

# Leveraging AI in REMS: Insights and Applications

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**ANNUAL MEETING**

**COLLABORATE, STANDARDIZE,  
INNOVATE TO MODERNIZE REMS**

MARCH 11-12, 2026 • WESTIN  
ARLINGTON, VIRGINIA

# Session Objectives:

- Have an interactive discussion about Artificial Intelligence (AI)
- Present results from Innovation and Technology Workgroup's Survey on the Use of AI in REMS from December 2025 (n=9)
- Obtain updated results to select survey questions in realtime
- Capture opportunities, best practices, and lessons learned

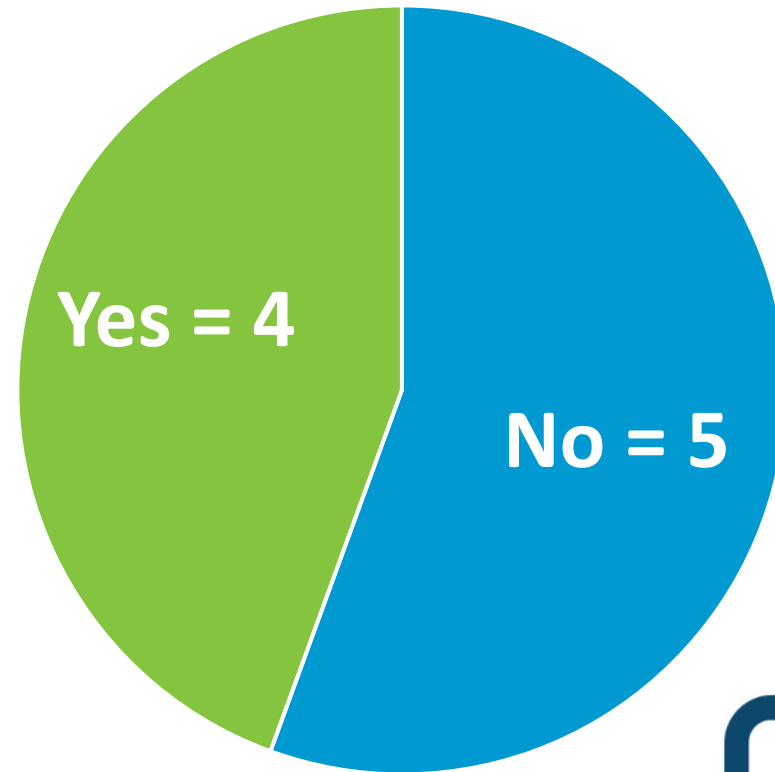


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## *Results from December 2025 Innovation and Technology Work Group Survey*

Are you currently using AI technologies to support the development, operation, and assessment of your REMS programs?



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Poll Question 1: Are you currently using AI technologies to support the development, operation, and assessment of your REMS programs?

- Open the Whova mobile app, click Agenda, click this session “Leveraging AI in REMS: Insights and Applications”, click Polls
- [POLL RESULTS](#)



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Poll Question 2: Please provide any feedback (positive or negative) of the use of AI?

- [POLL RESULTS](#)



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# Results from December 2025 Innovation and Technology Work Group Survey

## Positives

- **Efficiency and Analytics Gains:** AI is viewed positively for reducing manual effort, improving operational efficiency, accelerating trend identification, and enabling faster, more informed decision-making.
- **Improved Insights & Scalability:** Respondents value AI's ability to analyze large volumes of data quickly, generate objective insights (e.g., sentiment and trend analysis), and scale monitoring efforts without added resources.
- **Human-in-the-Loop Is Critical:** Confidence in AI adoption depends on close human review; respondents emphasized caution in regulated environments and the need for validation and oversight.
- **Uneven Adoption:** While some report strong positive experiences, others have not yet implemented meaningful AI use cases or received formal feedback.

## Concerns

- **Data Quality, Accuracy, and Hallucinations:** Concerns around low OCR accuracy, unreliable outputs, model bias, and hallucinations mean significant human review is still required.
- **Regulatory, AE, and Compliance Risk:** Strong apprehension about chatbots missing adverse events, late FDA reporting, loss of control over responses, and unclear regulatory alignment.
- **Training and Expertise Gaps:** Many teams feel unprepared to use AI effectively, citing limited prompt-writing skills, lack of SMEs, and insufficient training.
- **Governance, Cost, and Strategy Concerns:** Perceived AI hype without clear strategy or governance has led to fears of wasteful spending, unclear use cases, and resistance to adoption.
- **Change Resistance and Limited Adoption:** Internal resistance driven by job security concerns and uncertainty has resulted in few or no significant AI implementations in REMS to date.



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# Poll Question 3: What functional areas are you currently using AI on your REMS programs??

- [POLL RESULTS](#)



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Poll Question 4: Which functional areas do you plan to use AI in your REMS programs in the future?

- [POLL RESULTS](#)

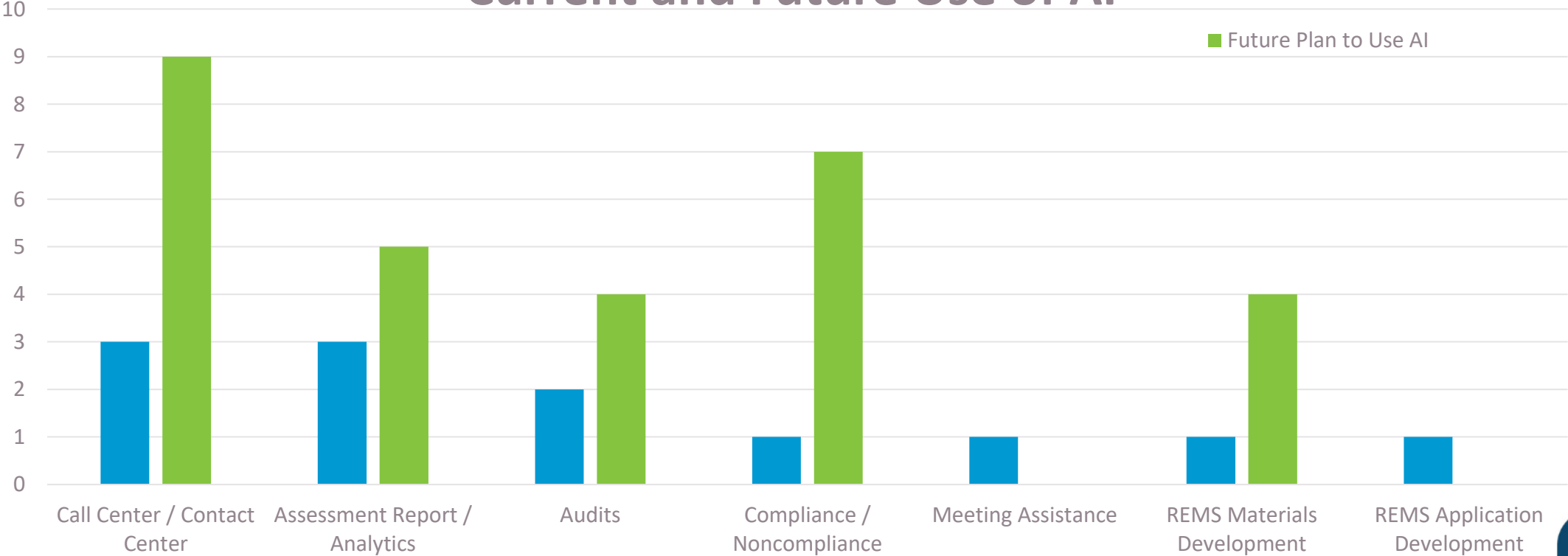


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# Results from December 2025 Innovation and Technology Work Group Survey

## Current and Future Use of AI



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# Results from December 2025 Innovation and Technology Work Group Survey

FUNCTIONAL AREA	CURRENT AI USE
Call Center Support	Chatbot pilots, call report drafting
Compliance Monitoring	Risk identification, trend analysis
Assessment Reporting	Automated summaries, analytics
Document Automation	Email summarization, meeting prep
PV Intake	Follow-up prioritization



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# Poll Question 5: What challenges have you faced in implementing AI within your REMS programs?

What challenges have you faced in implementing AI within your REMS programs? (Select all that apply)

- Input / Output (Data Quality Issues, e.g. output/validation/accuracy)
- Lack of Expertise
- General Compliance (Legal, Ethical, Regulatory - privacy/data security)
- High Costs
- Legal Concerns
- Ethical Concerns
- Resources
- Other...

- [POLL RESULTS](#)



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# Results from December 2025 Innovation and Technology Work Group Survey

CHALLENGE	IMPACT
Data Accuracy Issues	Manual review remains necessary, slowing efficiency gains
Regulatory Uncertainty	Fear of noncompliance and audit findings
Privacy & Security Risks	Potential exposure of sensitive data
Adverse Event Detection Risk	Missed safety signals in automated workflows
Lack of Expertise	Difficulty in prompt design and output validation
Change Resistance	Slower adoption due to job security concerns



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## Poll Question 6: What Benefits do you expect from the greater use of AI?

- [POLL RESULTS](#)



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# Results from December 2025 Innovation and Technology Work Group Survey

BENEFIT	DESCRIPTION
Efficiency Gains	Automation reduces manual effort and accelerates processes
Enhanced Data Analysis	Faster trend identification and anomaly detection
Improved Patient Safety	Early detection of compliance risks and adverse events
Cost Reduction	Lower labor costs and streamlined workflows
Scalability	Handle large data volumes without proportional resource increases



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# Lessons Learned

*Results from December 2025 Innovation and Technology Work Group Survey*

## Governance, Data Quality, and Human Oversight Are Foundational

- AI must be implemented with defined processes, high-quality data, and human-in-the-loop review to support compliant, audit-ready REMS operations.

## Targeted, Controlled Use Cases Demonstrate Value

- Narrow applications (e.g., vendor performance monitoring, quality/compliance report analysis) reduced manual effort while maintaining regulatory control.

## Sustainable Adoption Requires Training and Phased Implementation

- Clear business objectives, stakeholder education, and pilot-based scaling are essential to mitigate risk and support compliant integration



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# Thank You



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# Executive Summary of Survey Findings



## AI Adoption Benefits

Survey respondents reported efficiency gains, faster insights, cost reduction, and improved patient safety from AI adoption.

## Challenges and Concerns

Concerns include data accuracy, hallucinations in AI models, regulatory uncertainty, privacy, and risks of missing adverse events.

## Key Adoption Areas

AI is adopted in call center support, compliance monitoring, assessment reporting, and document automation within REMS.

## Success Factors and Recommendations

Success depends on human-in-the-loop oversight, governance frameworks, high data quality, training, and phased AI implementation.



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