5.3 Three Practical Cases of Validation Errors (9)

a) Case 1: Incorrectly Named Module Folder (EMA) – In one reported case, a company submitted a Marketing Authorization Application (MAA) to the EMA with a minor error: they intended to include the UK-specific Module 1 but mistakenly added an extra empty folder named m1/ukr, possibly copied from another country's structure. The EMA's validation system immediately detected this as an "extra folder" error, resulting in the application being rejected. EMA instructions specify that Module 1 should only contain the designated regional subfolders (for example, m1/UK for MHRA), so the unexpected folder caused the failure. Resolving this issue was straightforward: remove the unneeded folder and submit the application again.

b) Case 2: Incorrect Sequence Assignment (FDA) – A sponsor mistakenly attempted to submit Sequence 0005 while Sequence 0004 was still under review. The FDA's ESG rejected the submission because the portal considers 0004 as still "submitted" (in the queue) and does not permit skipping or repeating sequence numbers. The vendor had to withdraw the upload, reassign the ZIP file as 0004 once it was returned, and then continue with Sequence 0006. This situation demonstrates that the portal's processing rules strictly enforce the "no gaps, no duplicates" policy.

c) Case 3: Broken Bookmark (FDA) – A 50-page human study report included bookmarks for each chapter. While compiling the eCTD, a junior publisher cut and pasted some pages, which caused errors in the PDF, but did not update the PDF bookmarks. During validation, the tool detected multiple "broken bookmark" errors. The team discovered that the bookmarks were still linked to the original page numbers. They had to correct the PDF by completely recreating the bookmarks before resubmitting.

These cases exemplify that minor technical errors can frequently lead to significant consequences. (9)

An important measure of validation effectiveness is the rejection rate. According to a 2023 conference presentation referenced in industry publications, the FDA's rejection rate for submissions in eCTD format was reported to be "less than 2%." Although this is impressively low, indicating high overall compliance, 2% of millions of submissions still represents a substantial number, potentially tens of thousands. Considering that the average cost of a new drug submission is approximately $10–30 million (including development costs), and that each additional delay incurs millions more, these rejections have significant financial implications. (10)

5.4 Tools for Publishing and Validation of eCTD

To create and validate eCTD submissions, companies utilize specialized software platforms such as LorenZ docuBridge and Extedo eCTD Manager.

eCTD Validator Tools

Choosing the appropriate eCTD validator tool is essential for effective validation prior to submission. Different validator tools offer varying features, ease of use, and specific regulatory compliance capabilities. Two leading tools in the market are Lorenz Validator and Extedo eValidator, each designed to meet different organizational needs.Lorenz Validator provides thorough checking functions. It enables users to validate their eCTD submissions against regulatory standards. Extedo eValidator offers a highly customizable validation service tailored to specific organizational workflows. (11)

Table 2. The main features of Lorenz Validator and Extedo eValidator (11)

Lorenz Validator	Extedo eValidator
➢ Support for multiple submissions across different regions. ➢ Generation of detailed reports highlighting components that failed validation ➢ Regular updates to maintain compliance with the latest eCTD specifications.	➢ Real-time validation integrated into document management processes ➢ Smooth integration with existing electronic publishing and submission systems ➢ Detailed visual representations of submission structures to facilitate issue tracking

6. Transition to eCTD version 4.0

The upcoming major update involves the worldwide shift to eCTD version 4.0. The ICH M8 (version 4.0 specification) was adopted in 2022, and the FDA started accepting version 4.0 submissions in September 2024 with a published target for mandatory use of 2029. The EMA permits optional use of version 4 for certain applications after December 2025 and mandatory use for CP in 2027, while other regulatory bodies, such as Japan, have announced mandates for 2026. In Health Canada (Canada), eCTD v4.0 transition expectations include voluntary adoption of eCTD v4 beginning in 2027 and mandatory adoption in 2029. eCTD version 4.0 is set to revolutionize electronic submissions. This latest version brings a range of new features, such as an enhanced XML schema, expanded use of controlled vocabulary, improved life cycle management, easier metadata corrections, and better document support. (1,12)

7. Conclusion

Vigilance in preparing the eCTD is not merely to meet compliance requirements but also to simplify the submission process, allowing regulatory reviewers to focus on the scientific content rather than technical corrections. Conducting the eCTD structural specification regulates the electronic submission framework to ensure seamless regulatory compliance. The region-specific customization of Module 1 demands precise adherence to local regulatory requirements. The architectures of EU Module 1 and GCC Module 1 are meticulously structured

to ensure clarity and regulatory compliance with their regional specifications. The validation process plays a quintessential role in minimizing submission errors and reducing costly delays. The ongoing transition to eCTD version 4.0 will mark a significant evolution in submission standards and will help companies achieve quicker approval timelines and faster availability of new products for patients.

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Conflict of Interest

The author declares that there is no conflict of interest regarding the publication of this article.

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