

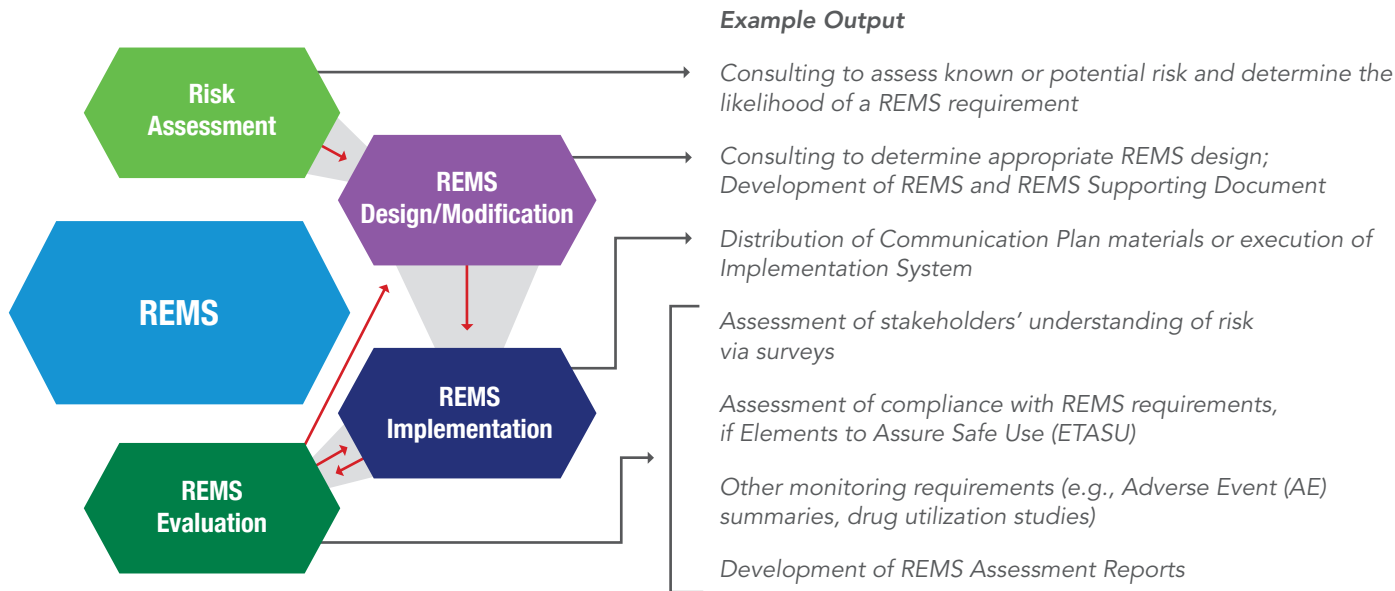
Evidera, PPD’s Peri- and Post-Approval business unit, has a broad and comprehensive range of experience in Risk Evaluation and Mitigation Strategy (REMS) programs. With a long history in risk assessment to identify known or potential serious risks associated with a product, we are well positioned to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

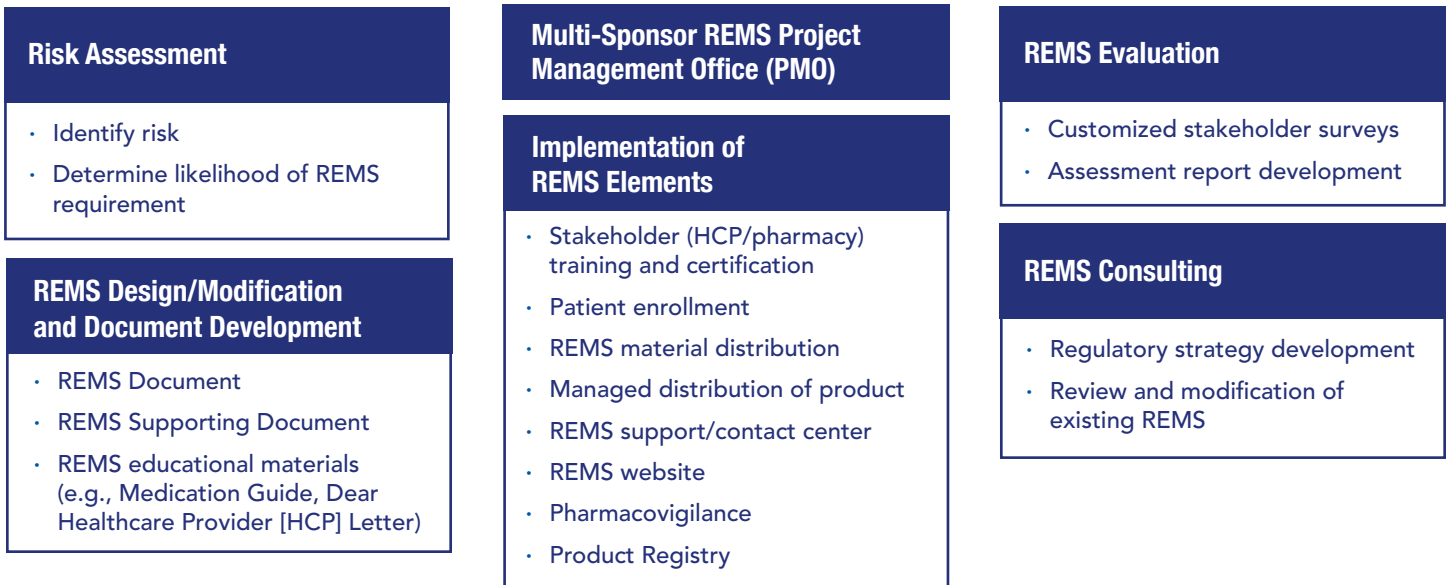
Why Evidera?

- **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 program management
- **PPD’s REMS Technology Platform – developed in partnership with Microsoft® and the first of its kind to:**
 - 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



REMS Services



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 perfectly positioned to help you address all of your REMS needs successfully. Our experts have designed, implemented, and evaluated REMS programs ranging from simple Medication Guide and Communication Plan REMS to complex multi-sponsor and ETASU REMS.



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

