



REMS Performance Assessments

The Common Element to REMS

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When developing a Risk Evaluation and Mitigation Strategy (REMS) to support the safe and appropriate use of a product, one question arises in the design of every program: “How do I evaluate whether the REMS program is effective in protecting patients from harm?”

Actually, the first question may be “Does my product need a REMS?” Title IX of the Food and Drug Administration Amendments Act of 2007 (FDAAA) requires sponsors to submit a Proposed REMS as part of an application prior to product approval if interventions beyond labeling are necessary to assure “the benefits of the drug outweigh the risks.”

REMS may consist of any one or more of the following elements:

- **Medication Guide** – a document written for the patient, highlighting the most important safety information the patient needs to know
- **Communication Plan** – a description of the company’s plan to educate healthcare professionals on the safe use of the product to support implementation of the REMS
- **Elements to Assure Safe Use** – a description of controls required to mitigate a serious risk; elements could include physician or pharmacy certification, specialty distribution, or a patient registry
- **Implementation System** – a detailed description of how certain elements to assure safe use will be implemented
- **Timetable for Submission of Assessments** – the frequency of assessing REMS performance in achieving its goal(s)

But the only element that is common to ALL REMS is an assessment of program performance.

FDA’s minimum expectation is that companies answer the following questions no less frequently than at 18 months, 3 years, and 7 years after REMS approval:

- Is the program effective in mitigating the identified risk(s)?
- Are the communications in the program conveying a clear safety message? (For example -- Do patients understand the information contained in the Medication Guide or in the Patient Brochure?)
- Has the program helped to prevent patients from being exposed to the identified risk(s)?

As one means of assessing program performance, a company may choose to conduct **surveys of targeted stakeholders** (physicians, patients, or pharmacists) to periodically assess their knowledge and understanding of the risk(s) as conveyed through the REMS communications.

The objective of these periodic REMS knowledge and understanding assessments is to track stakeholder recognition and comprehension of the product risk(s) to inform continuous improvement of the REMS program. Surveys can be designed to provide specific FDA-reportable information, such as:

- Prescriber or patient demographics
- Composite knowledge/understanding assessment scores
- Answers to individual questions and trends over time
- Receipt of Medication Guides by patients from pharmacists (if applicable) to assess distribution compliance

Questions remain as to how a company sets a threshold for performance that satisfies FDA requirements and when surveys are inadequate for assessing performance. These are topics requiring customized discussions and solutions. A good place to start is with a discussion of benchmarks that may guide setting thresholds for your product.