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Exploring the advancements and challenges of digitalizing eCTD using AI software tools

Senthil Prabhu R [1,*], Dhanusiya V [2], Varshini K [2], Mahalakshmi C [2] and Yogashruthi S [3]

[1] *Department of Pharmaceutics, College of Pharmacy, Madurai Medical College, Madurai-625020, Affiliated to The Tamil Nadu Dr. M.G.R. Medical University, Chennai-600032, Tamil Nadu, India.*
[2] *Department of Pharmaceutics, College of Pharmacy, Madurai Medical College, Madurai.*
[3] *K.M. College of Pharmacy, Madurai.*

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Abstract

The traditional workflows are challenged by complex lifecycle management and increasing data volumes, despite the fact that the electronic Common Technical Document (eCTD) is the global standard for regulatory submissions. Common Technical Document (CTD) is a standardized document which is developed by the International Council for Harmonisation (ICH) for providing information required in regulatory submissions for pharmaceutical registration. electronic Common Technical Document (eCTD) is electronic format of CTD utilised for providing information for regulatory authorities using ai software tools. Automation, standardization, and analytics are changing the way that submissions are prepared thanks to regulatory systems powered by artificial intelligence (AI). This evaluation examines the ways in which AI-powered solutions update eCTD procedures, concentrating on LORENZ docuBridge, Veeva Vault RIM, and EXTEDO. Structured content management, automated publishing, metadata-based dossier building, validation checks, and regulatory tracking are among the key capabilities that were examined. The contribution of AI techniques is examined in terms of quality, speed, and risk reduction. These techniques include intelligent document classification, content reuse, rule-based compliance verification, and predictive regulatory insights. In comparision with CTD shows that these platforms facilitate effective lifecycle management, boost cross-functional cooperation, and improve data integrity. This review describes AI-enabled regulatory software creates a more intelligent regulatory process that speeds up and simplifies compliant submissions, thereby helping patients.

Keywords: eCTD pipeline; LORENZ docuBridge; Veeva Vault RIM; EXTEDO; Docshifter; Real time submission; Metadata tagging; Computer keystroke.

1. Introduction

The pharmaceutical regulatory affairs specialist plays a crucial role at every stage of a product's lifecycle, from developing regulatory strategies following the discovery of a new chemical entity to managing post-marketing operations [1]. The pharmaceutical sector uses eCTD as an interface to convey regulatory information across agencies. CTD format serves as the foundation for the main content. It was created by the Multidisciplinary Group 2 Expert Working Group (ICH M2 EWG) of the International Conference on Harmonization (ICH). In essence, the electronic Common Technical Document (eCTD) will serve as a transport format that will enable electronic submissions and be transferred into an agency's review environment. In addition to facilitating the production, evaluation, life-cycle management, and archiving of the electronic submission, the eCTD will act as an interface for the transmission of regulatory information from industry to agency. The requirements for an electronic submission to be considered technically valid are outlined in the eCTD specifications. A significant advancement in the submission of data to support

* Corresponding author: Senthil Prabhu R

a new medication application is the eCTD. In the future, businesses may be able to use a single computer keystroke to submit their work to multiple regulatory bodies at once [2].

1.1. Electronic Commom Technicaln Documet (eCTD)

eCTD, or electronic CTD, is an XML file (Extensible Markup Language) that defines the submittal's structure by connecting to additional files and metadata, such as checksum information.

- There is very little flexibility in the XML standard.
- Easy for evaluation and sharing.
- A more economical and stress-free use of the company's resources.
- Self-confirmation

1.2. eCTD modules

- Details peculiar to a region
- Synopsis papers
- Details about quality
- Reports from nonclinical studies
- CSRs, or clinical study reports

1.3. eCTD submissions for various approval process

- Investigational Novel Drugs (INDs)
- New Drug Applications (NDAs)
- Abbreviated New Drug Applications that are shortened (ANDAs)
- Application for a Biological License (BLAs)
- All applications submitted after the aforementioned applications were submitted.
- Every Master File (MF) included in any of the aforementioned programs [3].

1.4. ICH guidelines for Content specification

- Technical details: Software for electronics
- The table of contents in a document or PDF
- XML Backbone for eCTD

1.5. Characteristics of eCTD

- The structure of eCTD
- Modules 1 through 5 offer granularity options.
- PDF documents linked using an XML framework.
- More accurate document search.
- The transparency of the entire submission.
- Review and navigation are easy [4].

2. AI tools for modernizing eCTD

Artificial intelligence (AI) has emerged as a transformative force in the pharmaceutical industry, addressing the long-standing challenges of high costs, lengthy timelines and high attrition rates in drug development [5]. The key challenges and advantages of incorporating these cutting-edge systems into regulatory procedures are examined by the current AI-based tools that are actively used by regulatory professionals across the world [6], such as

- DocShifter [7]
- Veeva Vault [8]
- RiskWatch [9]
- Freyr SubmitPro [10]
- Litera Microsystems [11]
- cortical.io [12]

Table 1 AI tools for modernizing eCTD

S.No	Pipeline	AI implementation	AI Tools	Outcomes
1	Collection of documents	capturing of AI-assisted data NLP-based extraction ML validation	Veeva Vault EDC Medidata Rave Oracle Clinical One	Collection of clinical, nonclinical, and CMC data (error free)
2	Data Integration	NLP semantic mapping ML-based data harmonization	NuMantra AI Dip-AI	Conversion of Heterogeneous data into standard regulatory-ready formats
3	Content Authoring	Generative AI Natural Language Generation (NLG)	Yseop Copilot Narrativa Navigator GPT-based regulatory copilots	Drafting of Module 2 summaries fastly
4	Content Reuse and Knowledge Management	AI-driven semantic search Knowledge graphs	Veeva Vault RIM Docuvera	Reuse of approved content across submissions Reduced duplication and rework
5	Compilation of eCTD and Publishing	RPA and AI for XML generation Metadata tagging	Extedo eCTD manager Freyr freya submit	Creation of Automated folder structure Correction of metadata population,
6	Validation and Quality Check	AI-based rule engines	Lorenz eValidator NuMantra Validation Extedo Validator	Earlier detection of structural errors and missing files
7	Submission Lifecycle Management	AI analytics Dashboards Predictive tracking	Veeva Vault RIM Freyr SPLICE NuMantra Submission Tracker	Tracking of Real-time submission
8	Compliance and Regulatory Intelligence	AI-driven Regulatory Intelligence Engines for automatic policy scanning and summarisation	IQVIA Regulatory Intelligence AI	Increases awareness of real-time global updates and ensures faster compliance

NLP-Natural Language Processing, ML-Machine Learning, EDC-Electronic Data Capture, RIM-Regulatory Information Management, RPA-Robotic Process Automation, SpLiCE-Sparse Linear Concept Embeddings. IQVIA- I=IMS health (Intercontinental Marketing Statistics) Q=Quintiles, and VIA signifies a path forward, specifically in using Human Data Science.

3. AI-tools for regulatory information management (rim) system

RIM systems are integrated, enterprise-level platforms that manage regulatory data across the entire product lifecycle. They centralize global registration information, submission tracking, approvals, commitments, correspondence, and country-specific regulatory intelligence, serving as a central control hub for regulatory affairs [13]. Commonly used cloud-based RIM solutions include

- Veeva Vault RIM
- ArisGlobal LifeSphere RIM
- MasterControl Regulatory Excellence
- Ennov Regulatory Suite
- IQVIA RIM Smart, Amplexor (Acolad)

- Rimsys [13]

3.1. eCTD publishing and submission tools

These tools are purpose-built systems for compiling, validating, and publishing electronic regulatory dossiers. Common examples include

- Lorenz DocuBridge
- EXTEDO eCTD manager
- eCTD OneClick, and PubliSheCTD
- RIM or EDMS platforms.

Core strength of above softwares lies in automated compliance and validation engines that ensure correct structure, formats, links, and metadata, thereby minimizing technical errors and reducing the risk of regulatory rejection [15].Among all these types, currently used tools are LORENZ docuBridge, Veeva Vault RIM, EXTEDO eCTDmanager

3.1.1. LORENZ docuBridge

Courtesy: Vector life science GmbH.

Figure 1 LORENZ docuBridge

Lorenz docuBridge is most widely used platforms for eCTD publishing and is recognized for its stable publishing engine and fine-level control throughout the submission lifecycle [15]. The system automates essential publishing functions, including XML backbone generation, bookmark creation, and execution of lifecycle operations such as new, replace, and delete. Its collaborative project structure allows multiple users to work in parallel without document conflicts, while also supporting both eCTD and legacy NeeS submissions within a single environment [16][17]. To meet the needs of organizations of different sizes, Lorenz provides scalable docuBridge editions (ONE, TWO, and FIVE), with licensing models tailored to submission volume, regional scope, and number of user [16]. Industry use cases, including Orchid India, indicate improved preparedness for eCTD mandates and faster, error-free regulatory submissions using docuBridge [18].

3.2. Key Features

3.2.1. Automated Compliance Updates

docuBridge automatically incorporates regulatory specification updates without software reinstallation, ensuring immediate alignment with new eCTD and eCTD v4 requirements.

3.2.2. Multi-format Publishing

A single docuBridge sequence can be published in multiple formats, including eCTD, NeeS, HTML, PDF, and paper, without recreating source content [19].

3.2.3. Lifecycle Transparency

The system clearly displays document lifecycle actions (new, replace, delete) while consistently preserving leaf titles and anchors during compilation.

3.2.4. Powerful Validation (eValidator)

The integrated eValidator provides extensive regional and technical rule checks, enabling early identification of issues at draft or final stages.

3.2.5. Deployment Options

docuBridge supports both on-premises installation and Lorenz-managed cloud hosting, accommodating varied organizational and data residency needs.

3.2.6. Audit Trail and Security

All user actions are logged to support Part 11 compliance, with controlled multi-user access to prevent version conflicts.

3.3. Veeva vault rim

Courtesy: Veeva systems Inc

Figure 2 Veeva vault RIM system

Veeva Vault Submissions is a component of Veeva's cloud-based life sciences platform, which also includes modules for content management, clinical, quality, and regulatory functions. It delivers an integrated, end-to-end solution for managing the regulatory submission lifecycle and is closely connected with Vault RIM, enabling shared metadata and controlled vocabularies across planning, authoring, and publishing processes [20]. This unified architecture allows content stored in Vault to be published directly through Vault Submissions without separate file transfers.

Key Features

- Unified Metadata and Content

Vault Submissions connects submission planning and content management, enabling consistent metadata use (such as leaf titles and regional identifiers) and automatic population of eCTD XML fields, reducing manual entry and improving traceability [21].

- Cloud Scalability

As a cloud-based SaaS platform, Vault Submissions supports elastic scaling, allowing multiple regulatory sequences to be built and validated in parallel without local infrastructure limits [21].

- Built-in Workflows and Dashboards

The system provides predefined workflows for submission preparation, review, and approval, along with real-time dashboards to monitor submission status across global regulatory authorities.

- Automation and Active Pharmaceutical Ingredients (API)

Vault Submissions offers APIs and configurable workflows to automate routine submission tasks, notifications, and data exchange with analytics or reporting systems.

3.3.1. EXTEDO eCTDmanager

Courtesy: EXTEDO GmbH.

Figure 3 EXTEDO eCTDmanager

EXTEDO is a recognized provider of regulatory submission solutions, offering the on-premises eCTDmanager typically used with its validation tools, and the cloud-based EXTEDOpulse, which extends into a broader RIM platform. The company is known for strong regional coverage across North America, Europe, and Asia, with preconfigured Module 1 templates that simplify setup and support faster expansion into new regulatory markets.

Key Features

- Region-Aware Templates

EXTEDO offers preconfigured Module 1 templates for the US, EU, and Japan, enabling faster system setup and supporting expansion into additional regulatory regions [22].

- Validation Integration

eCTDmanager is tightly integrated with EXTEDO's eValidator, which applies current rulesets and produces clear error logs linked to specific file paths for efficient issue resolution [22].

- Versatile Publishing

The platform supports both eCTD and NeeS submissions, while the cloud-based EXTEDOpulse extends publishing to additional regional and legacy formats.

- User Enablement

EXTEDO places strong emphasis on training and professional services, helping teams—especially first-time eCTD users—adopt best practices more quickly [23].

Key obstacles

- There are potential uses of AI to ease regulatory affairs but various challenges exist.
- It requires high quality and consistent data that is often limited or absent in regulatory systems.
- AI models may hold biases and lack transparency, typically operating as "black boxes" whose inner workings are unknown.
- It raises ethical issues such as data privacy, security, and responsibility for errors.
- To achieve this benefit, we need careful planning, regulation and governance [24][25].

3.4. Future outlook

Future eCTD submissions are expected to be automated by AI tools creating, validating and managing documents to meet compliance requirements. Automated smart tagging, real-time checks and alerts will reduce manual work and improve quality, review speed, and audit coverage. Advanced AI will monitor rules over time, provide easy access to

law, and will be linked to quality assurance systems. Key sectors like health care and finance will be transformed by reasoning, governance, and human support.

4. Conclusion

This review concluded that AI tools aid in the better way of modernizing eCTD by reducing manual errors and improving compliance and efficiency. AI tools standardize the data structures, track the real time data and integrate with ICH guidelines. The accuracy of document compilation, validation, lifecycle management and submission is increasing by using techniques like machine learning, natural language processing and automations. Despite many limitations, AI platforms always enhancing the speed, transparency and decision making of submissions of eCTD. In conclusion, AI speeds up the global regulatory approval processes.

Compliance with ethical standards

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The authors have no conflicts of interest regarding this investigation.

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