3Analytics

BUSINESS WHITE PAPER

Revolutionizing Coding Efficiency

AI-Driven Automation

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Introduction

Post-market surveillance is an ongoing responsibility for drug, device, and vaccine manufacturers, requiring continuous monitoring of product performance and safety once they are available to the public. The need for standardized coding of adverse events through established frameworks like MedDRA and IMDRF has never been more crucial. As the industry faces mounting pressures from regulatory bodies and the public, leveraging advanced technologies such as artificial intelligence (AI) presents a compelling solution.

MedDRA CODING

MedDRA(Medical Dictionary for Regulatory Activities) is a standardized medical terminology used primarily in the pharmaceutical industry for coding and reporting adverse drug reactions (ADRs), clinical trial outcomes, and medical events. It's hierarchical structure ranges from broad System Organ Classes (SOCs) to specific Preferred Terms (PTs), promoting consistency and accuracy in regulatory submissions.

IMDRF CODING

The International Medical Device Regulators Forum (IMDRF) plays a pivotal role in harmonizing the regulatory landscape for medical devices worldwide. Its guidelines and annexures provide essential coding standards for adverse events and medical device malfunctions, ensuring clarity and consistency in reporting across jurisdictions.

Challenges

1

Increased Costs

Regulatory agencies face rising operational expenses due to manpower needs, training, and system updates.

2

Public Health Risks

Delays in adverse event reporting can lead to public health crisis.

3

Industry Implications

Non-compliance and legal liabilities can result in millions of losses for manufacturers.

Post-market surveillance systems face significant inefficiencies due to manual data entry and the use of outdated legacy systems. These systems are often inefficient at data handling and lack integration with modern platforms, leading to extensive manual data transfers.

This not only heightens the risk of human error but also extends processing times. Moreover, the diverse documentation standards required by various regulatory bodies complicate submissions, demanding substantial manual labor to maintain accuracy and compliance.

Impact of PMS Challenges

Regulatory Agencies
The increasing responsibilities of organizations like the FDA and EMA leads to inflated operating budgets and resource allocation challenges.

Public Health
Delayed identification of safety signals can strain health systems and compromise patient safety.

Industry Implications
The pharmaceutical and medical device sectors face extensive financial repercussions, including operational adjustments, legal liabilities and potential recalls which can exceed billions.

AI-Driven Solutions

The application of AI-driven automation offers transformative solutions to PMS challenges:

Automating Complaint Coding

AI systems utilizing natural language processing (NLP) can automate the extraction of relevant information from complaint narratives, generating accurate MedDRA and IMDRF codes in real-time.

Handling Multiple Allegations

Advanced AI models can analyze multiple device allegations or adverse events in a single complaint, ensuring comprehensive data entry and minimizing oversight.

Reducing Human Error

By automating the coding process, AI reduces the risk of human error, leading to more reliable and consistent data for regulatory reporting.

Real-Time Regulatory Adaptation

AI can quickly adapt to regulatory changes, ensuring compliance without major disruptions to complaint handling processes.

Improving Safety Signal Detection

AI technologies can identify patterns in data more effectively than traditional methods, allowing for early detection of safety signals and proactive risk management.

Case Study

Implementation of AI in PMS

A leading pharmaceutical company successfully implemented an AI-based automation solution, achieving 100% compliance in coding and significantly reducing manual effort and processing time. The system provided real-time updates to adapt to regulatory changes, illustrating the potential for AI to streamline PMS.

95%

Desired Accuracy Achieved

Challenges Faced

Keyword based model

Findings

- Model Failed to understand the contextual meaning and the results were not logical.
- Accuracy not up to the expectation.

Narrative based model- Traditional NLP Approach

Findings

- Insufficient data. The data provided by the customer was insufficient and uneven distribution of dataset.
- Inconsistent coding (knowledge Gap, Oversight, Missed Allegation) across the data provided by client.
- No logical understanding was established.

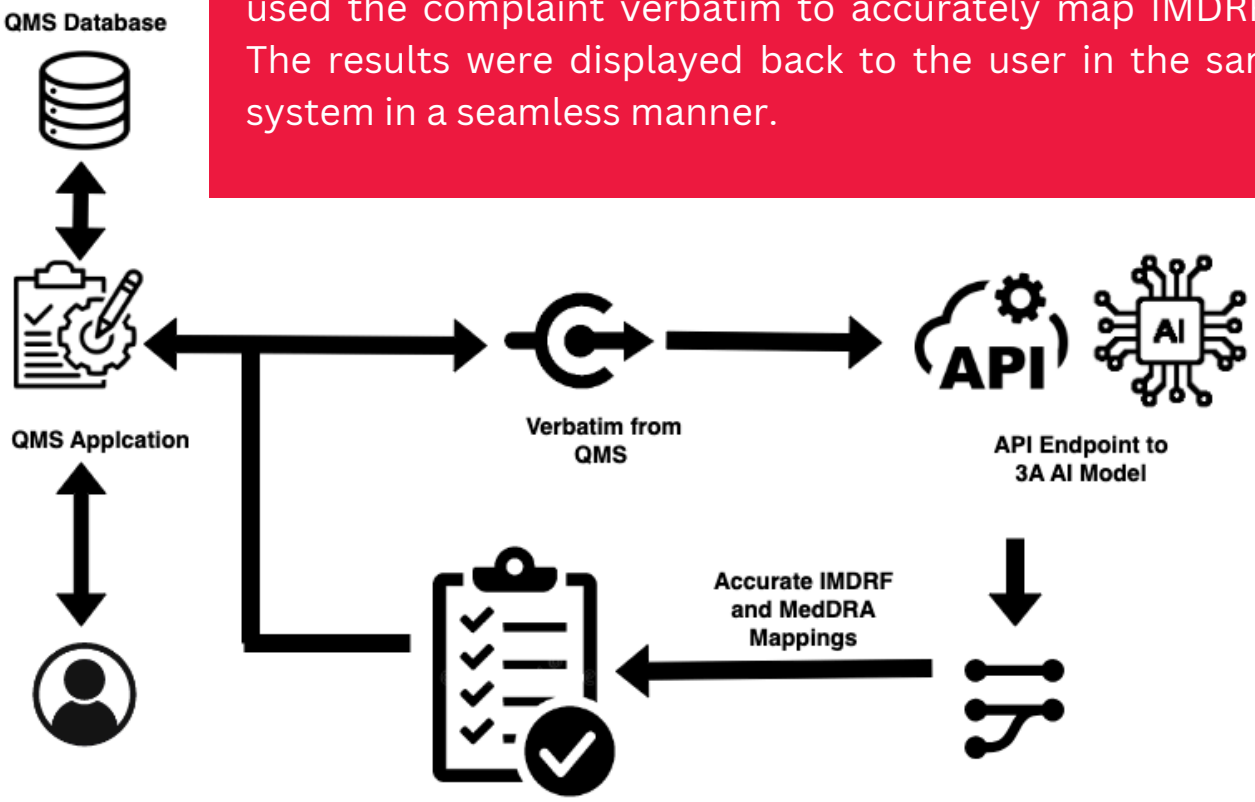
Customized LLM approach

Findings

- The model understood the nuances of the narratives and coding were appropriate with few fine tunings.
- Accuracy greatly improved with reaching 95% desired accuracy.

Case Study - Solution

The existing QMS system of the client was integrated with the IMDRF Coding AI Powered Solution created by 3Analytics, which used the complaint verbatim to accurately map IMDRF codes. The results were displayed back to the user in the same QMS system in a seamless manner.

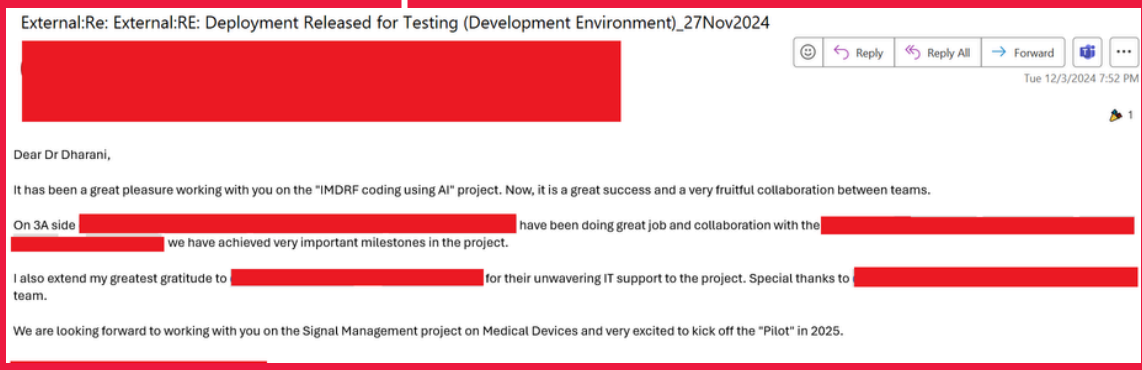


From 15 Minutes to avg.04-06 seconds

Time Saving

More than 95%

Accuracy



External:Re: External:RE: Deployment Released for Testing (Development Environment)_27Nov2024 [redacted]

Reply | Reply All | Forward

Tue 12/3/2024 7:52 PM

Dear Dr Dharani,

It has been a great pleasure working with you on the "IMDRF coding using AI" project. Now, it is a great success and a very fruitful collaboration between teams.

On 3A side [redacted] have been doing great job and collaboration with the [redacted] we have achieved very important milestones in the project.

I also extend my greatest gratitude to [redacted] for their unwavering IT support to the project. Special thanks to [redacted] team.

We are looking forward to working with you on the Signal Management project on Medical Devices and very excited to kick off the "Pilot" in 2025.

Customer Feedback:

"We have found that the majority of the predicted codes are relevant. Updates based on our feedback were completed quickly, the response time has been great, and there is consistency in the coding."

Conclusion

As the landscape of post-market surveillance evolves, embracing AI-driven automation is not just an option but a necessity for compliance, efficiency, and enhanced patient safety. The potential benefits far outweigh the challenges, positioning organizations for long-term success.

Call to Action

Organizations seeking to optimize their PMS processes should consider investing in AI-driven solutions. By doing so, they can enhance regulatory compliance, reduce costs, and ultimately improve patient outcomes. Contact us today to learn more about how our AI solutions can transform your post-market surveillance strategies.