



The Evolution of REMS Assessments: Intelligence Over Effort

*Leveraging AI in REMS Knowledge
Surveys & Assessment Reports*



Knowledge surveys and assessment reports have long been a requirement of most REMS programs

KNOWLEDGE SURVEYS

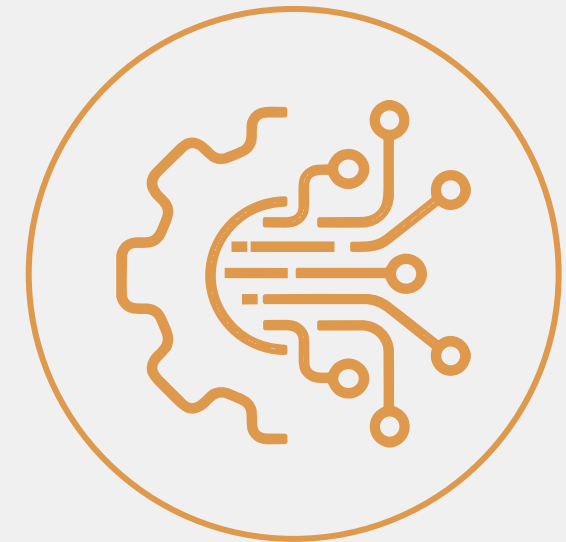
Tool fielded to REMS stakeholders to evaluate whether a REMS is achieving its educational goals

Design uses objective, scored questions to assess educational effectiveness of a REMS program, focusing on key risk messages

ASSESSMENT REPORTS

Report used to convey insights and data about REMS program performance relative to achieving educational and risk-management goals

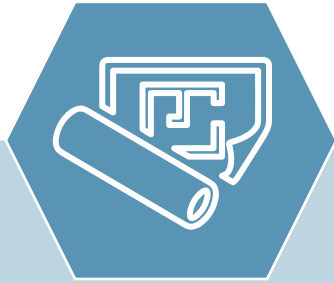
Primary tool used by FDA to determine if a REMS is still necessary and effective to ensure that the benefits of the drug outweigh its risks?



AI TECHNOLOGIES
STREAMLINE EFFORT
**FREEING REMS TEAMS TO
WORK SMARTER**

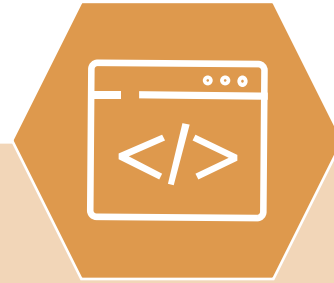
Focus is now on enhancing the clarity, strategic value, and effectiveness of program evaluation tools.

AI developed and trained specifically for surveys and the resulting data can support knowledge survey success in ways that Copilot & ChatGPT cannot



DESIGN

- Develop questions
- Rephrase for clarity
- Suggest answer options
- Apply best practices for surveys flow



PROGRAMMING

- Input questions into the fielding platform from text
- Catch grammar and logic issues
- Test programming (e.g., skip logic)



ANALYSIS

- Suggest meaningful analyses to apply
- Apply existing analysis approach to new data
- Create exportable tables and listings



REPORTING

- Draft narratives based on data analysis
- Apply new data to existing reporting template or sample report (e.g., last year's assessment report)

Specialized AI tools can apply multiple sources to create key assessment reporting deliverables, drawing on both content and format



1. REPORT TEMPLATE

- Regulatory documentation
- Prior assessment reports for same product
- Prior assessment reports for other REMS products



2. DATA MAP

- Regulatory documentation
- REMS system specifications
- Call center interface specifications



3. DRAFT REPORT

- Template and/or past reports
- Knowledge survey data
- Pharmacovigilance data
- REMS system data
- Contact center data



HUMANS IN THE LOOP
FOR SURVEYS &
REPORTS ENSURE
**REGULATORY CREDIBILITY,
SCIENTIFIC VALIDITY, &
INSIGHT ACCURACY**

Use of AI does not change the resources needs for these tasks, rather it reduces the administrative burden for focus on clear, meaningful insights



Q&A





THANK YOU

RIC Annual Meeting 2026

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Melissa C. Landers

Founder & Vice President

Shepherd Safety Services at Two Labs

REMS CHALLENGES

Challenges that increase risk, and limit program growth



Scaling Under Volume Pressure

Growing REMS enrollment strains teams, creates bottlenecks, and increases the risk of processing errors that can compromise patient safety.



Incomplete Form Submission

Missing stakeholder data drives repeated back-and-forth, creating data gaps, and costly rework.



Slow Stakeholder Onboarding

Manual fax and PDF workflows slow stakeholder certification and enrollment, delaying patient access and adding unnecessary burden to the REMS program.



Delayed Noncompliance Detection

Delayed identification of issues can lead to compliance gaps, increased scrutiny from regulators, and potential harm to patients if corrective actions are not taken promptly.



AI ACROSS THE REMS LIFECYCLE



UBC RAPID: AI Non-compliance Risk Intelligence

- Trend & anomaly detection across REMS data to identify safety issues early
- Proactively flag potential risks across healthcare providers and sites
- Human-in-the-loop review & remediation



AI-Enhanced REMS Form Processing

- Multi-channel automated intake: Fax, Email
- AI-powered data extraction and validation with controlled human review
- End-to-end auditability to support inspections and regulatory requirements



AI-Enhanced Web Chat

- Real-time AI monitoring of stakeholder chat transcripts
- Automated identification of potential reportable events with escalation support
- Secure interactions with complete audit-ready records



AI-Enhanced Stakeholder Audit

- AI-assisted review of audit documentation to identify compliance gaps
- Human-validated findings with full transparency and control
- Prepares compliance audit summaries



OUTCOMES



Scalable Operations

Grow without proportional headcount increase



Faster Standard Reviews

Accelerated processing across forms, stakeholder audits, and inquiries



Reduced Rework

Fewer data gaps and manual follow-ups



Earlier Risk Detection

Proactive identification of noncompliance risk



Stronger Oversight

Full traceability with comprehensive audit trails

