

# REMS: Risk Evaluation & Mitigation Strategies



With the passage of FDAAA Title IX, FDA now has broad powers to require expanded post-market risk management for both new and previously approved prescription drugs.

PEGUS is already engaged supporting clients in several current REMS (Risk Evaluation and Mitigation Strategy) initiatives.

We have expertise and experience in the following key REMS-related areas:

- **Recruiting specialized physician and patient groups** for assessments
- **Comprehension studies** to evaluate medication guides, package inserts, boxed warnings and other written materials
- **Observational / behavioral studies** to evaluate real-world compliance and outcomes
- **Patient Registries and AE Monitoring**
- **Other innovative methods** to address your specific REMS needs

We would be happy to discuss your REMS needs.

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