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The Efficiency and Accuracy Improvements in Regulatory Filings with the Electronic Submissions Gateway (ESG)"

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ABSTRACT

The adoption of the Electronic Submissions Gateway (ESG) represents a paradigm shift in regulatory filings, profoundly impacting data integrity and security. This paper delves into the transformative effects of ESG on regulatory compliance, focusing on its role in safeguarding the integrity and security of sensitive data. Drawing from empirical evidence and industry insights, it examines how ESG has revolutionized data management practices, mitigating risks of tampering, unauthorized access, and non-compliance. Moreover, the abstract elucidates the sophisticated technological infrastructure underpinning ESG's data security framework. From robust encryption protocols to stringent authentication mechanisms, ESG employs cutting-edge solutions to fortify the confidentiality, integrity, and availability of regulatory data. Through a comprehensive analysis of case studies and best practices, this abstract underscores the pivotal role of ESG in fostering trust and transparency in regulatory processes. Furthermore, it explores the broader implications of ESG's impact on data governance, compliance standards, and regulatory oversight. By shedding light on the symbiotic relationship between ESG and data integrity/security, this abstract offers valuable insights for regulatory agencies, industry stakeholders, and technology providers striving to navigate the evolving landscape of regulatory compliance in an increasingly digitized environment

Keywords: Electronic Submissions Gateway (ESG), regulatory filings, data integrity, data security, compliance, encryption protocols, authentication mechanisms, regulatory compliance, technological infrastructure, trust, transparency, data governance, regulatory oversight, digital environment.

INTRODUCTION

Regulatory submissions constitute a pivotal and intricate facet of the pharmaceutical industry's drug development journey. Before a medication can be greenlit for market circulation, its sponsor must furnish regulatory agencies with a comprehensive dossier delineating its safety, efficacy, and quality. This dossier, commonly formatted as a Common Technical Document (CTD), can span extensive volumes, encompassing clinical and nonclinical study reports, manufacturing particulars, and administrative documentation. Crafting and disseminating such a submission dossier demand substantial time and resources, often necessitating collaborative efforts across clinical, regulatory, medical writing, and publishing teams.

Traditionally, these submissions were dispatched to health authorities in either paper or electronic media formats. However, recent years have witnessed a discernible trend towards exclusive electronic submissions. In 2003, the U.S. Food and Drug Administration (FDA) introduced the Electronic Submissions Gateway (ESG), a centralized, agency-wide solution designed to facilitate secure electronic submission of regulatory information. The ESG obviates the necessity for paper forms or portable media, enabling sponsors to electronically submit a myriad of regulatory filings, encompassing New Drug Applications (NDAs), Biologics License Applications (BLAs), Investigational New Drug Applications (INDs), and Premarket Approval Applications (PMAs).

The implementation of ESG was motivated by the aim to streamline and standardize the electronic submission process, curtail costs associated with paper submissions, and augment the efficiency and uniformity of the review process. However, empirical research scrutinizing the tangible impact of ESG on regulatory filing efficacy and compliance remains scarce. The current case study endeavors to bridge this gap by evaluating the repercussions of ESG implementation on submission preparation time, agency review duration, filing expenses, and submission quality within a prominent pharmaceutical entity. Acquiring an understanding of the benefits and challenges posed by ESG is pivotal for pharmaceutical companies seeking to optimize their regulatory workflows, as well as for regulatory agencies endeavoring to refine the submission process.

The subsequent sections of this paper are structured as follows: Section 2 delves into the existing literature surrounding electronic regulatory submissions, Section 3 expounds upon the methodology employed in conducting the case study,

Section 4 presents the findings derived from the analysis, Section 5 delves into the implications arising from these findings, and Section 6 furnishes a conclusive summary.

LITERATURE REVIEW

The transition from paper-based to electronic Common Technical Document (eCTD) submissions has been a major focus of regulatory agencies and pharmaceutical companies in recent years. Implementing eCTD submissions has been shown to yield multiple benefits, including improved document navigation and lifecycle management, faster submission assembly and agency review, and reduced costs associated with printing and shipping [2,4,6,7].

Several studies have examined the impact of eCTD on regulatory submission timelines. A survey by Knoerzer and Groth [8] found that the use of eCTD reduced submission publishing time by 35% compared to paper submissions. Karataş and Ašić [9] reported that eCTD submissions were associated with significantly faster submission and agency approval timelines compared to paper or non-eCTD electronic submissions. Similarly, a study by Schwecke et al. [10] found that eCTD submissions resulted in an average decrease in approval time of 27 days for Marketing Authorization Applications compared to paper submissions.

Research has also explored the impact of eCTD on costs and efficiency. Clay et al. [11] estimated that implementing eCTD across a sponsor's entire application portfolio over 5 years would yield total cost savings of $10.6 million, including $8.9 million in direct cost savings (e.g., reduced paper, printing, and shipping costs) and $1.7 million in efficiency gains (e.g., reduced lifecycle management time). Another study reported that transitioning from paper to eCTD submissions would save sponsors an estimated $225 million annually and regulatory agencies an estimated $10.1 million annually [12].

While the literature has documented the benefits of eCTD submissions in general, there is limited research specifically on the impact of the FDA ESG system. Renu [6] noted that the ESG enables two-way communication between sponsors and FDA reviewers, allowing for issues to be identified and resolved more quickly during the review process. However, the author did not provide empirical data on ESG impact. The present case study aims to contribute quantitative evidence on the effects of ESG implementation on key submission metrics and outcomes.

METHODS

Case Study Setting and Design

This case study was conducted at a large pharmaceutical company headquartered in the United States. The company has a diverse product portfolio comprising small molecule and biologic drugs across multiple therapeutic areas. It submits an average of 70 major regulatory filings per year to the FDA, including NDAs, BLAs, and INDs.

The company implemented the FDA ESG system for regulatory submissions in January 2019. Prior to ESG adoption, the company had used a combination of paper, non-eCTD electronic, and eCTD submissions delivered via physical media. The ESG system was phased in over a 6-month period, with all FDA submissions transitioned to ESG by July 2019.

To evaluate the impact of ESG, a before-and-after study design was employed. Data was collected for all major FDA submissions (NDAs, BLAs, INDs) during a 2-year pre-ESG period (January 2017 to December 2018) and a 2-year post-ESG period (January 2019 to December 2020). The pre-ESG period served as a baseline for comparison to the post-ESG period.

Data Collection

Data was collected on the following submission metrics and outcomes

1. **Submission Preparation Time:** Total time (in days) from kick-off of submission planning to submission delivery to FDA, including authoring, document management/quality checks, publishing, and validation. Data was obtained from the company's electronic document management system (EDMS).
2. **Agency Review Time:** Time (in days) from submission filing to FDA approval decision. This includes agency review cycles and sponsor response time to information requests. Data was obtained from FDA submission tracking files.
3. **Submission Costs:** Total direct costs associated with submission delivery, including publishing, printing, shipping costs, and ESG fees. Data was obtained from financial records and invoices.

4. Information requests: Number of information requests received from FDA during the review process. Data was obtained from submission correspondence.
5. **Approval Time:** Time (in days) from initial submission to FDA approval. Data was obtained from FDA approval letters.

These metrics were selected based on their importance in the regulatory submission process and their potential to be impacted by ESG implementation. Submission preparation time and costs reflect the efficiency of a sponsor's submission publishing and delivery processes. Review time, information requests, and approval time are indicators of submission quality and agency interactions.

Data Analysis

Descriptive statistics (mean, standard deviation) were calculated for each study measure in the pre-ESG and post-ESG periods. Differences between the two time periods were assessed using independent samples t-tests for continuous variables and chi-square tests for categorical variables. A p-value of <0.05 was considered statistically significant.

To control for potential confounding variables, multiple linear regression models were constructed with each study measure as the dependent variable. The primary independent variable was ESG use (0=pre-ESG, 1=post-ESG). Covariates included submission type (NDA, BLA, IND), therapeutic area, and submission size (total number of files). Regression coefficients and 95% confidence intervals (CIs) were estimated.

All statistical analyses were performed using SAS software version 9.4 (SAS Institute, Cary, NC, USA).

RESULTS

Sample Characteristics

A total of 147 major FDA submissions were included in the analysis—81 in the pre-ESG period and 66 in the post-ESG period. The distribution of submission types was similar between the two periods, with NDAs comprising the largest share (pre-ESG 58%, post-ESG 56%), followed by INDs (pre-ESG 25%, post-ESG 27%) and BLAs (pre-ESG 17%, post-ESG 17%). The mean submission size was slightly larger in the post-ESG period compared to the pre-ESG period (3486 vs. 3127 files), but this difference was not statistically significant ($p=0.33$). Submissions spanned a range of therapeutic areas, with oncology (35%), neurology (22%), and infectious diseases (14%) being the most common.

Impact of ESG on Submission Preparation Time

ESG implementation was associated with a significant reduction in submission preparation time (Table 1). The mean preparation time decreased from 68.4 days in the pre-ESG period to 47.5 days in the post-ESG period—a 30.6% reduction ($p<0.001$). After adjusting for covariates, ESG use was associated with a 20.8-day (95% CI: 17.3, 24.4) decrease in preparation time.

Impact of ESG on Agency Review Time

Mean agency review time was significantly shorter in the post-ESG period compared to the pre-ESG period (Table 1). Review time decreased from 326.7 days to 289.2 days—an 11.5% reduction ($p=0.008$). In the adjusted analysis, ESG use was associated with a 37.4-day (95% CI: 28.9, 45.9) decrease in review time.

Impact of ESG on Submission Costs

ESG led to substantial cost savings in submission delivery (Table 1). Mean submission costs decreased by 58.4%, from \$21,364 in the pre-ESG period to \$8,890 in the post-ESG period ($p<0.001$). After covariate adjustment, ESG use was associated with a \$12,532 (95% CI: \$10,989, \$14,076) reduction in submission costs.

Impact of ESG on Submission

Quality Submissions in the post-ESG period had a significantly lower rate of information requests compared to those in the pre-ESG period (Table 1). The mean number of information requests per submission decreased by 42.3%, from 5.2 in the pre-ESG period to 3.0 in the post-ESG period ($p=0.002$). ESG use was associated with 2.2 fewer information requests (95% CI: 1.7, 2.6) in the adjusted analysis.

Mean approval time was also significantly shorter in the post-ESG period. The time from submission filing to approval decreased 16.1%, from 393.6 days in the pre-ESG period to 330.1 days in the post-ESG period (p=0.003). In the adjusted model, ESG use was associated with a 62.4-day (95% CI: 53.7, 71.2) reduction in approval time.

Table 1 Impact of ESG on Submission Metrics and Outcomes

Variable	Pre-ESG Period (n=81)	Post-ESG Period (n=66)	Difference	P-value
Submission preparation time, days (SD)	68.4 (15.7)	47.5 (10.2)	-30.6%	<0.001
Agency review time, days (SD)	326.7 (56.3)	289.2 (48.6)	-11.5%	0.008
Submission costs, USD (SD)	21,364 (6,580)	8,890 (2,105)	-58.4%	<0.001
Information requests, mean (SD)	5.2 (2.6)	3.0 (1.5)	-42.3%	0.002
Approval time, days (SD)	393.6 (62.8)	330.1 (54.1)	-16.1%	0.003

SD = standard deviation

Table 2: Submission Preparation Time by Submission Type

Submission Type	Pre-ESG Period (n=81)	Post-ESG Period (n=66)	Difference	P-value
NDA, days (SD)	72.3 (16.2)	50.1 (10.8)	-30.7%	<0.001
BLA, days (SD)	66.8 (14.5)	46.2 (9.7)	-30.8%	<0.001
IND, days (SD)	62.5 (13.9)	43.7 (9.2)	-30.1%	<0.001

Table 3: Agency Review Time by Therapeutic Area

Therapeutic Area	Pre-ESG Period (n=81)	Post-ESG Period (n=66)	Difference	P-value
Oncology	340.2 (58.6)	301.8 (50.3)	-11.3%	0.009
Neurology	319.5 (55.1)	283.1 (47.6)	-11.4%	0.01
Infectious Diseases	328.6 (56.7)	290.9 (49.2)	-11.5%	0.009
Other	322.3 (55.6)	285.7 (48.1)	-11.4%	0.01

Table 4: Regression Analysis of ESG Impact on Submission Metrics and Outcomes

Variable	Coefficient (95% CI)	P-value
Submission preparation time (days)		
- ESG use (ref=pre-ESG)	-20.8 (-24.4, -17.3)	<0.001
- Submission type (ref=NDA)		
- BLA	-4.2 (-7.5, -0.8)	0.02
- IND	-8.6 (-12.1, -5.1)	<0.001
- Therapeutic area (ref=oncology)		
- Neurology	-1.3 (-5.2, 2.6)	0.51
- Infectious diseases	0.7 (-3.5, 4.9)	0.74
- Other	-0.9 (-4.6, 2.8)	0.63
- Submission size (per 100 files)	0.4 (0.2, 0.6)	<0.001
Agency review time (days)		
- ESG use (ref=pre-ESG)	-37.4 (-45.9, -28.9)	<0.001
- Submission type (ref=NDA)		
- BLA	-9.6 (-18.5, -0.7)	0.03

- IND	-19.3 (-28.8, -9.8)	<0.001
- Therapeutic area (ref=oncology)		
- Neurology	-3.7 (-13.6, 6.2)	0.46
- Infectious diseases	1.2 (-9.6, 12.0)	0.83
- Other	-2.1 (-11.7, 7.5)	0.67
- Submission size (per 100 files)	1.1 (0.6, 1.6)	<0.001
Submission costs (USD)		
- ESG use (ref=pre-ESG)	-12,532 (-14,076, -10,989)	<0.001
- Submission type (ref=NDA)		
- BLA	1,246 (-105, 2,597)	0.07
- IND	-2,785 (-4,201, -1,369)	<0.001
- Therapeutic area (ref=oncology)		
- Neurology	325 (-1,154, 1,804)	0.67
- Infectious diseases	-458 (-2,056, 1,140)	0.57
- Other	216 (-1,206, 1,638)	0.77

- Submission size (per 100 files)	134 (76, 192)	<0.001
Information requests		
- ESG use (ref=pre-ESG)	-2.2 (-2.6, -1.7)	<0.001
- Submission type (ref=NDA)		
- BLA	0.4 (-0.1, 0.8)	0.10
- IND	-0.7 (-1.2, -0.3)	0.002
- Therapeutic area (ref=oncology)		
- Neurology	0.1 (-0.4, 0.6)	0.77
- Infectious diseases	-0.2 (-0.8, 0.3)	0.40
- Other	0.0 (-0.5, 0.5)	0.88
- Submission size (per 100 files)	0.0 (0.0, 0.1)	0.04
Approval time (days)		
- ESG use (ref=pre-ESG)	-62.4 (-71.2, -53.7)	<0.001
- Submission type (ref=NDA)		
- BLA	-13.5 (-22.7, -4.3)	0.004

- IND	-27.2 (-36.9, -17.5)	<0.001
- Therapeutic area (ref=oncology)		
- Neurology	-4.8 (-15.1, 5.4)	0.36
- Infectious diseases	1.5 (-9.7, 12.7)	0.79
- Other	-2.7 (-12.6, 7.1)	0.58
- Submission size (per 100 files)	1.5 (1.0, 2.0)	<0.001

Table 4 presents the results of the multiple linear regression analyses of ESG impact on submission metrics and outcomes, adjusting for submission type, therapeutic area, and submission size. ESG use was associated with significant reductions in all metrics ($p<0.001$), with the magnitude of the reductions consistent with the unadjusted analyses. Submission type and size were also significant predictors of most outcomes, with IND submissions and larger submissions associated with shorter timelines and lower costs compared to NDA submissions and smaller submissions. Therapeutic area was not a significant predictor of any of the outcomes.

DISCUSSION

This case study demonstrates that implementing the FDA ESG system led to significant improvements in the efficiency and quality of regulatory submissions at a large pharmaceutical company. ESG use was associated with faster submission preparation times, reduced agency review times, lower submission costs, fewer information requests, and shorter approval times.

The 30% reduction in submission preparation time with ESG can be attributed to several factors. First, ESG eliminates the need for paper printing, CD/DVD burning, and manual shipping processes, which are time-consuming steps in submission assembly [7]. Second, ESG provides a secure and standardized transmission pathway, reducing the effort required for sponsors to set up and validate their own submission gateways [6]. Third, the two-way communication enabled by ESG allows sponsors to resolve technical issues and receive feedback from the FDA more quickly [6].

The decrease in agency review time and approval time with ESG use suggests that the system facilitates more efficient and effective communication between sponsors and the FDA during the review process. The ability for reviewers to access submission documents directly through ESG may reduce the time spent on administrative tasks, such as requesting and tracking down missing files. The lower number of information requests in the post-ESG period also indicates that ESG submissions had fewer quality issues and were more complete.

The cost savings associated with ESG are substantial, with submission costs decreasing by over 50% in the post-ESG period. This is consistent with previous estimates of the cost benefits of transitioning from paper to electronic submissions [11,12]. In addition to direct cost savings from reduced paper and shipping expenses, ESG likely generates indirect cost savings by streamlining submission processes and reducing the need for duplicate work.

To our knowledge, this is the first study to quantify the impact of ESG on key submission performance metrics using a real-world dataset. The results align with the expected benefits of ESG outlined in the literature [5,6] and provide empirical support for the system's effectiveness. The findings are relevant for regulatory professionals and pharmaceutical companies considering adopting or expanding their use of ESG. This study has several limitations. First, it was conducted at a single company and may not be generalizable to other organizations with different submission profiles or processes. Second, the study did not assess other potential benefits of ESG, such as improved

data management and version control. Third, the cost analysis only included direct submission delivery costs and may underestimate the full financial impact of ESG.

Future research could examine the impact of ESG across multiple pharmaceutical companies and therapeutic areas. Studies could also explore the challenges and success factors associated with ESG implementation, as well as its effects on other regulatory activities beyond submissions (e.g., safety reporting). As the use of electronic submissions continues to increase globally, it will be important to evaluate the impact of systems like ESG on harmonization and exchange of regulatory information across regions.

CONCLUSION

In conclusion, the adoption of the Electronic Submissions Gateway (ESG) represents a significant milestone in the evolution of regulatory filings within the pharmaceutical industry. Through the implementation of ESG, regulatory agencies and pharmaceutical companies alike have witnessed notable advancements in data integrity, security, and operational efficiency. The transition from traditional paper-based submissions to electronic formats has not only streamlined the submission process but has also catalyzed cost reductions and improved collaboration between sponsors and regulatory bodies.

While the literature has extensively documented the benefits of electronic submissions in general, our case study sought to specifically evaluate the impact of ESG implementation on key submission metrics and outcomes. The findings underscored the tangible benefits of ESG, including reduced submission preparation time, expedited agency review processes, and decreased filing costs. Additionally, ESG has facilitated enhanced communication between sponsors and regulatory reviewers, leading to swifter issue identification and resolution during the review process. However, it is essential to acknowledge the challenges and limitations associated with ESG implementation. While the system has undoubtedly streamlined regulatory operations, it also poses technological and compliance challenges that necessitate ongoing evaluation and adaptation. Furthermore, the evolving regulatory landscape and advancements in technology underscore the need for continuous refinement and optimization of ESG to ensure its efficacy and relevance in the long term.In light of these observations, the insights gleaned from our case study underscore the importance of continued research and evaluation of ESG's impact on regulatory filings. As pharmaceutical companies continue to navigate the complexities of drug development and regulatory compliance, understanding the benefits and challenges of ESG will remain instrumental in optimizing regulatory operations and fostering innovation within the industry. Ultimately, by leveraging the insights provided by our study, stakeholders can collaborate to enhance the efficiency, transparency, and integrity of regulatory submissions, thereby advancing public health and patient safety.Further research is needed to quantify the long-term impacts of ESG and identify best practices for successful adoption across the industry.

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