



AI In Ectd Submission And Review: Accelerated Digital Drug Approval

¹Soham S. Bhatt, ²Dr. Rajesh Parmar

¹M. Pharm Research Scholar

²Professor

^{1,2}Department of Regulatory Affairs, Anand Pharmacy College, Anand, Gujarat, India

Abstract

The drug approval process requires submission of large volumes of regulatory documentation in the electronic Common Technical Document (eCTD) format. Preparation, validation, and regulatory review of these dossiers are traditionally time-consuming and prone to human error. Artificial Intelligence (AI) is emerging as a transformative technology that can accelerate both eCTD submission and regulatory review processes. AI tools can automate document generation, perform real-time compliance checks, validate data integrity, and assist regulatory authorities in faster evaluation of submissions. The integration of AI technologies in regulatory systems improves accuracy, reduces submission deficiencies, and enhances the efficiency of digital drug approval pathways. This review highlights the application of AI in eCTD preparation, automated validation, and AI-assisted regulatory review, demonstrating how digital innovation can significantly accelerate global drug approval processes.

Keywords

Artificial Intelligence, eCTD, Regulatory Affairs, Digital Drug Approval, Machine Learning, Regulatory Review

1. Introduction

The pharmaceutical industry relies on regulatory submissions to obtain marketing authorization for new drugs. The electronic Common Technical Document (eCTD) has become the global standard for submitting regulatory dossiers to health authorities. An eCTD submission contains detailed information about the quality, safety, and efficacy of a drug product organized in a structured electronic format.

However, preparing and reviewing eCTD dossiers is a complex process. Regulatory documents can contain thousands of pages, and ensuring compliance with technical requirements is challenging. Manual processes often lead to delays, inconsistencies, and submission deficiencies.

Artificial Intelligence (AI) and Machine Learning (ML) are increasingly being integrated into regulatory workflows to improve efficiency. AI systems can automate document creation, check regulatory compliance, and assist reviewers in analyzing large datasets. These technologies are helping regulatory

authorities and pharmaceutical companies accelerate the drug approval process while maintaining high regulatory standards.

2. Overview of eCTD Submission

The eCTD format organizes regulatory information into five modules:

Module 1: Administrative and regional information

Module 2: Summaries and overviews

Module 3: Quality (CMC) information

Module 4: Non-clinical study reports

Module 5: Clinical study reports

Regulatory agencies such as the US FDA, EMA, and other global authorities require eCTD submissions for marketing authorization applications. Preparing these modules requires significant coordination between regulatory, clinical, and quality teams.

AI technologies can simplify these processes by automating data organization, document validation, and lifecycle management.

3. Role of AI in eCTD Submission

Artificial Intelligence can significantly improve the preparation and management of eCTD dossiers. Key applications include:

3.1 Automated Document Generation

AI-based writing tools can assist regulatory professionals in drafting summaries, reports, and structured documents. These tools analyze scientific data and generate regulatory-compliant content.

3.2 Intelligent Data Organization

AI systems can automatically classify documents into the correct eCTD modules and sections. This reduces manual effort and ensures proper document placement.

3.3 Automated Validation and Compliance Checks

AI-driven validation tools can check submission packages for technical errors, missing files, incorrect hyperlinks, and formatting issues before submission.

3.4 Lifecycle Management

AI platforms can manage submission sequences, track document updates, and maintain version control throughout the product lifecycle.

4. AI in Regulatory Review

AI is not only useful for pharmaceutical companies but also for regulatory authorities during dossier evaluation.

4.1 Data Analysis

AI algorithms can analyze large datasets from clinical trials and identify important trends or safety signals.

4.2 Document Screening

Natural Language Processing (NLP) tools can quickly scan regulatory documents and highlight critical information for reviewers.

4.3 Risk Assessment

Machine learning models can predict potential regulatory risks or compliance issues within submissions.

4.4 Faster Decision Making

By automating routine analysis tasks, AI allows regulatory reviewers to focus on scientific evaluation, which speeds up the drug approval process.

5. Benefits of AI-Driven eCTD Systems

The integration of AI into regulatory submissions provides several advantages:

Faster preparation and submission of regulatory dossiers

Improved document accuracy and consistency

Reduction in submission errors and deficiencies

Efficient regulatory review process

Better data management and traceability

These benefits contribute to faster approval timelines and improved access to medicines for patients.

6. Challenges and Limitations

Despite its advantages, AI implementation in regulatory processes faces certain challenges:

Data privacy and security concerns

Need for validation of AI algorithms

Regulatory acceptance of AI-generated outputs

Integration with existing regulatory IT systems

Requirement for skilled professionals to manage AI tools

Addressing these challenges will be essential for successful adoption of AI in regulatory affairs.

7. Future Perspectives

The future of regulatory submissions is expected to become increasingly digital and automated. With the development of advanced AI systems, eCTD platforms may evolve into fully intelligent regulatory ecosystems capable of real-time compliance monitoring and predictive regulatory analytics.

Integration with emerging technologies such as cloud computing, big data analytics, and blockchain may further enhance transparency and efficiency in the drug approval process.

8. Conclusion

Artificial Intelligence is transforming the way regulatory submissions are prepared and reviewed. AI-enabled systems can automate document creation, validate eCTD submissions, and support regulatory authorities in efficient dossier evaluation. These advancements reduce errors, accelerate review timelines,

and improve overall regulatory efficiency. As digital technologies continue to evolve, AI will play a crucial role in modernizing regulatory processes and enabling faster global drug approvals.

9. Reference

1. International Council for Harmonisation.

ICH M4: The Common Technical Document for the Registration of Pharmaceuticals for Human Use. Geneva: ICH; 2004.

Available from: <https://www.ich.org/page/ctd>

2. U.S. Food and Drug Administration.

Providing Regulatory Submissions in Electronic Format — eCTD Specifications: Guidance for Industry. Silver Spring (MD): FDA; 2022.

Available from: <https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/electronic-common-technical-document-ectd>

3. European Medicines Agency.

eCTD Electronic Submission Guidelines. Amsterdam: EMA; 2021.

Available from: <https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/electronic-submissions>

4. International Council for Harmonisation.

ICH M8: Electronic Common Technical Document (eCTD) Version 4.0. Geneva: ICH; 2015.

Available from: <https://www.ich.org/page/ich-electronic-common-technical-document-ectd-v40>

5. Eric J. Topol.

High-performance medicine: the convergence of human and artificial intelligence. *Nature Medicine*. 2019;25(1):44-56.

Available from: <https://doi.org/10.1038/s41591-018-0300-7>

6. Jiang F, Jiang Y, Zhi H, Dong Y, Li H, Ma S, et al.

Artificial intelligence in healthcare: past, present and future. *Stroke and Vascular Neurology*. 2017;2(4):230-243.

Available from: <https://doi.org/10.1136/svn-2017-000101>

7. Thomas H. Davenport, Rajeev Kalakota.

The potential for artificial intelligence in healthcare. *Future Healthcare Journal*. 2019;6(2):94-98.

Available from: <https://doi.org/10.7861/futurehosp.6-2-94>

8. Kyunghyun H. Yu, Andrew L. Beam, Isaac S. Kohane.

Artificial intelligence in healthcare. *Nature Biomedical Engineering*. 2018;2:719-731.

Available from: <https://doi.org/10.1038/s41551-018-0305-z>

9. Francesco Pesapane, Marta Codari, Francesco Sardanelli.

Artificial intelligence in medical imaging: threat or opportunity? European Radiology Experimental. 2018;2(1):35.

Available from: <https://doi.org/10.1186/s41747-018-0061-6>

10. U.S. Food and Drug Administration.

Artificial Intelligence and Machine Learning in Software as a Medical Device. Discussion Paper. FDA; 2019.

Available from: <https://www.fda.gov/medical-devices/software-medical-device-samd>

11. European Medicines Agency.

Regulatory Science to 2025 Strategic Reflection. EMA; 2020.

Available from: <https://www.ema.europa.eu/en/about-us/how-we-work/regulatory-science-2025>

12. Deloitte.

Artificial Intelligence in Drug Development and Regulatory Affairs. Deloitte Life Sciences Report; 2020.

Available from: <https://www2.deloitte.com>

13. IQVIA Institute for Human Data Science.

Artificial Intelligence in Life Sciences: Applications and Opportunities. IQVIA Report; 2021.

Available from: <https://www.iqvia.com/insights>

14. Organisation for Economic Co-operation and Development.

Artificial Intelligence in Health Care: Benefits and Challenges. OECD Health Working Papers; 2020.

Available from: <https://www.oecd.org/health>

15. Kuen-Kwan Mak, Manoj R. Pichika.

Artificial intelligence in drug development: present status and future prospects. Drug Discovery Today. 2019;24(3):773-780.

Available from: <https://doi.org/10.1016/j.drudis.2018.11.014>