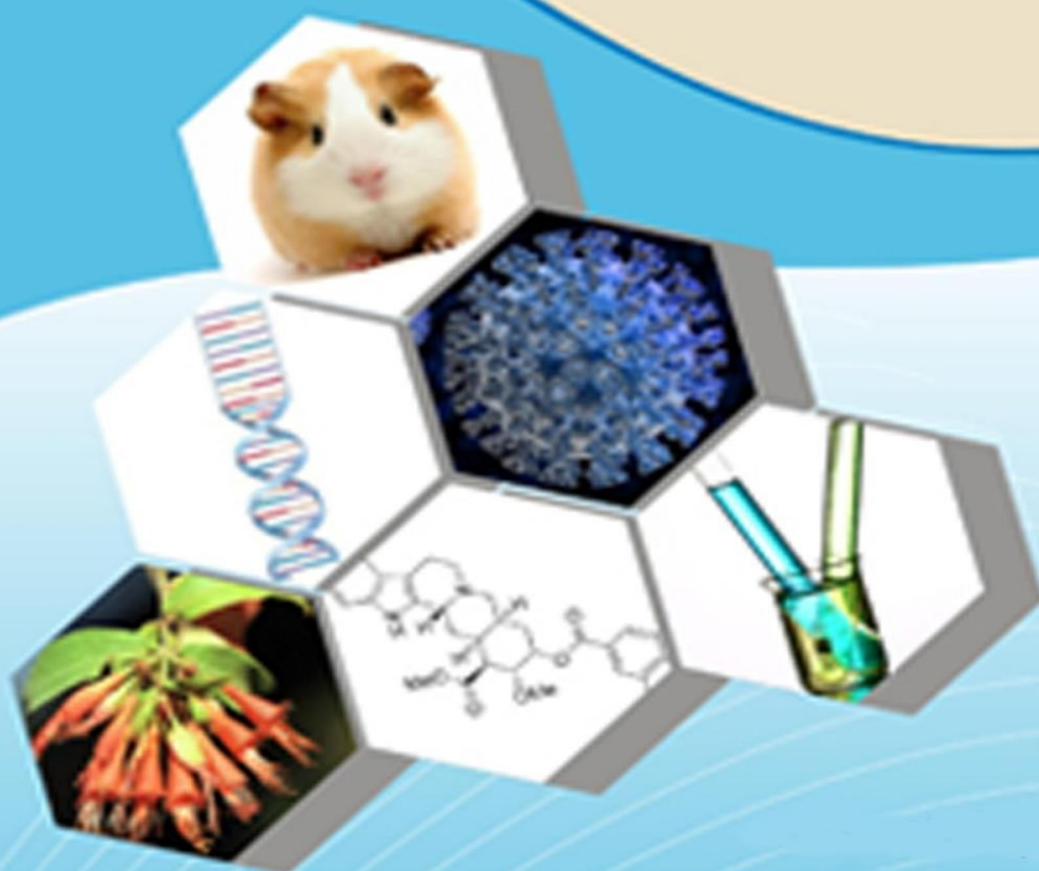




ISSN : 2347-2251
**Indo-American Journal of
Pharma and Bio Sciences**



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AI and Automation in Regulatory Operations: The Future of eCTD Submissions

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Abstract: *The focus of this study is the effect that AI and automation will have on the efficiency, accuracy and compliance with the process using the Electronic Common Technical Document (eCTD) Submission Process as the case study. Construction of the submission workflow was made easier utilising the AI-driven tools machine learning (ML), robotic process automation (RPA) and predictive analytics to make them streamline, decrease errors and help the regulatory decision-making. The case studies of case studies, such as using AI with optimisation of compliance and uploading product information for Roche, Pfizer, and Novartis, have been demonstrated. One of the well-known challenges of data security, AI can nevertheless significantly increase regulatory efficiency. More research should be done towards more automated submission of regulatory data without losing interactions on the seamless global level and with integration problems in existing systems.*

Keywords: *AI, Automation, RPA, AI-driven tools, eCTD*

I. INTRODUCTION

A. Background to the Study

AI and automation are the most useful advanced technologies, especially in the regulatory operations which enhance the submission process of “electronic Common Technical Document (eCTD)” submission. The eCTD format needs a proper accuracy

where AI and automation come in and help to increase the accuracy, streamline multiple processes, and also help in the data-driven decision-making process [1]. AI and automation streamline the eCTD submission through the help of different factors that revolutionised the whole process of eCTD submission such as automating routine tasks, enhancing accuracy, faster submission, and increases efficiency of the submission processes.

B. Overview

Particularly when it comes to automatic and AI-assisted, regulatory operationalised revolutionization during eCTD submission. The document that is being processed via the word classification, tagging and digital marketing of metadata and compliance check uses AI to process it. Using the RPA also means that the compiling and formatting of the document will be sped up. Workflow management enabled by AI is collaborative, respects the timeline and much more [2]. Therefore, what follows is cloud integration, Blockchain for protecting submissions, and AI based decision making. The innovations become successful, especially in getting errors down and getting back on track with compliance and efficiency to accelerate and have submissions straight away. The future of eCTD is intelligence data and data-driven intelligence of automation.

C. Problem Statement

The “electronic Common Technical Document (eCTD)” submissions are



becoming more complex with more data loads, and the submissions process has never been more difficult for a company to manage. Human intervention is the main route for the traditional methods, and they are prone to regulatory rejections with delay. This is because data validation, document, and moving up to global guidelines are costly and laborious for submissions [3]. The regulatory processes do not need a very high level of accuracy and efficiency, and when they do need approval quickly, one cannot depend on conventional methods. AI and automation to be able to know things like what should be included in the submission workflow and what should be done for compliance.

D. Objectives

The study aims to analyse the role of AI and automation in regulatory operations which enhance the submission process of eCTD. The primary objectives for the study are: 1. To analyze the process of improving the eCTD submission efficiency through the help of AI and automation that helps in the processing of documents and enhances the submission process by aligning with regulatory compliances. 2. To evaluate enhancement of the compliance and data accuracy by leveraging different AI-driven tools, such as predictive tools to decrease the processing and errors and improve consistency in submission. 3. To ensure collaboration and workflow with the help of real-time automation and regulatory compliance

E. Scope and Significance

This study is within the scope of change that is specific to AI and automation in eCTD submissions of Document Processing, Compliance Validation, Workflow Optimization, and Regulatory Intelligence. The topic is about how automation helps to increase the efficiency, accuracy and opportunities for decision making in

regulatory operations [4]. It is important, and there is no more need for manual errors or speed approvals. AI and automation are needed in the future regulatory affairs where regulatory affairs wings will stretch to include eCTD submissions and will have to incorporate AI-driven solutions to make submission simpler and cheaper, facilitating a higher success rate on submissions.

II. LITERATURE REVIEW

A. AI and Automation in eCTD Efficiency

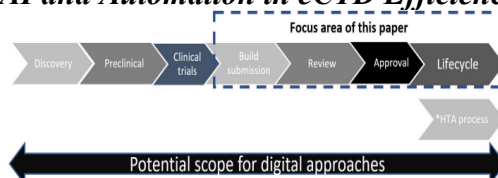


Figure 1: Potential scope of advanced approach

[5]

The study considers how digital innovation has paved the way for new and improved regulatory submission, review, and approval processes, as well as a new and improved regulatory ecosystem through which these changes occur. On that note, the article explores how AI and automation can play an increasing share of the same by helping to eCTD submissions of manual inefficiencies and some level of regulatory evolution. It also includes the use of AI-driven tools to quicken the processes, and document classification, validation and risk assessment are all handled [5]. The authors have felt the need to make digital demands. Medicinal product regulation can add an application of AI-driven automation, which can make the approval of medicinal products accurate, efficient, and agile. Standardisation, the passage of a regulation, and security in data make it an obstacle in the process of innovating and developing despite having stakeholders.

The eCTD submission in the pharmaceutical industry is a change in role at the level of



regulatory affairs that takes away all the challenge to expose the problem caused by manual process, inconsistent data, due to global regulation changes or longer approvals by global regulators, that's the document, data validation, and AI based regulatory intelligence worldwide. In establishing the error control on the AI process and to reduce the time of a submission setup in pharmaceutical companies [6]. It is because the AI-powered tools propose more than what they say, as the regulators approve the planes of the tools and doing so should be quick. Whether it comes from the background of investigation or if it is a future regulatory affair, this demands digital transformation and AI as the key for compliance and operational efficiency.

B. Enhancing Data Accuracy and Compliance

AI plays an important role in eCTD submission by providing quicker response and also fostering streamlined submission processes, which increases efficiency. The AI-powered validation tools can analyse FHIR-based submissions for adherence to regulatory standards by flagging inconsistencies before they reach regulatory agencies such as the FDA and others [7]. This also ensures that submissions comply with eCTD specifications, which decreases rejection rates and review time. This also saves time, which helps to increase the submission processes regarding eCTD format to meet the standards. The regulatory documents often require consistent formatting and structure content as well.

“Artificial Intelligence” is transforming “regulatory compliance” by choosing the correct submission tool of AI-powered eCTD, which is important. On the other hand, this also ensures adherence to the eCTD format, which helps to decrease manual intervention and formatting errors. This also

ensures real-time compliance validation, which flags errors before submission by preventing costly delays [8]. This also helps to decrease the compliance error by 30% which increases the efficiency as well. API integration is also the most important aspect that can be synced with the existing document management system. For example, Veeva Vault and OpenText facilitate efficient data exchange.

C. Optimising Workflow and Collaboration

Workflow and collaboration are crucial aspects which enhance the submission process of eCTD. This ensures seamless teamwork across multiple departments that ensure better version control and submission tracking as well. Selecting the right eCTD tools, which are AI-powered, helps to enhance the efficiency of submission and also helps in teamwork to sustain the submission process and decrease manual errors [9]. This can decrease the risks of compliance and accelerate market approvals. Investing in automation not only enhances the regulatory submission but also decreases the “operational burden” by allowing teams to focus on high-value activities.

Real-time work is real-time working by real people and real-time communications and real-time streamlining and real-time automating of real-time management of tasks. eCTD submissions with the aid of AI-based tools are more accurate than the ones before, putting in less effort and being more efficient. It shortens delays, redundancies and manual errors, thereby shortening regulatory submission timelines [10]. Cloud-hosted collaboration platforms make the possibility of enabling collusion at any point in time, irrespective of the geolocations, to enable the remote working by the teams to other teams due to the changing regulatory requirements. The organization is more productive, creates better and faster regulatory operation, and



more accuracy, and more agility to constantly changing values in the industry, therefore.

III. METHODOLOGY

A. Research Design

The data collected is used by the research design framework for this study to address and decide the path of the investigation. An **explanatory research approach** is used to examine the study. This approach helps to find and analyse the study, such as AI and automation in regulatory operation, which enhances the efficiency of eCTD submission. This research approach analyses the topic through the help of limited information which explains the topic and helpful for the understanding.

B. Data Collection and Analysis

“Secondary qualitative and quantitative” data collection is the methodology employed in this investigation. Numerous sources, such as industry reports, journals, papers, websites, and many more, are examined by the qualitative data technique. On the other hand, the quantitative data approach looks at a variety of graphs and charts that are used to analyse the topic related to AI and automation in regulatory operation that enhances the submission process of eCTD. All the information that is collected is from accurate and valid source that gives correct information.

C. Case Studies/Examples

Case Study 1: Roche: AI-Powered Regulatory Submissions

Roshe Holding AG, which is commonly known as Roche, is a Swiss multinational holding healthcare company that operates globally in two divisions, pharmaceuticals and Diagnostics. The integration of AI-driven automation and the regulatory submission process at Roche is now integrated, and eCTD submission timelines are much shorter compared to others, which has improved Roche approvals. The

company uses “machine learning (ML)” and “natural language processing (NLP)” to automate document classification, metadata tagging and metadata validation to take it out of man’s hands and reduce manpower as well as address submission errors [11]. Real-time tracking and regulatory compliance with agencies like the FDA or EMA are taken care of by the AI-powered tools.

Case Study 2: Pfizer: Automating Compliance and Submission Tracking

Pfizer is an American multinational pharmaceutical and biotechnology corporation that operates in different parts of the globe. By ensuring the streamlined submission process, Pfizer integrated multiple AI-powered tools and “robotic process automation (RPA)” to optimise their eCTD submission and also enhance their efficiency that helps the company to ensure their regulatory compliances such as FDA. The integration of RPA helps to reduce human errors and also uses structure inputs and logic which enhances the submission processes for the company. This can reduce submission delays and enhance submission speed by using data-driven decision-making processes. RPA and AI-powered advanced technology enhance the document formatting and also increase the submission tracking system in real-time [12]. This increases the workflow collaboration across different teams around the globe, which enhances the efficiency of the operational work such as eCTD submission processes and also regulates with the multiple regulatory compliances.

Case Study 3: Novartis: AI for Predictive Regulatory Intelligence

Upon regulatory submissions and eCTD processes, Novartis uses AI-based predictive analytics to streamline the process. AI can base its predictions on both historical regulatory decisions, approval patterns and



updated guidelines and adjust documents to satisfy agency expectations. Instead, it decreases the risks of delay, rejection and compliance error at the front end rather than at the back end. About regulatory strategy, the first goal involves using AI to inform teams on how to alter submission content and adjust submission before filing [13]. Moreover, data validation and tracking of documentation are combined through automation. Novartis has integrated predictive technologies such as AI in a capacity where intelligent non-human-based technology is being used to improve compliance, decision-making, and approval rates of the pharmaceutical industry.

IV. RESULTS

A. Data presentation

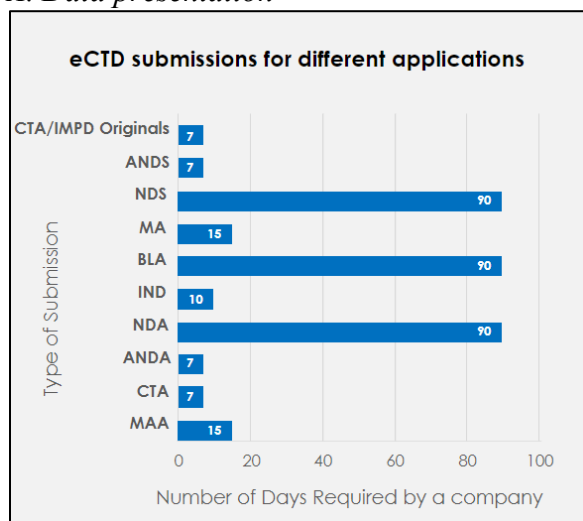


Figure 2: Regulatory Publishing & Submission with Automation
[14]

NDA timelines dropping from 90 (the usual time required to manually create) down to 30 (the requisite time to automate) is a clear affirmation of how drastically regulatory submissions can be automated. Automation's ability to increase 57% efficiency gain shows how automation impacts the work of compliance. The automations from Freyr's AI-driven publishing toolkit via RPA and

NLP result in faster, error free submissions to global regulatory authorities, towards the company's mission to bring about scalable, intelligent, cloud based regulatory operations [14].

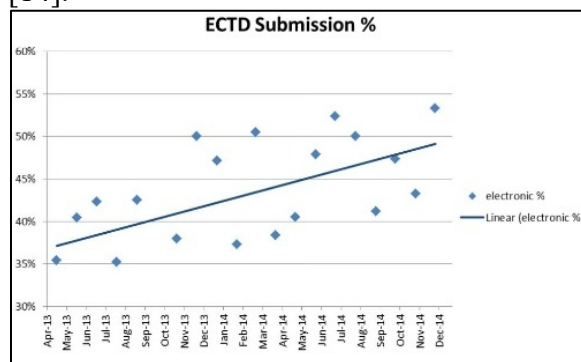


Figure 3: Increase of eCTD submissions of DMF
[15]

Increasing adoption in the industry driven by regulatory preference and efficiency benefits means that the upward trend in eCTD submissions is indeed characterized as such. This shift has been reinforced by the FDA's mandate that is meant to standardize and simplify application reviews. This is critically important that the eCTD completion rate in the first cycle is higher than the paper and thus supports the incentive to transition and go modern in the regulatory workflows lead to faster approvals [15].

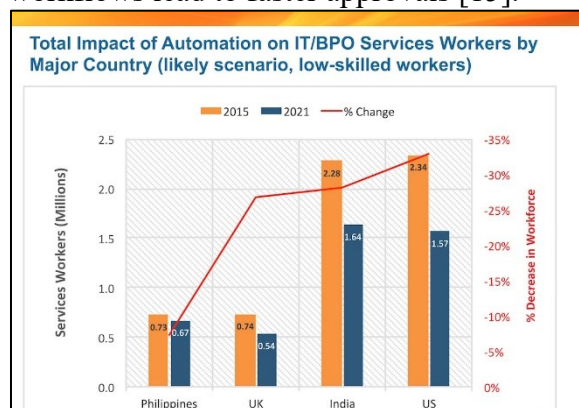


Figure 4: Total Impact of Automation on IT/BPO Services Workers
[16]



Working IT indicates by 2021, as low skilled US IT/BPO workforce is forecast to plunge from 2.34 million to 1.57 million (-33%), with automation of back office functions the engine to it. There is also a 27% decrease from 0.74 million to 0.54 million in the UK. In contrast, the Philippines experiences only an 8% drop, from 0.73 to 0.67 million, due to voice-centric services [16].

B. Findings

Consistent with the environmental benefits, automation greatly speeds up submission timelines, eliminating much of the manual work and accurately improving compliance with the help of AI-based tools such as Freyr's RPA and NLP systems [14]. This transformation of regulatory bodies' preference towards digital formats for eCTD submissions is rooted in their belief in the advantages of digital filing over physically formatted documents based on increased digitization first cycle approval rates [15]. Automation, on the other hand, has a wider reach, as disclosed previously in the decreasing nomenclature in the IT/BPO sectors and the reduction in workforce through IT/BPO services, mostly on low skilled jobs in developed regions, and on services based of voice in regions like the Philippines, which have a somewhat more robust appeal [16].

C. Case Study Outcomes

Case Study	Key Findings	Relevance
Case Study 1: Roche: AI-Powered Regulatory Submissions	Uses AI for automation. Reducing errors and manpower [11].	Improves speed, accuracy, and compliance.
Case Study 2: Pfizer:	RPA and AI streamline	Enhances efficiency

Automating Compliance and Submission Tracking	tracking and minimise errors [12].	and accelerates approvals.
Case Study 3: Novartis: AI for Predictive Regulatory Intelligence	AI predicts regulatory challenges Ensuring better data validation and compliance [13].	Optimizes decision-making and approval rates.

Table 1: Case Study Outcomes

(Source: Self-developed)

Table 1 highlights the outcomes of case studies that are used in the study to make it more understandable. The key findings from the Roche case study are that the company uses AI for automation that enhances its operations. On the other hand, Pfizer implemented RPA to improve their efficiency and Novartis implemented AI to predict challenges in regulatory.

D. Comparative Analysis

Auth ors	Focus Area	Key Finding s	Limitation s
[5]	AI in eCTD efficiency	AI improve s submission speed, accuracy, and compliance [5].	Standardisa tion and data security issues.



[6]	AI error control	AI reduces manual errors and submission time.	Regulatory acceptance challenges.
[7]	Data accuracy & compliance	AI flags submission errors, reducing rejections [7].	Integration issues with existing systems.
[8]	Compliance & document management	AI reduces errors by 30%, improving efficiency.	High costs & structured data dependency [8].
[9]	Submission tracking & teamwork	AI enhances workflow, version control, and approvals.	Adoption barriers & training needs.
[10]	Remote teamwork & real-time tracking	AI improves efficiency, accuracy	Data security risks & regulatory delays.

		y, and agility [10].	
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Table 2: Comparative Analysis

(Source: Self-developed)

Table 2 highlights the comparative analysis of different authors that can evaluate their views through the help of their study. Different authors focused on different factors, such as how AI can increase the efficiency of eCTD submission and many more.

V. DISCUSSION

A. Interpretation of Results

AI and automation are the most important aspects of future eCTD submission processes. AI helps to reduce human errors and also analyse the challenges related to the eCTD submission processes [5]. AI and automation enhance the eCTD format, which helps in different forms such as increasing efficiency, reducing submission delays, and streamlining the processes of submission. This can also ensure that regulatory agencies, such as the FDA, maintain regulatory compliance.

Automation is rewiring both the regulatory and workforce corotation of the industry. Intelligent automation makes submissions and complying with compliance goals quicker and more accurate in regulatory publishing [14]. At the same time, the IT/BPO has considerable workforces falling — particularly in countries where high bulk is of automated back office roles. The U.S. and the U.K. are the most affected, and the Philippines is resilient because it is focus on voice stress services [16]. Together, these findings provide a picture of automation's dual capacity to generate efficiency while simultaneously displacing low skilled labor in all its industries.



B. Practical Implications

AI and automation in regulatory operations enhanced the submission processes of eCTD, which revolutionised the future format. AI and automation can reduce the delays in submission, decrease human errors, and respond quickly to ensure a seamless process that increases the efficiency of submission processes. Different AI-powered tools and RPA can increase the efficiency of organisations such as Pfizer by which they can ensure the regulatory compliances smoothly and efficiently [12].

C. Challenges and Limitations

However, there are challenges involved with secondary data collection, such as reliability, relevance and accuracy of the data because of outdated or biased data. Data quality and scope have limited control over research validity [17]. Furthermore, depending on current study objectives, the use of such data is limited by incompatibility with exploration, incomplete datasets and copyright restrictions.

D. Recommendations

To give secondary data collection a boost, use more than one source of data to ensure correctness and gather data that is relevant to their objectives. The study should check the credibility of the data. However, the datasets can be refined and validated using AI-based analytics [18]. Additionally, copyright needs to be addressed and make sure that the data is compatible with the research framework for reliability improvement to reduce biases and the limitation on the decision when dealing with data.

VI. CONCLUSION AND FUTURE WORK

In conclusion, AI and automation are playing a crucial role in enhancing the submission processes of the eCTD format. The eCTD format can be improved through the help of AI and automation implementation. This can

ensure a seamless submission process and also ensure regulatory compliance, which enhances efficiency. On the other hand, different case study examples can help to understand the process of AI, and automation can improve their eCTD submission processes and also ensure regulatory compliance.

Future work will require more relevant data related to the study. The lack of accurate secondary data forces this study to include more specific data which can be incurred for the future study that will enhance the credibility of future study by linking with objectives.

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