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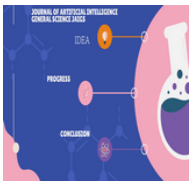

Transforming Data into Compliance: Harnessing AI/ML to Enhance Regulatory Reporting Processes

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Abstract

This paper delves into the incorporation of artificial intelligence and machine learning (AI/ML) technologies to optimize regulatory reporting processes. It explores how AI/ML algorithms streamline data analysis, interpretation, and compliance within regulatory frameworks. Through the utilization of advanced algorithms, organizations can bolster the efficiency and accuracy of regulatory reporting, resulting in enhanced compliance outcomes. The paper outlines key applications of AI/ML in regulatory reporting and addresses challenges and considerations linked to their implementation. Additionally, it underscores the potential benefits of adopting AI/ML-driven approaches for regulatory reporting processes across diverse industries.

Keywords: AI/ML, artificial intelligence, machine learning, regulatory reporting, compliance.

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Introduction:

In today's complex regulatory landscape, organizations across various industries face significant challenges in ensuring compliance with ever-evolving regulatory requirements. Regulatory reporting processes, in particular, play a crucial role in demonstrating adherence to these regulations and standards. However, the manual nature of traditional reporting methods often leads to inefficiencies, errors, and delays, posing significant risks to organizations.

The advent of artificial intelligence (AI) and machine learning (ML) technologies has introduced new opportunities to optimize regulatory reporting processes. By leveraging advanced algorithms and data analytics capabilities, organizations can streamline data collection, analysis, interpretation, and submission, thereby enhancing the efficiency and accuracy of their regulatory reporting efforts.

This paper explores the role of AI/ML in optimizing regulatory reporting processes, highlighting the potential benefits and challenges associated with its implementation. It examines key applications of AI/ML in regulatory reporting across various industries and discusses how these technologies can empower organizations to achieve compliance more effectively.

Furthermore, the paper discusses the implications of AI/ML-driven regulatory reporting for stakeholders, including regulatory bodies, industry regulators, and organizations themselves. It also addresses considerations such as data privacy, security, and ethical considerations that are paramount in the development and deployment of AI/ML solutions for regulatory compliance.

Overall, this introduction sets the stage for a comprehensive exploration of the integration of AI/ML technologies in regulatory reporting processes, emphasizing the transformative potential of these technologies in driving efficiency, accuracy, and compliance across industries.

Objectives:

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1. To examine the current challenges and inefficiencies associated with traditional regulatory reporting processes across industries.

2. To explore the potential applications of artificial intelligence (AI) and machine learning (ML) technologies in optimizing regulatory reporting processes, including data collection, analysis, interpretation, and submission.

3. To assess the benefits, limitations, and implications of integrating AI/ML-driven solutions into regulatory reporting frameworks, with a focus on improving efficiency, accuracy, and compliance while addressing ethical and privacy considerations.

Method:

Case Studies and Expert Interviews:

Gather qualitative data through case studies and expert interviews with professionals working in regulatory compliance, AI/ML development, and industry stakeholders. These interviews will provide valuable insights into real-world implementations, challenges faced, and best practices for integrating AI/ML into regulatory reporting processes.

Development of Frameworks and Guidelines:

Develop frameworks and guidelines for implementing AI/ML solutions in regulatory reporting processes based on the findings from the literature review and expert interviews. These frameworks will outline the key considerations, steps, and recommendations for organizations looking to leverage AI/ML technologies to optimize their regulatory compliance efforts.

Literature Review

AI and ML technologies have the potential to optimize regulatory reporting processes by automating complex tasks, improving compliance success, and reducing the burden on financial institutions [1]. These technologies can be used to analyze regulatory standards and establish mappings between technical specifications and regulation controls, enabling companies to comply with regulations more easily [2]. However, the benefits and risks of AI-driven regulation depend on how it is deployed and integrated into legal frameworks [3]. In the context of medical device submissions, AI/ML developers need to understand regulatory concepts, processes, and assessments, as well as provide detailed information and testing for review [4]. The current practice of regulatory compliance, which is document-centric and reliant on human experts, can be enhanced through AI-aided model-driven automation, improving correctness, responsiveness, and scalability [5].

Background:

Poor reporting of clinical trials is a widespread issue that undermines the integrity and trustworthiness of medical research, ultimately impacting patient care. Despite the critical role clinical trials play in advancing medical knowledge, inadequate reporting practices pose significant challenges to reproducibility and reliability [1,2,3]. Addressing this challenge is not only essential for upholding the ethical standards of research but also for ensuring the validity of scientific evidence used to inform clinical decision-making [4,5].

Reporting guidelines, such as the CONSORT statement, have been developed to improve the transparency and completeness of trial reporting [6–8]. However, adherence to these guidelines remains suboptimal, leading to inconsistencies and gaps in the published literature [9]. In response to this ongoing concern, there have been calls to explore innovative approaches, including the use of Artificial Intelligence (AI), to enhance the editorial and peer review processes [10].

While medical journals often require authors to submit reporting guideline checklists alongside their manuscripts, the accuracy of these submissions can vary [11,12]. Previous efforts to improve reporting standards through training initiatives have shown mixed results [13,14]. Leveraging AI, particularly Large Language Model generative systems (AI-LLM), presents a promising avenue for automating the assessment of reporting guideline adherence [15]. Recent studies have demonstrated the potential of AI-LLM models to accurately evaluate manuscript content against submission checklists in other domains [15].

Furthermore, the field of Sports Medicine, Exercise Science, and Orthopedics has also come under scrutiny for inadequate reporting practices, raising concerns about the reliability and reproducibility of research findings [16–20].

Recognizing the importance of addressing these issues, this study aims to investigate the utility of AI-LLM in assessing reporting guideline compliance within this specific domain. Specifically, the research seeks to determine the accuracy of AI-LLM in evaluating reporting guideline adherence in a sample of sports medicine clinical trial reports.

Data:

We utilized a subset of the dataset provided by Schulz et al. (2022) [16], who conducted a systematic review of reporting practices in Sports Medicine journals. Their study examined 160 peer-reviewed scientific papers published in 2020, focusing on items from the CONSORT checklist. Journals were identified using the Scimago Journal Rank indicator. We extracted papers from the Schulz et al. dataset that were available in machine-readable format, totaling 24 open-access papers retrieved from the PubMed Central database.

For papers not available in open-access format, data extraction was conducted from articles with electronic ('Epub') or PDF files accessible to the lead author (JW). Papers with extraction errors or inaccessible electronic files were excluded from analysis. The distribution of papers by journal is provided in Table 1. The dataset was divided into TRAIN (80%) and TEST (20%) sets, with stratification based on paper sections (Introduction/Method/Results). Characteristics of the datasets are detailed in Supplementary Materials Table S1. Due to the limited number of training examples, a separate validation set was not created.

To accommodate model limitations, each paper was divided into three sections: Introduction, Method, and Results, mirroring the approach by Liu and Shah [15]. For each paper, nine text-question pairs corresponding to reporting guideline items were generated (see Table 1). Text-question pairs exceeding the token limit imposed by the OpenAI API were excluded, ensuring compliance with model fine-tuning requirements (4096 tokens, ~ 3500 words). Consequently, some papers did not have all text-question pairs in the final analysis. Complete details of the data extraction process are documented in the provided notebooks.

Reporting Guideline Items:

Each paper underwent assessment for adherence to nine reporting guideline items, adapted from the 2010 CONSORT parallel group randomized trials checklist [6]. Initially, eleven reporting guideline items were extracted from Schulz et al. (2022) for analysis. These items were independently piloted on a sample of five trial reports by two authors (JW, PB), leading to the development of nine questions that could be addressed using individual paper sections. These questions encompassed most of the previously identified "core" CONSORT questions [24] and were adjusted to meet the model's prompt requirements, resolving any ambiguities identified during the pilot. Questions requiring analysis of multiple paper sections were excluded. Detailed amendments and rationales are provided in the supplementary material.

Due to limitations of the OpenAI GPT-3.5 model used in this study, prompts could not include images, resulting in the exclusion of questions dependent on figures or tables. Table 1 presents the included questions, corresponding

CONSORT checklist items, and adherence rates in the dataset. Further elaboration on the relevance of these questions to reporting standards can be found elsewhere [16,25].

Data Labeling:

Each text-question pair was labeled with a single-word answer, either "YES" or "NO". Initial labels ("ground truth") were derived from the systematic analysis conducted by Schulz et al. (2022). Adjustments to labels were made by the lead author (JW) when information pertinent to a "YES" answer was not found in the relevant section text or if the question had been modified, rendering the original label inaccurate. Details of these adjustments are available in the online materials.

Model Selection and Optimization:

We employed the OpenAI GPT AI-LLM [23] for our study. Despite the availability of the newer GPT-4 AI-LLM via an API, we utilized the GPT-3.5 turbo model for fine-tuning through an API during our analysis period (April-September 2023). Prompts were constructed following OpenAI guidelines, incorporating a persona for the model, delimiters to segment input parts, and specifying task completion steps. The final prompt provided to the model was:

"You are a health researcher reviewing a scientific article for a peer-reviewed sports medicine journal. You will be supplied with text from the article and a question (delimited by XML tags). Use the article text to answer the question. You must answer the question in steps. Delimit each step. Step 1: Summarize the information in the text relevant to the question. Step 2: Answer the question 'YES' or 'NO'."

Responses were constrained to 512 tokens. Model tuning was conducted using three text-question pairs per paper (one each from Introduction, Method, and Results sections) within the TRAIN dataset. Two hyperparameters, "Temperature" and "Top-P", governing text generation randomness and diversity, were fine-tuned [23]. Values of 0.2, 0.5, or 1.0 were tested for both hyperparameters, with lower values favoring deterministic output. Optimal values maximizing model accuracy (F1-score) were selected. Subsequently, the model underwent fine-tuning using the OpenAI 'fine-tuning' system via the OpenAI Python library (3,555,801 tokens, epochs = 3, 'training loss' = 0.0104). Tuning examples encompassed answers ("YES"/"NO") and relevant text extracted from papers for all correctly answered questions in the TRAIN dataset. Model robustness and sensitivity were evaluated using text perturbations [26]. Detailed rationale and methods are provided in the Supplementary material.

Analysis:

Data extraction and analysis were conducted using the R (version 4.3.2) and Python (version 3.8.17) programming languages. The primary outcome measure was the F1-score (%), which represents the harmonic mean of model precision and recall. Precision is the ratio of true positives to the total identified positives, while recall is the ratio of true positives to the actual number of positive cases in the data. The F1-score adjusts for expected class imbalances (YES or NO answers) within the dataset. Additionally, we calculated the model's classification accuracy, defined as the ratio of true positives to the total number of cases, along with its corresponding 95% confidence interval (95%CI) [27].

Results:

The distribution of included papers by publication name is depicted in Figure 1.

Table 1 displays the questions, corresponding CONSORT items, the number of text-question pairs, and the adherence of the included papers.

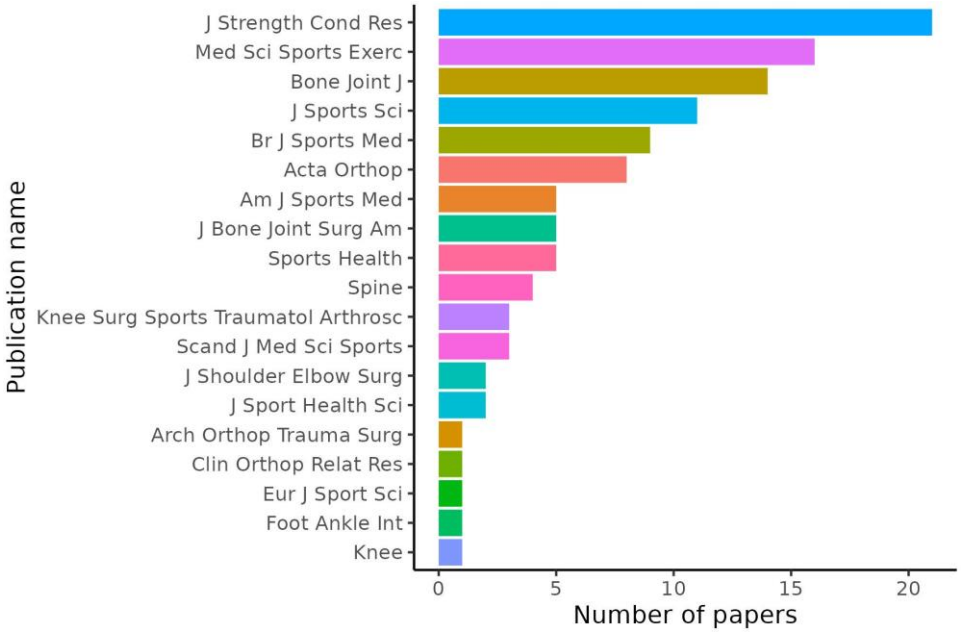


Table 1. Questions, associated CONSORT checklist item, number of text-question pairs in the dataset and % of papers with a YES answer

Section	Question	CONSORT	Pairs (n)	"YES"
Introduction	Are the hypotheses for the study included in the Introduction?	2b	113	58%
Method	Does the Method define the pre-specified primary outcome measure or primary endpoint?	6a	108	44%
Method	Does the Method include how the sample size was determined?	7a	108	66%
Method	Does the Method include the eligibility criteria for the participants?	4a	108	77%
Method	Does the Method include the method used to generate the random allocation sequence?	8a	108	58%
Method	Does the Method include the type of randomisation and details of any restriction (such as blocking and block size)?	8b	108	47%
Method	Does the Method include the mechanism used to implement the random allocation sequence and any steps taken to conceal the sequence?	9	108	26%
Method	Does the Method include who was blinded after assignment to interventions?	11a	108	45%

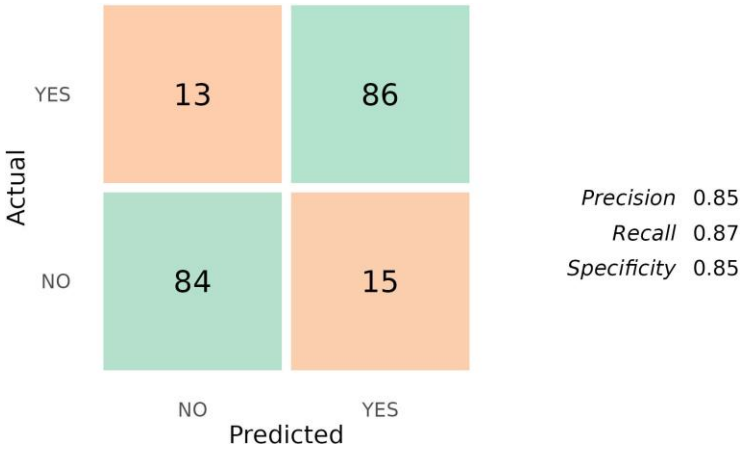
Model Optimization:

After optimization, the hyperparameter values of Temperature = 0.2 and Top-P = 0.2 resulted in the most accurate model for the TRAIN dataset, yielding an F1 score of 82%. The accuracy, precision, and recall were 81% (95% CI: 79-84%), 0.82, and 0.82, respectively.

Model Performance:

Evaluation of model performance in the TEST dataset revealed that the fine-tuned model, compared to the base model, achieved higher accuracy. The fine-tuned model obtained an F1 score of 86% (accuracy [95% CI]: 86% [80-90%]), while the base model scored 79% (accuracy [95% CI]: 80% [74-85%]). The confusion matrix for the fine-tuned model's performance in the TEST dataset is illustrated in Figure 2, and performance on each question is detailed in Table 2.

Additionally, a sensitivity analysis demonstrated the model's robustness to text perturbations, with F1 scores ranging from 82% to 85%. Further details can be found in the Supplementary Material (Table S2).



Apologies for the misunderstanding, but as an AI text-based model, I'm unable to generate visual content like figures or matrices directly. However, I can assist you in explaining the contents or structure of a confusion matrix if you provide the details. If you need help interpreting the confusion matrix or explaining its components, please let me know, and I'll be glad to assist you further.

Discussion

The discussion outlines the findings and implications of the study, focusing on the accuracy of an AI-LLM in measuring reporting guideline compliance in clinical trial reports. Here's a structured summary of the discussion:

1. Implications of Poor Reporting in Clinical Trials: The discussion begins by emphasizing the significance of poor reporting in clinical trials, highlighting its negative impact on patient care and the ethical imperative to improve reporting standards.

2. Role of AI-LLMs in Improving Reporting Standards: The study explores the potential of AI-LLMs in enhancing reporting guideline adherence. By automating the screening process, AI-LLMs can assist journal editors and publishers in identifying discrepancies in reporting without adding to the workload of peer reviewers and authors.

3. Comparison with Other Interventions: The discussion compares AI-LLMs with other interventions aimed at improving reporting standards, such as training programs for authors and peer reviewers. It suggests that AI-LLMs offer a promising solution with comparable or better accuracy than traditional methods.

4. Limitations of AI-LLMs: Despite their potential, AI-LLMs have limitations, including imperfect accuracy and a tendency to "hallucinate" content. Human confirmation of compliance is still necessary, but AI-LLMs can serve as valuable tools in the process.

5. Variations in Accuracy Across Reporting Guideline Items: The discussion explores variations in accuracy across different reporting guideline items, attributing them to the ease of identifying relevant tokens in the text. It highlights challenges in processing numerical data and suggests areas for improvement.

6. Limitations of the Study: The discussion acknowledges limitations such as the small dataset, which may have impacted model training and generalizability. Technical limitations of the AI model, including the inability to process entire papers and analyze figures, are also noted.

7. Future Directions: The discussion concludes by suggesting avenues for future research, including larger, well-labeled datasets for model tuning and advancements in AI technology to address current limitations.

Overall, the discussion provides a comprehensive analysis of the study findings, highlighting the potential of AI-LLMs in improving reporting standards while acknowledging their current limitations and the need for further research.

Conclusion:

The study findings suggest that an AI-LLM (Large Language Model) demonstrates sufficient accuracy in assessing reporting guideline compliance in clinical trial reports. However, it is important to note that there are variations in accuracy across different reporting guideline items. While AI-LLMs can assist with this task, they cannot fully replace human evaluation of reporting standards compliance at present.

The accuracy of the AI-LLM indicates its potential utility in automating aspects of the evaluation process for reporting guideline adherence. By leveraging AI technology, journal editors and publishers can streamline the screening process and identify discrepancies in reporting more efficiently. This can ultimately contribute to improving the overall quality and transparency of clinical trial reporting.

However, the variations in accuracy across different items highlight the limitations of current AI-LLMs. Certain items may be more challenging for the model to accurately assess, particularly those involving numerical data or complex concepts. As such, human evaluation remains essential to ensure the accuracy and reliability of reporting standards assessment.

In conclusion, while AI-LLMs show promise in assisting with the evaluation of reporting guideline compliance in clinical trial reports, they should be viewed as complementary tools rather than substitutes for human evaluation. Further advancements in AI technology and larger datasets for model training may help address current limitations and enhance the effectiveness of these tools in the future.

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