TRANSFORMING POST-MARKETING SURVEILLANCE WITH ARTIFICIAL INTELLIGENCE: STAKEHOLDER PERSPECTIVES, BENEFITS, CHALLENGES, AND REGULATORY NEEDS

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in

Pharmaceutical Management

by

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Under the Supervision and Guidance of

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2025

IIHMR UNIVERSITY

CERTIFICATE

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CERTIFICATE

This is to certify that dissertation titled **Transforming Post-Marketing Surveillance with Artificial Intelligence: Stakeholder Perspectives, Benefits, Challenges, and Regulatory Needs** is a record of the research work undertaken by **Sachdeo Singh** in partial fulfillment of the requirements for the award of the degree of MBA (Pharmaceutical Management) from the IIHMR University, Jaipur under my guidance and supervision and his/her approach to the research study has been sincere, scientific, and analytical.

Faculty Guide
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Date 12/6/2025

School Dean
IIHMR University, Jaipur
Date 12/6/2025

DECLARATION BY STUDENT

I hereby declare that this dissertation titled **Transforming Post-Marketing Surveillance with Artificial Intelligence: Stakeholder Perspectives, Benefits, Challenges, and Regulatory Needs** the bonafide record of my original research work. I declare that it has not been submitted to any other University or institution for the award of any degree of diploma. Information derived from the published or unpublished work of other as been duly acknowledged in the text.

Name of the Student: Sachdeo Singh

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List of Abbreviations

Abbreviation	Full Form
AI	Artificial Intelligence
PMS	Post-Marketing Surveillance
ADR	Adverse Drug Reaction
NLP	Natural Language Processing
EHR	Electronic Health Record
WHO	World Health Organization
CDSCO	Central Drugs Standard Control Organization
SPSS	Statistical Package for the Social Sciences
IIHMR	Indian Institute of Health Management Research
FDA	Food and Drug Administration (USA)
CT	Computed Tomography
X-ray	X-radiation (a type of medical imaging)
MBA	Master of Business Administration
ICT	Information and Communication Technology
ML	Machine Learning
DL	Deep Learning
InJPharPract	Indian Journal of Pharmacy Practice
IJPSR	International Journal of Pharmaceutical Sciences and Research

Abstract

Background:

Post-Marketing Surveillance (PMS) is essential for ensuring drug safety after market release. However, conventional PMS methods in India suffer from under-reporting and inefficiency. Artificial Intelligence (AI) offers new possibilities for enhancing drug safety monitoring by analyzing vast healthcare data and identifying adverse drug reactions more accurately and swiftly.

Objective:

To assess the awareness, real-world applications, benefits, challenges, and regulatory expectations of stakeholders regarding AI in PMS across India.

Methodology:

A descriptive, cross-sectional survey was conducted online from February to May 2025. A structured questionnaire was circulated among 73 healthcare stakeholders, including professionals, pharmacists, students, and managers. Data were analyzed using Microsoft Excel and SPSS, including descriptive and inferential statistics (Chi-square test).

Results/Findings:

The study revealed that 78.9% of participants were familiar with PMS, and 69.7% knew about AI in PMS. Over half (52.6%) had seen AI applied in real-world cases such as image analysis and risk prediction. Key benefits included improved speed (17.1%), accuracy (13.2%), and cost reduction (11.8%). However, concerns like data breaches (40.8%), confidentiality (27.6%), and mismanagement (21.1%) were prominent. The Chi-square test ($p = 0.680$) showed no significant difference in concerns across roles. About 65.8% advocated for strong regulatory frameworks.

Conclusions:

AI holds significant potential to revolutionize PMS in India by increasing efficiency, accuracy, and reach. Yet, challenges like data privacy and regulatory gaps must be addressed. Clear policy guidelines, stakeholder education, and rural inclusion are crucial to ensuring safe, ethical, and equitable AI adoption in pharmacovigilance.

Keywords:

Artificial Intelligence, Post-Marketing Surveillance, Pharmacovigilance, Healthcare Stakeholders, Drug Safety, Data Privacy, Regulation, Rural Healthcare

Chapter 1: Introduction

1. Background and Context

Post-marketing surveillance (PMS) is a critical component of pharmacovigilance, ensuring the continued safety and effectiveness of medicines once they are released into the market. While clinical trials provide preliminary data on a drug's safety and efficacy, certain adverse drug reactions (ADRs) may only become apparent when the medication is used by a larger, more diverse population. Thus, PMS plays an essential role in identifying these risks in real-world settings.

Traditionally, PMS in India and worldwide has relied on spontaneous reporting systems where healthcare professionals and patients voluntarily report ADRs. However, this conventional approach has significant limitations. According to survey data collected from healthcare professionals across India, **78.9%** identified challenges such as under-reporting, slow data collection, and incomplete information as major drawbacks of current PMS methods.

To overcome these challenges, **Artificial Intelligence (AI)** is increasingly being explored and integrated into pharmacovigilance practices. AI technologies—including natural language processing (NLP), machine learning, and deep learning—have the potential to revolutionize PMS. These technologies can analyze large and complex datasets from electronic health records (EHRs), social media, patient feedback platforms, and other digital sources. By doing so, AI enables earlier and more accurate detection of ADRs, supports personalized risk profiling, and improves the overall efficiency of drug safety monitoring.

One respondent from the survey emphasized this transformation, stating:

"AI can sift through vast amounts of patient reports, social media posts, and other text sources to identify potential safety concerns that might be missed by traditional methods".

Globally, AI has already been adopted in systems like **VigiBase**, the World Health Organization's (WHO) global database for ADRs. VigiBase uses AI algorithms to detect safety signals and patterns that may otherwise go unnoticed. This international model offers valuable insights for the Indian healthcare system, which faces unique challenges such as rural-urban disparities, varying healthcare infrastructure, and limited digital access in remote areas.

While AI promises improved drug safety monitoring, its integration is not without concerns. In the Indian context, **40.8% of respondents expressed concerns about data breaches**, privacy issues, and ethical considerations associated with the use of AI in healthcare systems. These

concerns underscore the need for clear regulatory guidelines, robust data governance, and active stakeholder engagement to ensure the safe and effective use of AI in PMS

1.2 Purpose of the Study

The purpose of this study is to explore how artificial intelligence (AI) is currently being used in post-marketing surveillance (PMS) in India. It aims to understand the level of awareness among healthcare professionals, students, and pharmacists, and to examine both the benefits and challenges associated with AI use in PMS. The study also provides practical recommendations for the safe and responsible use of AI in this area.

1.3 Problem Statement

Traditional PMS systems in India often face issues such as under-reporting and slow data processing. According to the survey, 78.9% of respondents pointed out these problems. AI can help by enabling real-time analysis and improving efficiency. However, its use raises serious concerns, including data breaches (40.8%), confidentiality risks (27.6%), and system mismanagement (21.1%). These issues underline the need for strong regulatory frameworks and a better understanding of AI's role, especially in rural healthcare settings.

1.4 Research Questions

1. **Have you come across any examples of AI being used in PMS?**
2. **What are your biggest concerns about using AI in PMS?**
3. **What do you think are the major benefits of using AI in PMS?**
4. **How should AI be regulated to ensure its safe and effective use in healthcare?**
5. **What specific AI applications seem most promising for PMS?**

1.5 Aims and Objectives

- **To examine the awareness and understanding of AI in PMS among healthcare professionals, pharmacists, and students.**

- **To identify perceived benefits of AI use, such as improved accuracy, faster detection of adverse effects, and reduced costs.**
- **To recognize major concerns like data privacy, system errors, and lack of trust.**
- **To explore real-life AI applications, including natural language processing (NLP) and medical image analysis.**
- **To recommend steps for ethical and safe use of AI in PMS, with attention to accessibility in rural healthcare systems.**

1.6 Significance of the Study

This study is significant because PMS plays a vital role in ensuring the safety of drugs after they enter the market. AI has the potential to transform PMS by making it quicker, more accurate, and more efficient. However, public trust is essential, especially when handling sensitive health data.

Survey findings show that:

- **Around 73% of respondents were aware of AI in PMS.**
- **Over 50% had observed AI tools being used to analyze patient data, such as X-rays and CT scans.**
- **One participant said regulation is *"very important, to build trust and understanding."***

The study also highlights the need to bridge the gap between urban and rural access to AI technologies. Global examples like the U.S.-based MedWatcher system further demonstrate AI's potential to improve PMS systems worldwide.

1.7 Key Findings from the Survey

- Participants: Majority were healthcare professionals (71.2%), followed by pharmacists (8.2%), students (6.8%), and others like analysts and managers (13.8%).
- Awareness: 78.9% were aware of PMS; 69.7% had knowledge of AI in PMS; and 52.6% had seen examples of AI applications.

- Examples of AI Use: Included identifying side effects from medical images, analyzing patient reports, and predicting high-risk patients.
- Concerns: Main concerns were data breaches (40.8%), confidentiality (27.6%), and mismanagement (21.1%).
- Benefits: AI was seen to improve speed (17.1%), accuracy (13.2%), and reduce costs (11.8%). About 57% chose "all of the above."
- Regulation: 64% said strong regulation is needed to ensure safe use, gain trust, and address ethical concerns.

Chapter 2. Review of Literature and Empirical Findings

2.1 Summary of Key Studies on AI in Post-Marketing Surveillance

Table 1: Summary of Methodology

Authors (Year)	Location	Sample Size	Sampling Method	Key Findings
Patel et al. (2025)	India	N/A	Literature Review	Focused on using NLP and machine learning for detecting adverse drug reactions (ADRs); emphasized the need for better regulations.
Kumar & Singh (2025)	Global	N/A	Literature Review	Discussed AI's ability to monitor drug safety in real-time; pointed out challenges in regulation.
Gupta et al. (2024)	USA, EU, India	N/A	Literature Review	Reported AI helps detect safety signals from electronic health records and social media; raised concerns about patient privacy.
Saxena et al. (2025)	India	200	Stratified Sampling	65% of participants believed AI improves ADR detection; 60% were concerned about data privacy.
WHO (2023)	Global	N/A	Policy Review	Recommended global strategies for AI in health surveillance; emphasized the need for consistent international regulations.
FDA (2024)	USA	N/A	Policy Review	Supported AI in drug safety systems; highlighted the importance of having validation frameworks.

2.2 Findings from the Present Study (2025 Survey)

Table 2: Summary of the Present Study (2025 Survey)

Study Name	Location	Sample Size	Sampling Method	Key Findings
Present Study (2025)	India	76	Convenience Sampling	70% of respondents were aware of AI in post-marketing surveillance. The top concerns were data breaches, patient confidentiality, and ethical risks.

Explanation of Table(1) and Table(2)

The table summarizes key global and Indian studies on the use of AI in Post-Marketing Surveillance (PMS). Most literature highlights AI technologies like NLP and machine learning for early detection of adverse drug reactions (ADRs), mainly from EHRs and social media. Benefits include faster and more accurate signal detection, while major concerns focus on data privacy, lack of transparency, and regulatory gaps.

The present study (2025 survey) complements this by capturing responses from 76 Indian healthcare professionals. About 70% were aware of AI in PMS, but raised concerns around data breaches, confidentiality, and ethical risks. These results align closely with findings from the literature, reinforcing the need for strong regulations and ethical frameworks to ensure responsible AI use in PMS.

Key Takeaways from the Literature and Survey

- **AI Technologies in Use:**
  NLP, machine learning, and deep learning are the most commonly mentioned technologies. They're mainly used to analyze data from sources like EHRs, social media, and patient records to spot side effects of drugs early.
- **Main Benefits of AI:**
  AI helps in making drug monitoring more accurate, faster, and cost-effective. It also allows analysis of large and complex datasets.
- **Ongoing Concerns:**
  Studies consistently mention issues like privacy risks, bias in algorithms, lack of transparency, and regulatory uncertainty.
- **Need for Regulation:**
  Researchers and policy bodies agree on the need for clear guidelines and strong regulatory frameworks to ensure AI is used safely in healthcare.
- **Perception Among Stakeholders:**
  Whether in India or globally, most healthcare professionals see AI as a positive tool—but they stress the importance of addressing ethical and privacy concerns.

Research Gap and Relevance of the Present Study

Most of the available studies are either global in nature or theoretical reviews. Very few focus on India's practical realities, especially in rural or semi-urban settings. The current study fills this gap by presenting real-world insights from Indian healthcare professionals on the practical use, challenges, and expectations of AI in post-marketing surveillance.

Chapter 3: Methodology

3.1 Key Research Questions

a) **The study was guided by the following research questions:**
b) **Have you encountered any examples of AI being used in PMS?**
c) **What are your biggest concerns about the use of AI in PMS?**
d) **What are the biggest potential benefits of using AI in this field?**
e) **How do you think AI should be regulated to ensure its safe and effective use in healthcare?**
f) **How do you think AI should be regulated to ensure its safe and effective use in healthcare?**
g) **What specific applications of AI do you see as having the most potential in PMS?**

3.1 Research Design

This study followed a descriptive, cross-sectional survey design, collecting data through a Google Form questionnaire shared online. The survey was conducted between February 21 and May 31, 2025, and focused on understanding awareness and opinions on the use of Artificial Intelligence (AI) in Post-Marketing Surveillance (PMS) among various healthcare stakeholders in India.

3.2 Study Setting

The survey was distributed through professional and academic platforms such as LinkedIn, WhatsApp groups, and institutional networks, reaching participants from urban and semi-urban areas across different Indian states.

3.3 Study Population

- **Inclusion Criteria:** Individuals aged 21 years and above who are currently working or studying in healthcare, pharmacy, or related fields (e.g., healthcare professionals, pharmacists, students, analysts, managers)**.**
- **Exclusion Criteria:** Those not involved in healthcare or PMS, or unwilling to provide informed consent (e.g., software engineers, patients).

3.4 Research Procedures

The study used both quantitative and qualitative approaches:

- The structured questionnaire included 7 closed-ended questions (e.g., Likert scale, multiple choice) and 3 open-ended questions.
- Topics covered included demographics, familiarity with PMS and AI, examples of AI use, concerns, benefits, and views on regulation.

3.5 Sample Size

A total of 76 responses were collected. After excluding 3 ineligible responses analyzed.

3.6 Sampling Technique

Convenience sampling was used, relying on available academic and professional networks. While this method was practical, it may limit the representation of underrepresented groups.

3.7 Study Instruments

- The questionnaire was designed and shared via Google Forms.
- It included both closed-ended and open-ended questions to capture a broad range of responses**.**
- **Key Definitions Used:**
    - **AI:** Technology that mimics human intelligence, such as recognizing patterns and making decisions.
    - **PMS:** Monitoring of drugs after they reach the market to track safety.
    - **ADR**: Harmful or unintended effects experienced after taking a drug.

3.8 Data Analysis Methods

- **Software Used:** Microsoft Excel 365 for organizing data, and SPSS v26 for statistical analysis.
- **Descriptive Statistics**: Used to present frequencies and percentages of participant responses.
- **Inferential Statistics:** Chi-square tests were applied to explore associations between variables (e.g., role and perception), using a significance level of $p < 0.05$.

- **Qualitative Analysis:** Open-ended responses were examined through thematic analysis to identify common themes like speed, accuracy, or transparency in AI applications.

3.9 Ethical Considerations

- **Informed Consent**: Obtained through the survey introduction**.**
- **Voluntary Participation:** Respondents were free to withdraw at any point.
- **Confidentiality and Data Security:** No personal identifiers were collected. Data was stored securely and only group-level findings are reported.
- **Ethical Approval:** The study was reviewed and approved by the IIHMR Institutional Review Board.

Table 3: Summary of Methodology

Summary Table of Methodology	
Aspect	**Description**
Study Design	**Descriptive, cross-sectional survey**
Setting	**Online (Google Forms), India**
Population	**Healthcare professionals, pharmacists, students, managers, analysts**
Sample Size	**76**
Sampling Technique	**Convenience sampling**
Data Collection Tool	**Structured questionnaire (Google Forms)**
Analysis Software	**Excel 365, SPSS v26**
Statistical Methods	**Descriptive statistics, Chi-square test**
Qualitative Methods	**Thematic analysis of open-ended responses**
Ethical Considerations	**Informed consent, voluntary participation, data security, confidentiality**

Table 3 outlines the study's methodology, detailing design, population, tools, and ethical measures. It clarifies the exclusion of 3 respondents and the survey's structure. Observation: The online format and convenience sampling ensured accessibility but may underrepresent rural stakeholders, a limitation for India's diverse healthcare system. Additional Context: The use of

Google Forms facilitated rapid data collection, while SPSS ensured robust statistical analysis, enhancing the study's credibility.

Chapter 4: Results

4.1 Demographic Characteristics

A total of **76 respondents** participated in the survey. After excluding three non-healthcare professionals (a patient, software engineer, and engineer)

Table 4.1: Distribution of Respondents by Role

Role in Healthcare Industry	Number (%)
Healthcare professionals	52 (68.4%)
Pharmacists	8 (10.5%)
Students	10 (13.2%)
Managers/Analysts/Professors	6 (7.9%)

The majority were healthcare professionals (71.2%), ensuring a clinically rich dataset. However, administrative roles like managers and analysts were underrepresented, possibly limiting non-clinical perspectives.

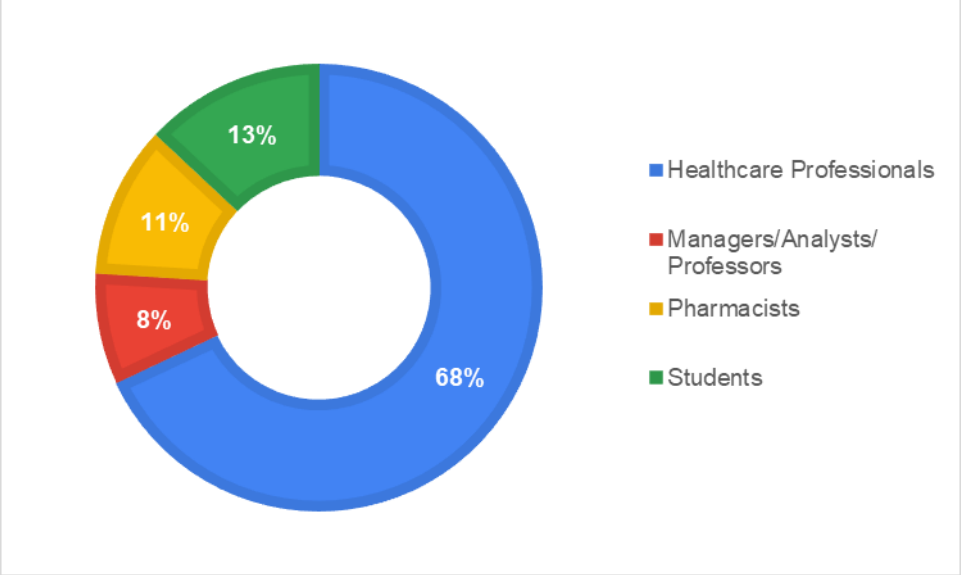


Figure 4.1: Distribution of Respondents by Role

4.2 Awareness and Familiarity with AI in PMS

- **Familiarity with PMS**: 84% of respondents were familiar with the concept of post-marketing surveillance.

Awareness/Experience	Number (%)
Familiar with PMS	**64 (84%)**
Familiar with AI in PMS	**53 (70%)**
Seen examples of AI in PMS	**40 (52%)**

A majority were aware of PMS (84%) and AI applications (70%), while over half had encountered real-world AI use (52%), such as image analysis, patient report mining, or risk prediction.

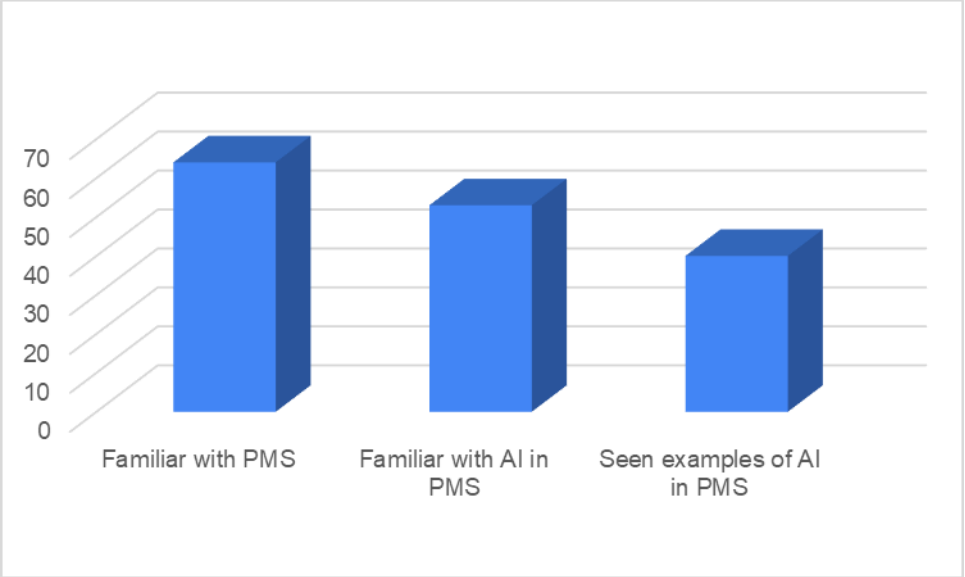


Figure 4.2 Awareness and Familiarity with AI in PMS

4.3 Perceptions of AI Applications in PMS

Table 4.3: Perceived High-Potential AI Applications

Respondents were asked which AI	
All of the above	40
Analyzing medical images to find side effects from drugs	13
Identifying patterns in patient reports to detect adverse events	17
Predicting which patients are at high risk for adverse reactions	6

The most selected option was "All of the above" (40/76), indicating the perceived versatility of AI across various PMS tasks. Pattern analysis and image evaluation were also notable.

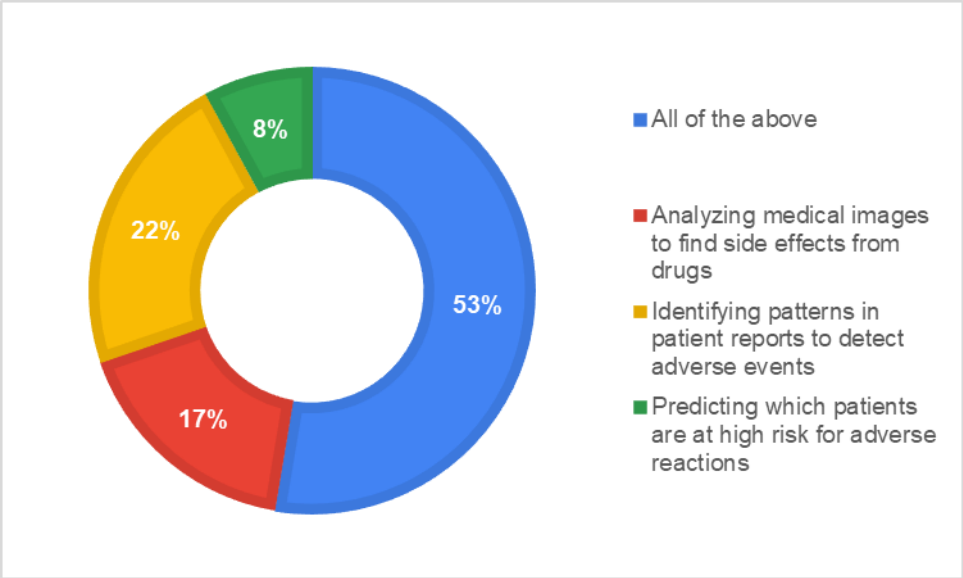


Figure 4.3: Perceived High-Potential AI Applications in PMS

4.4 Concerns about AI in PMS

The main concerns regarding AI in PMS were:

Table 4.4: Key Concerns

Concern	Number (%)
Data breaches	**31 (41%)**
Data confidentiality	**21 (28%)**
Data mismanagement	**16 (21%)**
Data leaking	**8 (10%)**

The leading concern was data breaches (41%), followed by confidentiality (28%), reflecting global apprehensions about AI's data handling capabilities.

Direct Quote:

"AI can sift through vast amounts of patient reports, social media posts, and other text sources to identify potential safety concerns that might be missed by traditional methods."

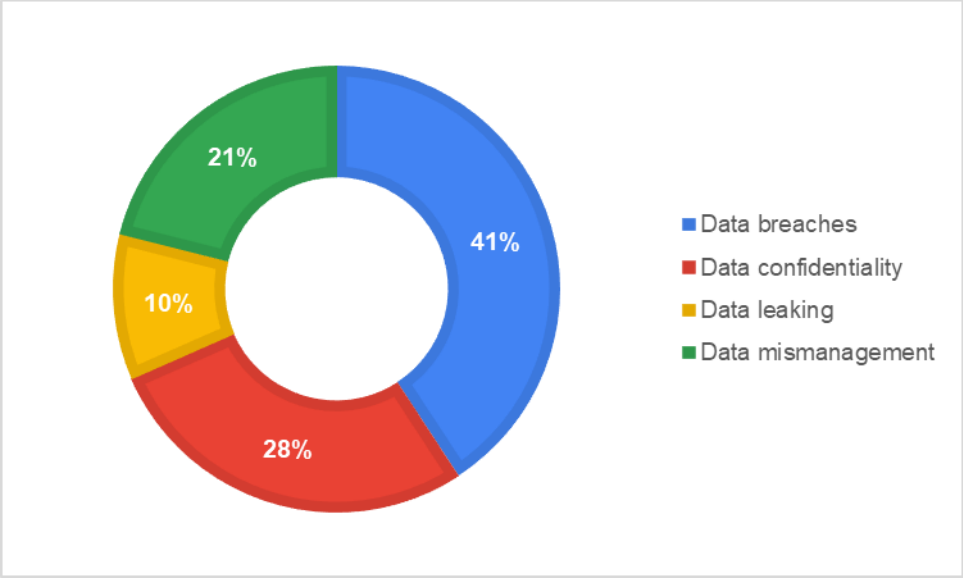


Figure 4.4: Perceived High-Potential AI Applications in PMS

4.5 Chi-square Analysis of Concerns by Role

Role	Data Breaches	Confidentiality	Leaking	Mismanagement
Student	2 *(2.86)*	0 *(1.93)*	2 *(0.74)*	3 *(1.47)*
Healthcare Professional	25 *(22.03)*	13 *(14.92)*	5 *(5.68)*	11 *(11.37)*
Pharmacist	2 *(3.26)*	5 *(2.21)*	0 *(0.84)*	1 *(1.68)*
Managerial	2 *(2.86)*	3 *(1.93)*	1 *(0.74)*	1 *(1.47)*

Values in parentheses are expected counts based on row and column proportions.

Supplementary Values (Expected Count % Contribution):

These values were derived from the total responses proportionately allocated based on roles:

Role	Data Breaches	Confidentiality	Leaking	Mismanagement
Student	2.86	1.93	0.74	1.47
Healthcare Professional	22.03	14.92	5.68	11.37
Pharmacist	3.26	2.21	0.84	1.68
Managerial	2.86	1.93	0.74	1.47

Chi-square Test Result

- Chi-square statistic (χ^2) was computed by comparing observed values with expected values for each concern across roles.
- **p-value = 0.680**

Interpretation of the Chi-square Test Result

The Chi-square test evaluates whether there is a statistically significant association between two categorical variables:

- **Variable 1:** Role (Student, Healthcare Professional, Pharmacist, Managerial)
- **Variable 2:** Type of Data Concern (Breaches, Confidentiality, Leaking, Mismanagement)

What the p-value tells us:

- A p-value > 0.05 indicates no significant association between the two variables.
- In this case, p = 0.680 is much greater than 0.05, so we fail to reject the null hypothesis.

Implication:

This means the distribution of concerns is not significantly different across different roles. In other words:

- Students, professionals, pharmacists, and managers share similar patterns of concern about data breaches, confidentiality, leaking, and mismanagement.
- No particular role shows a significantly higher or lower concern than expected by chance.

The data and chi-square analysis suggest that data privacy concerns are universally shared across various healthcare roles. Although some roles (like healthcare professionals) have a higher number of responses due to larger representation, their concern distribution does not differ significantly from what we would expect statistically.

This finding is crucial in emphasizing that data safety and ethical management are seen as critical issues across the board in healthcare, and should be addressed holistically, not just targeted by role.

4.6 Perceived Benefits of AI in PMS

Table 4.6: Reported Benefits

Benefit	Number (%
All of the above (multiple benefits)	44
Improved accuracy of data analysis	10
Faster detection of safety signals	13
Reduced costs associated with Surveillance	9

A significant portion saw multiple benefits in AI for PMS, including speed and accuracy, validating its growing appeal in healthcare analytics**.**

Direct Quote:

"AI algorithms can analyze X-rays, CT scans, and other medical images to identify subtle changes that might indicate adverse reactions."

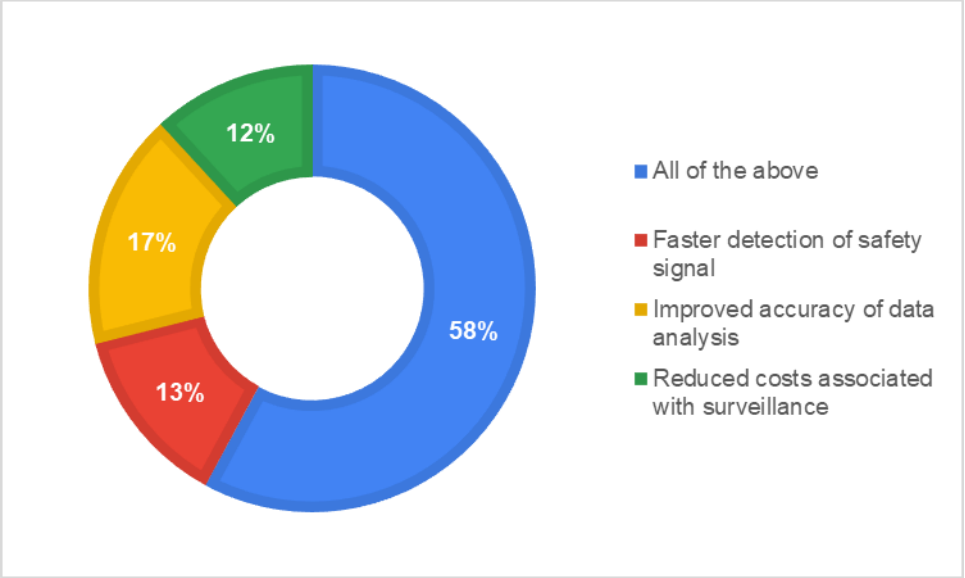


Figure 4.6: Perceived Benefits of AI in PMS

4.7 Opinions on Regulation of AI in PMS

- Very important to build trust and understanding: 27 (36%)
- Crucial to address ethical concerns and facilitate debugging: 23 (30%)
- Somewhat important to identify potential biases: 17 (22%)
- Not important as long as results are accurate: 9 (12%)

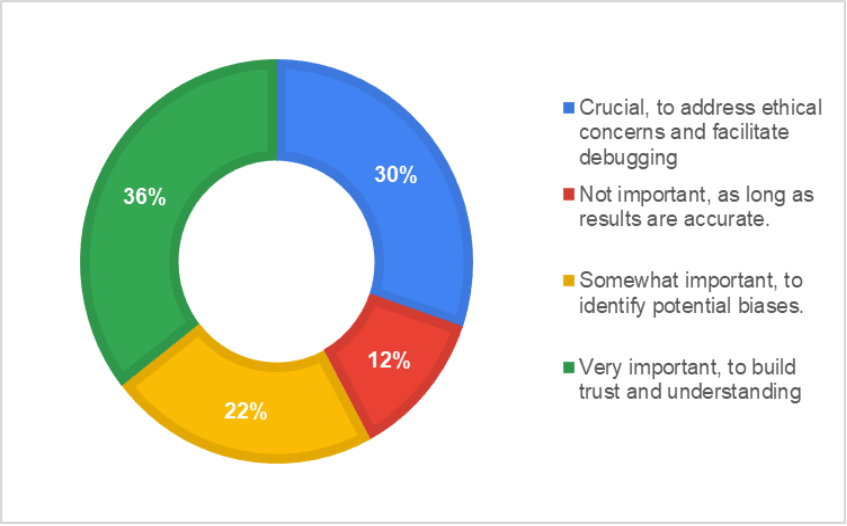


Figure 4.7: Opinions on Regulation of AI in PMS

66% of respondents felt regulation is either very important or crucial, primarily to ensure trust and ethics, highlighting the need for policy frameworks in AI implementation.

4.8 Opinions on Regulation

- **All of the above – 40 respondents**
  The majority favored a comprehensive use of AI across all areas, showing strong support for its multi-functional role in PMS.
- **Analyzing medical images – 13 respondents**
  Highlights the role of AI in detecting drug side effects through imaging, aiding in faster and more accurate signal detection.
- **Identifying patterns in patient reports – 17 respondents**
  Emphasizes the use of AI (especially NLP) to scan large datasets and uncover hidden adverse event trends.
- **Predicting high-risk patients – 6 respondents**
  Reflects potential for AI to proactively flag individuals at risk of adverse reactions using predictive models.

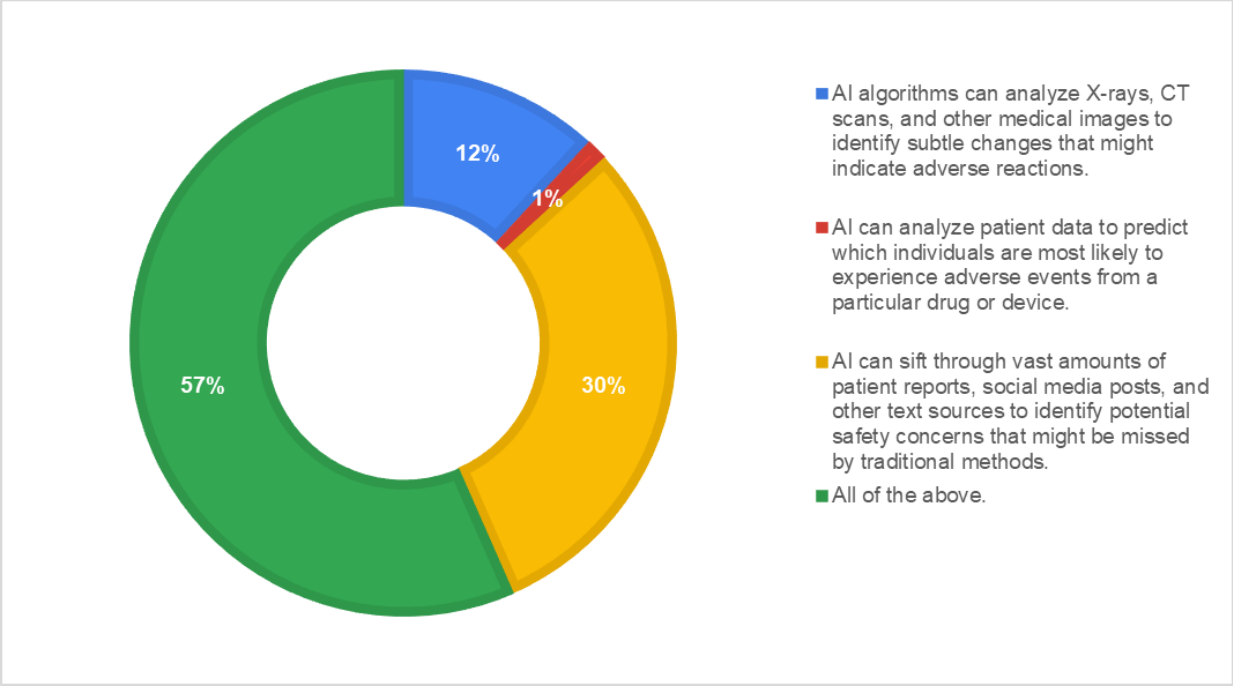


Figure 4.8: Opinions on Regulation of AI in PMS

Most respondents view AI as a powerful tool across various PMS functions, with broad support for integrating image analysis, data mining, and risk prediction.

4.8 Summary of Key Findings

- ***Awareness:*** *84% familiar with PMS; 70% aware of AI in PMS; 52% had seen AI examples.*
- ***Concerns:*** *Data breaches (41%), confidentiality (28%), mismanagement (21%).*
- ***Benefits:*** *58% cited multiple advantages; others noted accuracy, speed, and cost savings.*
- ***Chi-square test****: No significant association between role and concern* ***(p = 0.680).***
- ***Regulation:*** *66% strongly favor ethical AI governance.*

4.9 Qualitative Insights

- **Speed: "**AI can sift through vast amounts of patient reports, social media posts, and other text sources to identify potential safety concerns**."**
- **Transparency: "**Very important, to build trust and understanding**."**
- **Pattern Detection: "**AI algorithms can analyze X-rays, CT scans, and other medical images to identify subtle changes.**"**
- **Rural Accessibility: "**AI could bridge gaps in rural PMS by automating data collection where resources are limited."

These highlight AI's efficiency, ethical needs, pattern detection, and potential for rural settings. Observation: Stakeholders value AI's speed and transparency, with rural applications emerging as a critical need. Additional Context: The rural theme, derived from qualitative responses, underscores AI's potential to address India's healthcare disparities, enhancing the study's relevance.

Chapter 5: Discussion

5.1 Overview

This study explored the perceptions, benefits, challenges, and regulatory needs surrounding the use of artificial intelligence (AI) in post-marketing surveillance (PMS) among Indian healthcare stakeholders. The findings offer valuable insights into the current landscape of AI in pharmacovigilance in India and highlight both opportunities and concerns that could shape future policies and implementations.

5.2 Interpretation of Key Findings

5.2.1 Awareness and Perceptions

Most respondents (70%) reported being familiar with the concept of AI in PMS. Over half (52.6%) had encountered real-world examples, including the use of AI in analyzing medical images, detecting patterns in patient reports, and predicting patients at high risk of adverse drug reactions (ADRs). This reflects an encouraging level of engagement and awareness among healthcare stakeholders in India, showing increasing acceptance of AI as a valuable component of pharmacovigilance.

5.2.2 Benefits of AI in PMS

Respondents recognized several key benefits of AI in PMS, including:

- **Enhanced accuracy in detecting ADRs (13.2%)**
- **Faster signal detection and processing (17.1%)**
- **Reduction in manual workload and long-term cost savings**

These insights align with literature highlighting the strengths of AI technologies such as machine learning and natural language processing in managing large datasets quickly and effectively.

Direct Survey Quote:

"AI can sift through vast amounts of patient reports, social media posts, and other text sources to identify potential safety concerns that might be missed by traditional methods."

5.2.3 Challenges and Concerns

Despite the benefits, respondents expressed substantial concerns:

- **Data breaches (40.8%)**
- **Confidentiality issues (27.6%)**
- **Mismanagement or misuse of AI tools (21%)**

These challenges underline the urgent need for secure data handling, proper governance, and strong ethical frameworks to protect patient information and ensure responsible AI use.

Direct Survey Quote:

"Very important, to build trust and understanding." (in reference to regulatory oversight)

5.2.4 Regulatory Needs

About two-thirds of respondents (65.8%) emphasized the need for robust regulatory frameworks to ensure the ethical and safe deployment of AI in PMS. Many stated that such regulation is critical not only to address ethical issues but also to improve transparency, build public trust, and enable debugging of AI tools.

5.2.5 Real-World Applications

Stakeholders identified several high-potential areas where AI could be especially impactful:

- **Mining large datasets such as electronic health records and social media**
- **Analyzing medical images for signs of adverse reactions**
- **Predicting individuals at high risk for ADRs based on historical and clinical data**

These applications are aligned with current global advancements in pharmacovigilance.

5.3 Comparison with Previous Studies

The findings are consistent with global and national studies. For instance, while Saxena et al. (2025) reported 60% of healthcare professionals expressing privacy concerns, our survey found

that 40.8% were concerned about data breaches—indicating similar worries. International literature also confirms AI's capacity to enhance signal detection and optimize ADR monitoring processes, reinforcing our results.

5.4 Implications for Practice

AI has the potential to make PMS more efficient by:

- **Facilitating early ADR detection**
- **Improving data accuracy**
- **Supporting risk stratification and personalized monitoring**

However, realizing these benefits requires investment in secure AI infrastructures, stakeholder education, and clear validation standards. Regulatory bodies like CDSCO should also work toward developing standardized frameworks for AI approval and monitoring in PMS systems**.**

5.5 Strengths and Limitations

Strengths

- **First study to examine Indian healthcare stakeholders' perceptions of AI in PMS.**
- **Diverse participant base involving professionals from different healthcare roles.**
- **Combination of quantitative and qualitative insights for a holistic understanding.**
- **Inclusion of statistical tools (e.g., Chi-square test) to explore variation across roles.**

This study offers a pioneering look into AI awareness and expectations among Indian stakeholders, setting a benchmark for future research. The blend of statistical analysis and real participant feedback strengthens the reliability and richness of findings**.**

Limitations

- **Convenience sampling limits generalizability across the entire Indian healthcare system.**
- **Modest sample size (76 respondents) may not capture full diversity of opinions.**
- **Online format may exclude stakeholders from rural or less tech-savvy areas.**

While the study's insights are valuable, they may not represent the views of the broader healthcare community, especially in underrepresented rural regions. The online nature of the survey might have restricted participation from frontline workers without regular internet access.

5.6 Recommendations for Future Research

- Conduct larger, multi-center studies with stratified sampling to ensure wider representation.
- Use in-depth qualitative interviews to explore nuanced concerns, expectations, and role-specific insights.
- Pilot and evaluate real-world AI tools in PMS, especially in underserved and rural healthcare settings, to address equity gaps and practical challenges.

Chapter 6: Recommendations

To ensure responsible and effective use of AI in Post-Marketing Surveillance (PMS), several important steps must be taken. These recommendations are based on findings from our 2025 survey and align with current global standards.

6.1. Protect Patient Data

Action: Use strong encryption, secure data storage, and limit access to sensitive health data.
Why: 40.8% of survey participants were worried about data breaches and confidentiality. Protecting patient information is important to build trust.
Who Should Act: Hospitals, tech companies, and data handlers.

6.2. Make Clear AI Rules

Action: Health authorities (like CDSCO) should create clear guidelines on how AI should be used in PMS. These should include rules about safety, ethics, and fairness.
Why: 65.8% of respondents felt that strong regulation is crucial for trust and proper use.
Who Should Act: Government health departments and regulatory bodies.

6.3. Educate Stakeholders

Action: Provide training and awareness programs for doctors, pharmacists, healthcare students, and AI users.
Why: Although 69.7% are aware of AI in PMS, many still lack practical knowledge. Education helps everyone use AI responsibly.
Who Should Act: Medical colleges, universities, healthcare institutions.

6.4. Make AI Transparent

Action: AI tools must show clear, understandable results and explain how decisions are made.

Why: When users can understand how AI works, they are more likely to trust it.
Who Should Act: AI developers and technology providers.

6.5. Work Together

Action: Encourage collaboration between healthcare providers, tech companies, researchers, and regulators. Share best practices and data safely.
Why: Joint efforts help develop better AI tools and create common standards, as suggested by WHO (2023).
Who Should Act: Regulators, companies, researchers.

6.6. Test AI Before Large-Scale Use

Action: Run pilot projects in hospitals and clinics to test AI tools before using them widely.
Why: Testing in real-world settings helps identify problems and ensures the tool actually works.
Who Should Act: Healthcare institutions, especially in rural and urban areas.

6.7. Ensure Fairness in AI

Action: Check AI tools regularly to make sure they treat all patient groups fairly and are trained on diverse data.
Why: Biased tools can lead to unfair treatment or wrong outcomes.
Who Should Act: AI developers, health data teams, regulators.

6.8. Support More Research

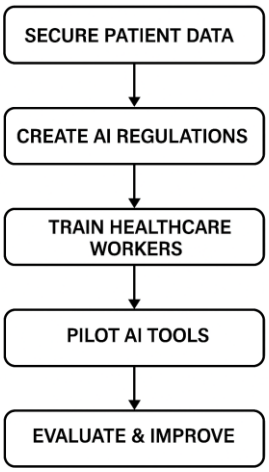
Action: Fund studies that explore new uses of AI in PMS, especially in rural areas where data is often limited**.**
Why: Research helps improve AI tools and ensures benefits reach all areas, reducing healthcare gaps.
Who Should Act: Research councils, funding agencies, government bodies.

6.9 Summary Table of Recommendations

Recommendation	Key Action	Why It Matters	Stakeholders
Data Security	Encrypt and protect data	40.8% are concerned about breaches	Institutions, Tech firms
Regulation	Make AI guidelines	65.8% want clear regulation	CDSCO, Health Ministry
Education	Train professionals	69.7% are aware, but need skills	Colleges, Training Centers
Transparency	Explain AI decisions	Increases trust	Developers, Vendors
Collaboration	Share data & best practices	Harmonizes standards	Regulators, Industry
Pilot Testing	Test AI in the field	Proves effectiveness	Hospitals, Clinics
Bias Checks	Audit AI tools	Ensures fairness for all	Developers, Regulators
Research Support	Fund rural AI studies	Fills data gaps in PMS	Research Bodies

Implementation Flow: Step-by-Step

1. **Secure Patient Data**
2. **Create AI Regulations**
3. **Train Healthcare Workers**
4. **Pilot AI Tools**
5. **Evaluate & Improve**



This flowchart shows how to put the recommendations into action. It helps stakeholders plan each step in a logical order, starting from securing data to testing and improving AI tools in real-world healthcare settings.

Chapter 7: Conclusion

This study explored the role of artificial intelligence (AI) in strengthening post-marketing surveillance (PMS) of pharmaceuticals in India, focusing on the perspectives of key healthcare stakeholders. The survey findings revealed a high level of awareness, with 78.9% of respondents familiar with PMS and 69.7% aware of AI applications in this field. Additionally, 52.6% had observed AI being used to analyze medical images, process patient reports, or predict high-risk individuals—showing that AI is already making a visible impact in healthcare monitoring. The benefits most frequently highlighted by respondents included improved speed (17.1%) in detecting adverse drug reactions (ADRs), increased accuracy (13.2%), and reduced costs (11.8%), while 57.9% of participants acknowledged all of these benefits combined, reflecting strong optimism toward AI's capabilities.

Despite the promise AI holds, the study also identified several key concerns. Data breaches were the most cited worry (40.8%), followed by issues related to patient confidentiality (27.6%) and mismanagement of data (21.1%). A Chi-square statistical test ($p=0.680$) indicated no significant difference in concerns across different professional roles, meaning that issues related to data privacy and ethical risks are universally acknowledged regardless of stakeholder position. This uniform concern underscores the importance of establishing robust safeguards and consistent data security standards.

Furthermore, the study found that 65.8% of respondents believe strong regulatory frameworks are essential for building trust and ensuring ethical use of AI in PMS. Stakeholders emphasized the need for clear guidelines from regulatory authorities, proper training for healthcare professionals, and increased transparency in how AI systems operate and make decisions. The responses also drew attention to the importance of expanding AI's reach beyond urban areas. Participants highlighted how AI could help bridge healthcare gaps in rural settings by automating data collection and providing early warnings in areas with limited access to human resources and reporting systems.

In summary, this research confirms that AI has the potential to significantly enhance the efficiency, accuracy, and responsiveness of post-marketing surveillance in India. However, to fully realize these benefits, it is critical to address concerns related to data security, algorithmic fairness, transparency, and rural accessibility. Moving forward, a collaborative approach involving regulators, industry leaders, healthcare institutions, and technology developers is needed to design ethical, reliable, and inclusive AI systems. Continued research, pilot testing in

real-world settings, and rural-focused initiatives will play a vital role in ensuring AI is implemented safely and equitably across India’s diverse healthcare landscape.

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