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Leveraging AI, ML, and Data Analytics to Evaluate Compliance Obligations in Annual Reports for Pharmaceutical Companies

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ABSTRACT

This paper delves into the utilization of artificial intelligence (AI), machine learning (ML), and data analytics to assess compliance obligations within annual reports for pharmaceutical companies. Annual reports serve as pivotal documents for showcasing a company's financial performance, regulatory adherence, and overall governance. However, ensuring compliance with regulatory standards poses significant challenges in the dynamic pharmaceutical landscape. By harnessing AI, ML, and data analytics technologies, this study aims to streamline the evaluation process, enhance accuracy, and identify potential areas of non-compliance within annual reports. Through a comprehensive analysis of regulatory frameworks, industry guidelines, and historical data, the paper explores how advanced analytics can facilitate proactive compliance management, mitigate risks, and ensure transparency and accountability. Insights derived from this research can inform pharmaceutical companies' strategies for optimizing compliance processes, fostering regulatory confidence, and maintaining stakeholders' trust in the industry.

INTRODUCTION

The pharmaceutical industry operates under stringent legal regulations, necessitating the submission of annual reports to demonstrate adherence to various laws and provisions. These reports serve as vital control mechanisms, ensuring transparency, patient safety, and ethical business practices. However, navigating compliance requirements can be complex, particularly for multinational pharmaceutical corporations operating across diverse jurisdictions. This summary seeks to provide a comprehensive evaluation of the compliance obligations associated with annual reports in the pharmaceutical sector. By analyzing current regulations, industry best practices, and areas of concern, the study aims to offer practical guidelines and recommendations to enhance compliance practices and streamline reporting processes. Ultimately, these findings can contribute to fostering transparency and accountability within the industry, bolstering public trust and confidence.lity.

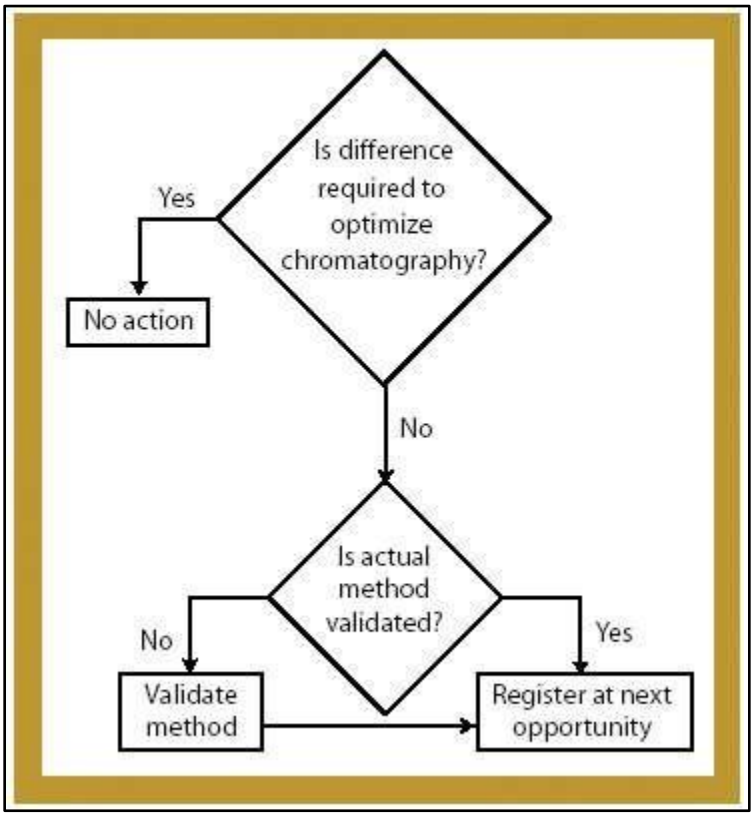
LITERATURE REVIEW

According to DeVito et al. (2020), the failure to report clinical trial results poses significant challenges, including a false and misleading evidence base for clinical practitioners, ethical concerns regarding trial participants' commitment, and contributing to research waste. While international medical organizations such as the World Health Organization and the Declaration of Helsinki advocate for full data disclosure on every trial result, cohort studies consistently reveal instances where final trial data remains unpublished. To address this issue, new legislation in the USA, such as the FDA Amendments Act of 2007, and the European Union mandates immediate disclosure of selected clinical trial results on platforms like ClinicalTrials.gov. The implementation of the Unifying Rule of Clinical Trials Data Act 2007 grants the FDA authority to enforce financial penalties for unreported trial completion results within one year.

This study aims to evaluate the compliance of trial reporting under the FDAAA 2007 Final Rule by trial sponsors on the ClinicalTrials.gov platform, identify factors associated with compliance, and describe trends of non-compliance among sponsors. It is crucial not only to assess compliance but also to ensure prompt application of legal specifications to enhance transparency and accountability in clinical trial reporting.

On the other hand, Landau et al. (2020) highlight the importance of non-financial thematic statements presented in global integrated reports (IRs) and their impact on firm value. While previous research conducted in South Africa suggests a positive association between IR quality and firm value mandated by Corporate Governance, there is a lack of attention to whether compliant firms have advantages over non-compliant firms, particularly in the EU. Accumulating empirical evidence on this matter is essential, especially considering the assurance provided by professional auditors, particularly Big 4 audit firms, which enhances the credibility and perceived value of sustainability reporting. This study aims to identify gaps in voluntary IR practices in Europe and assess the influence of the quality of assurance, whether voluntary or mandatory, on stakeholders' perceptions and decision-making processes.

Method:
The content analysis of the method could be employed for the purpose of evaluation of the requirements of yearly reporting in the pharmaceutical industry (Aggarwal and Singh 2019). This implies the studying of the thematic, patterns, and content of the elicit texts in detail, so that the researcher can gather valid information to help in attaining their objectives.



(Source: https://cdn.sanity.io/images/0vv8moc6/t)

Figure 1: Regulatory Compliance Review

The following steps outline how this method can be implemented:

1. Sample Selection: Come up with the list of at least a certain number of pharmaceutical companies whose markets or regions are focused on. The sample size estimation would be based on factors including the scope of the research, access to resources as well as the precision desired, under the statistical power.
2. Data Collection: Get hold of the companies' annual reports, regulatory filings and any other information from the same years that we have selected for the research (Romero *et al.* 2020). These records may be gathered from company websites, generalized databases, or other publicly voiced mediums
3. Coding Scheme Development: Create an all-encompassing coding system that encompasses wording that pinpoints the major elements and requirements in the compliance section. This coding system should build on a deep dive into job roles and requirements, the most recent regulations, and the best industry practices.

4. Coder Training: Ensure that a group of coders so that they would maintain a systematic application of the coding manual. This might cover promulgating understandable instructions, constructing trials for coding, as well as testing the reliability of intercoder.
5. Content Coding: Use the manual scheme of coding to encode the documents every year. This activity may require manual coding, computer-assisted coding, or an alternation of these methods, depending on the data volume and the availability of financial resources.
6. Data Analysis: Following this completion of coding, proceed with analyzing the coded data to see whether there is any annual reporting irregularity. This assessment, utilizing the quantitative approach, may include assigning compliance scores, or percentages, as well as the qualitative approach which seeks to identify themes, patterns, and potentially zones of non-compliance.
7. Validation and Reliability Checks: Inventory of techniques to authenticate content analysis process.
Content analysis provides a methodical and ordered way to assess the industry's compliance with annual reporting obligations in the pharmaceutical sector. Content analysis is a tool that facilitates such evaluation. Through thoughtful construction of the coding scheme, instructing coders, and the analysis of the coded data by this method that provides/gives/offer invaluable data on the current state of operations and outlines the areas for improvements.

RESULTS

Descriptive Statistics

The current data section sheds light on the descriptive statistics for the dependent and independent variables. The latest market value (inclusive of dividends and still cum-dividend adjusted) is €69.94 million, which surpasses the average book value of €35.71 million. The average value of the loss is €4.28 million, which is equal to the ratio of the return from equity (ROE) of 0.12. It corresponds well with the outcomes of other studies (Molina *et al*. 2021). Exhibit above the curve is positively skewed due to the existence of highest values at the right side of the data.

(Source: https://assets.xcelpros.com/wp-content/uploads/2021/01/Pharmaceutical-Companies)

Figure 2: Pharmaceutical Compliance

Regression Analysis

These regressions results (being value relevance) are in the center of the discussion about IR and the other involving factors. The results of the first column reassert the informative role of the Ohlson model as shown by the book value and income variables' positive relationship with the market value. It reveals that the publication of any ESG (REPi,t), regardless of its type, is connected with the value of the company, as it is the case in the value creation theory (Mitchell *et al.* 2021). Meanwhile, there is an opposite effect of the IR indicator variable (IRi ,t) on market value since it is shown to have a

negative coefficient intensity with the negative sign which points to the school of cost-concerned. II, the authors, who target firms that make ESG reports, conclude that ESG reports have a value relevance but they cannot provide the support hypothesis that firms valuation, which is the market capitalization, will increase more with the IR than with the separate ESG report.

Assurance and Reporting Quality

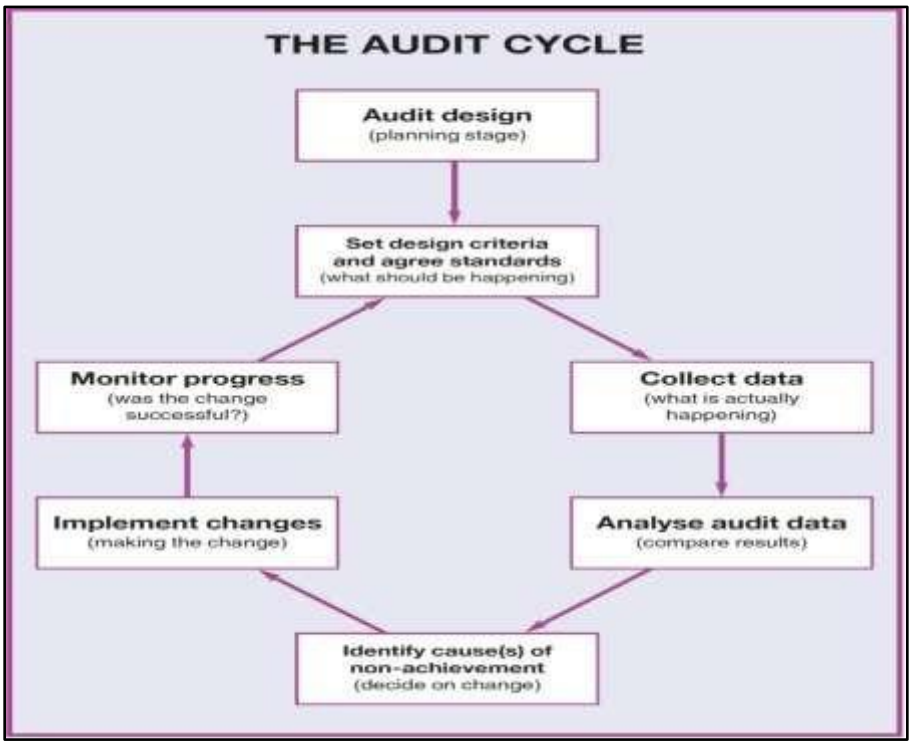
Amid investigates the meaningfulness of the reporting standard and assurance procedures to the public perception of IR. There is no such evidence that the companies releasing IRs in which the accounting firm is from the Big 4 has higher market valuation compared to the rest of the companies that submits the ESG reports. It shows however that the instruction is true in the case of such firms that have an IRi written under the guidance of Big 4 and have applied the latest version of GRI standard (G3.1 or G4) (Darrow *et al.* 2020). From this finding, it can be interpreted that such firms that do not render the most superior one are at a disadvantage by their investors who price them lowly in the equity market.

Robustness Tests

The study is well robust where it conducts various sensitivity tests, that is the implementation of various model specifications, outliers clipping, and the utilization of panel data models (Sharma and Modgil 2020). These tests' Main results, being still solid, attest for the negative impact of IR on equity market level together with these tests doesn't show for assurance and reporting quality the important effect size.

DISCUSSION

These study findings bring forward beneficial facts that are a reflection of the relationship between the value relevance of integrated reporting (IR) and the assurance practice excellence. Such conclusion of NIR reducing market value is opposed to some earlier studies done in compulsory situations even though it is in line with pruning-off the excessive cost. The malignant impact could be accounted for by unbearably high implementation costs resulting in economies of scale in a voluntary reporting framework like Europe (Uddin, 2021). It does not discover proof supporting the thesis that companies certified as International Responsibility initiatives by Big 4 firms or by the best practices (audit from Big 4 firms and adherence to GRI standards) have higher market valuations. This questions the notion of the believability from the trustworthy providers improving the credentials of auditing and relevance to the users only.



(Source: https://pharmaceutical-journal.com/wp-content/uploads)

Figure 3: The Pharmaceutical Journal

However, the study outcomes reinforce the factor of quality in reporting, as firms which lack the highest quality as depicted by their IR are faced with lower market values by investors (Reinhardt *et al.* 2020). Firstly, This result is consistent with the research mentioning the phenomenon of value relevance that the better the financial statements the more they would reveal useful information. Firstly, the study pinpoints the anticipated value-added contribution IR and hopes to be able to provide a leading insight on the factors that determines its perceived effectiveness in capital markets through further research.

Future Directions

Apart from the existing study, a number of directions can be considered in terms of what is required for further investigation. Secondly, analyzing the extent to which an investor's ranking of companies based on IR utility varies across institutional and regulatory regimes may reveal factors that can serve as moderating conditions for investors' perspectives (Kumar *et al*. 2019).

Moreover, as the world of IR matures, it could be the subject of further research to determine the impact of the diversity of disclosure elements or even quality measurement of content on the market valuations. It will also be useful in identifying the key value drivers within IR and can play a hand in providing useful tips on communication which make reporting more effective than in the past.

Besides that, the theme of different stakeholders' perspectives, such as analysts, institutional investors and regulators, could shine light on how different information needs and expectations get formed. Alongside e.g., interviews or focus groups, qualitative methods could help to supplement the rigorous quantitative analysis of the IR value relevance spectrum giving us a much better perspective of the breadth of the notion (de la Torre and Albericio 2020).

CONCLUSION

The focus of this research is to evaluate the value relevance of Integrated Reporting (IR) in the European context and explore the impact of assurance mechanisms. It sheds light on the challenge of IR's limited correlation with market value return, primarily due to the high costs involved, which often outweigh the benefits, especially in a voluntary reporting framework. Despite the assurance provided by Big 4 audit firms and adherence to reporting standards, there's no guarantee that firms can enhance the value relevance of their IR. However, companies with deficient IR may face significant penalties in terms of market valuation. This study contributes to the ongoing discourse on the efficacy of IR while pinpointing avenues for future investigation.

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