REMS

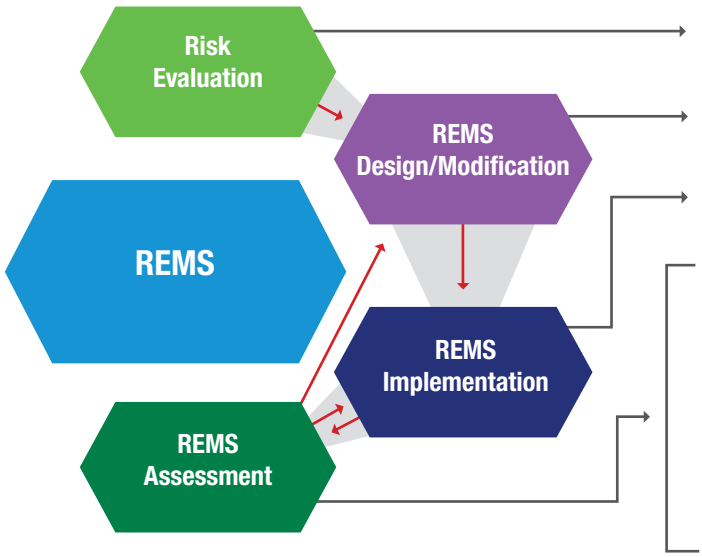
Evidera, PPD's Peri- and Post-Approval business, has a broad and comprehensive range of experience in Risk Evaluation and Mitigation Strategy (REMS) programs. With a long history in risk evaluation to identify known or potential serious risks associated with a product, we are well positioned to help clients determine the likelihood of receiving a REMS requirement, and then work together to design, implement, modify, and assess REMS programs when needed.

Extensive experience and proven processes enable us to deliver REMS solutions quickly and efficiently. Our scientists have expertise in the development of FDA-approved REMS documents, supporting documents, educational materials, survey instruments and methodologies, and assessment reports, while our dedicated, industry-leading operational team has experience in the management of both single-sponsor and large, multi-sponsor REMS.

Why Evidera?

- **A dedicated risk management team aligned with regulatory, safety, and epidemiology 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.**

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 of 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

U.S. +1 301 654 9729 EUR +44 (0) 208 576 5000 info@evidera.com evidera.com

REMS Services

Risk Evaluation

- Identify risk
- Determine likelihood of REMS requirement

REMS Design/Modification and Document Development

- REMS Document
- REMS Supporting Document
- REMS educational materials (e.g., Medication Guide, Dear Healthcare Provider [HCP] Letter)

Single Shared REMS Project Management Office (PMO)

- Project, financial, and vendor 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 Assessment

- Customized stakeholder surveys
- Assessment report development

Drug Master File (DMF) Holder

- Submission of REMS deliverables for Single Shared REMS to the FDA

REMS Consulting

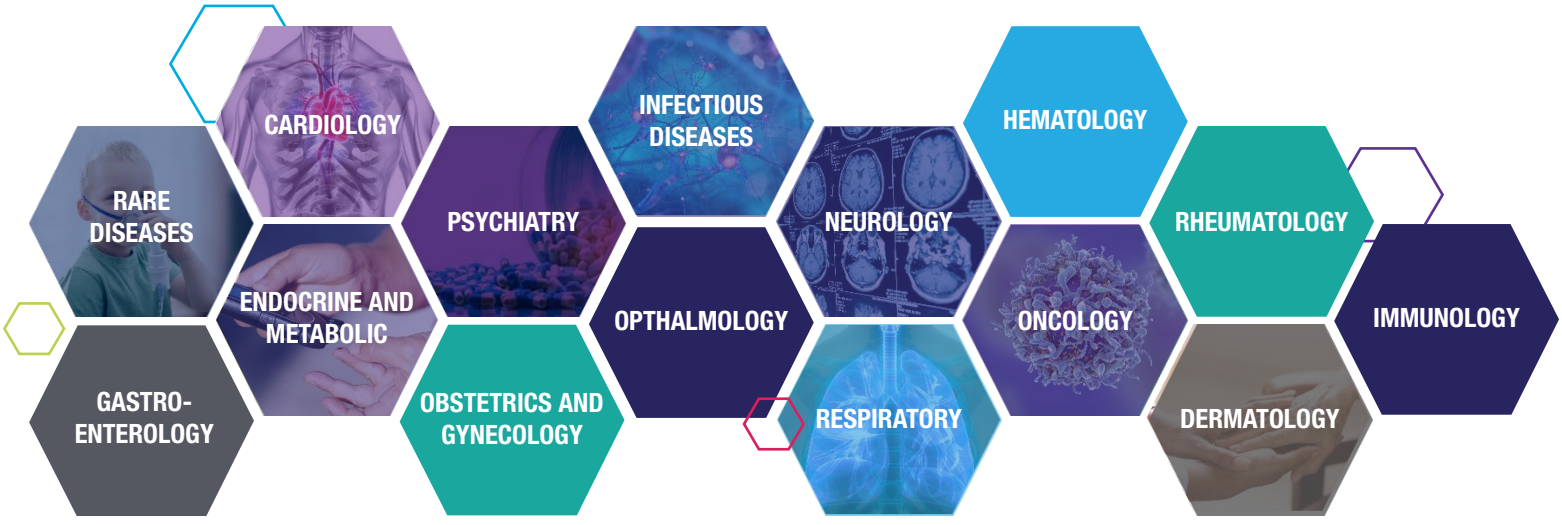
- Regulatory strategy development
- Review and modification of existing REMS

Experience

We have a team of dedicated REMS professionals with experience dating back to 2010 and spanning an expansive variety of therapeutic areas. 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.

Risk Evaluation	REMS Design/ Modification and Document Development	Single Shared REMS PMO	REMS Implementation	REMS Assessment	REMS Consulting

We have experience across our REMS offerings in the following therapeutic and disease areas.



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