Risk Evaluation and Mitigation Strategy (REMS)

Extensive Multidisciplinary Experience Enables Us to Deliver End-to-End REMS Solutions

Evidera, PPD's Peri- and Post-Approval business, has a broad and comprehensive range of experience in Risk Evaluation and Mitigation Strategy (REMS) programs. With a long history in Phase III-IV studies, including post-authorization safety studies, we are well positioned to help clients manage the risk and safety of their products in the real world. This includes the design, implementation, modification, and assessment of REMS programs.

Why Evidera?

- **A dedicated risk management team** aligned with multidisciplinary experts with a proven track record of scientific and operational success
- **Access to in-house expertise**
  - Including epidemiology, risk management, regulatory, pharmacovigilance, interventional and observational studies, health economics, outcomes research, market access, IT, medical communications/call center, medical writing, registries, and project management
- **REMS Technology platform**
  - Simplify the complex logistics of program management
  - Integrate operations and stakeholder tools
  - Provide sponsor transparency and control
- **Global capabilities for scalable programs and broader safety activities, including EU Risk Management Plans (RMPs), etc.**

11+
years of REMS experience

>40%
of active REMS programs touched

25+
REMS programs since 2010

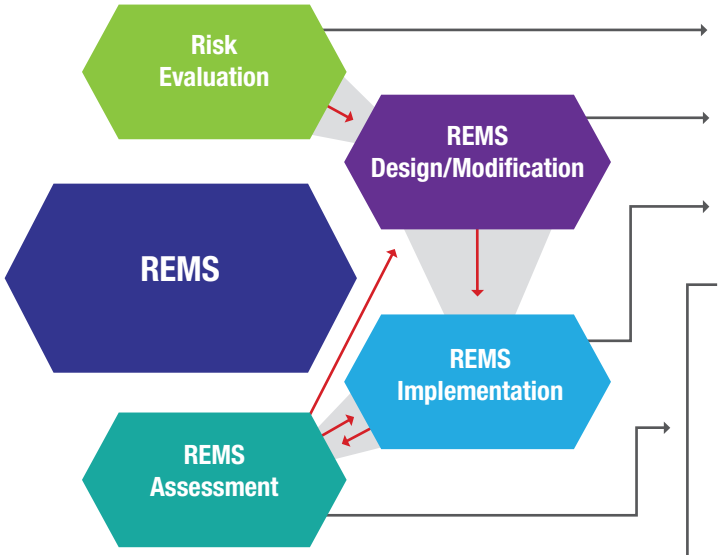
Experience

Having safety strategists with keen insights and understanding of the latest FDA requirements, an operational staff focused on excellence, and access to a wide array of scientists and consultants, we are well positioned to help you address all of your REMS needs successfully. Our experts have designed, implemented, and assessed REMS programs ranging from simple Medication Guide and Communication Plan REMS to complex multi-sponsor and ETASU REMS across a multitude of therapeutic and disease areas, including:

Rare Diseases | *Gastro-enterology* | *Endocrine and Metabolic* | *Cardiology* | *Psychiatry* | *Obstetrics and Gynecology* | *Opthalmology* | *Infectious Diseases*

Neurology | *Respiratory* | *Oncology* | *Hematology* | *Rheumatology* | *Dermatology* | *Immunology*

REMS Needs and Example Output



Example Output

Consulting to evaluate known or potential risk and determine the likelihood of a REMS requirement

Consulting to determine appropriate REMS design; Development of REMS and REMS Supporting Document

Distribution of Communication Plan materials or execution of Implementation System

Assessment of stakeholders' understanding or risk via surveys

Assessment of compliance with REMS requirements, if Elements to Assure Safe Use (ETASU)

Other monitoring requirements (e.g., Adverse Event summaries, drug utilization studies)

Development of REMS Assessment Reports

REMS Services

Risk Evaluation

- Identify risk
- Determine likelihood of REMS requirement

REMS Design/Modification and Document Development

- REMS Document
- REMS Supporting Document
- REMS materials (e.g., Medication Guide, Dear Healthcare Provider [HCP] Letter, Stakeholder Enrollment Forms)
- Product registry

REMS Vendor Transfers

- Program transitions
- Data migration

Single Shared REMS Project Management Office (PMO)

- Project, financial, vendor, and sponsor management

REMS Implementation

- Stakeholder (HCP/pharmacy) training and certification
- Patient enrollment
- REMS material distribution
- Managed distribution of product
- REMS support/contact center
- REMS website
- Pharmacovigilance
- Product registry
- REMS database

REMS Assessment

- Customized stakeholder surveys
- Assessment report development

Drug Master File (DMF) Holder

- Preparation and submission of REMS deliverables for Single Shared REMS to the FDA

REMS Consulting

- Regulatory strategy development
- Review and modification of existing REMS

Visit evidera.com to learn more about our REMS capabilities.

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