

## Regulatory agencies and sponsors are under enormous pressure to ensure the safety of marketed drugs.

Companies must perform pre-market assessment and evaluation of potential risks associated with a product to determine the benefit/risk balance associated with a product and measures that will be put into place to minimize the risk of adverse medical consequences. In the U.S., post-marketing requirement studies and REMS are increasingly being mandated as a condition of approval for new products with potential safety issues.



REGISTRAT-MAPI provides Sponsors the following Risk Management design, implementation, and support services.

- Risk Management consulting
- Design and execution of Risk Management interventions including:
  - Risk Evaluation and Mitigation Strategies (REMS)
  - European Union Risk Management Programs (EU-RMP)
  - Performance Linked Access Systems (PLAS)
- Pregnancy exposure registries
- Post-marketing requirement studies
- Observational studies
- Disease and product registries
- Large simple safety studies
- Epidemiology studies
- Safety surveillance studies

### EU-RMP

European Risk Management Plans (EU-RMP) are required for all products submitted for registration in the European Union. These are written documents that outline the product risks, the post-marketing surveillance plan and the risk minimization activities.

We have expertise in working with sponsors to develop these plans to meet the needs of regulatory agencies in Europe. We also provide support for the development and maintenance of these documents as part of required periodic updates to the European regulatory authority (EMA).

### REMS

REMS is a component of Title IX of the FDA Amendments Act (FDAAA) passed in September 2007. A REMS is a strategy to manage a known or potential serious risk associated with a drug or biological product. A REMS will be required if FDA finds that a REMS is necessary to ensure that the benefits of the drug or biological product outweigh the risks of the product, and FDA notifies the sponsor.

Considerations for REMS for new drugs or biologics include:

- Size of the population likely to use the drug
- Seriousness of the disease or condition indicated for the drug
- Expected benefit of the drug with respect to such disease or condition
- Expected duration of treatment with the drug
- Seriousness of any known or potential adverse events associated with use of the drug
- Whether the drug is a new molecular entity

Elements to assure safe use as defined in FDAAA include:

- Healthcare providers who prescribe the drug have particular training or experience, or are specially certified
- Pharmacies, practitioners, or health care settings that dispense the drug are specially certified
- The drug is dispensed to patients only in certain health care settings, such as hospitals
- The drug is dispensed to patients with evidence or other documentation of safe use conditions, such as laboratory test results
- Each patient using the drug is subject to certain monitoring
- Each patient using the drug is enrolled in a registry (see section 505-1(f)(3) of the Act)
- To assure safe product use regulatory agencies may mandate controlled distribution or a PLAS to link product access to laboratory testing results or other documentation