Thermo Fisher SCIENTIFIC

Risk evaluation and mitigation strategy (REMS)

Extensive multidisciplinary experience in delivering end-to-end REMS solutions

The PPD™ clinical research business of Thermo Fisher Scientific offers a broad and comprehensive range of expertise in risk evaluation and mitigation strategy (REMS) programs, backed by a strong history in Phase III-IV studies. We are a full-service strategic REMS business partner, delivering operational excellence and innovative solutions supported by agile technology to meet your needs. Our solutions ensure that REMS sponsors confidently and effectively fulfill regulatory REMS and risk management programs requirements by providing adaptable solutions to navigate evolving regulatory demands.

Our team of dedicated REMS professionals specialize in the design, development, implementation, management, modification, and assessment of REMS programs.

In-house expertise
Ability to quickly tap into additional resources if needed across epidemiology, risk management, regulatory, pharmacovigilance, IT, medical communications, medical writing, registries, and project management

15+ Indications
across all major therapeutic areas including cardiology, immunology, oncology, endocrinology, neuroscience, and rare diseases

Keen understanding
of latest FDA requirements and industry trends

35+
REMS programs since 2010
Provided services, including risk evaluation, REMS design / modification and document development, PMO, REMS implementation, REMS assessment, REMS consulting, and DMF holder

Simple MG/CP REMS to complex ETASU REMS
Single and Multi-sponsor REMS

Proven processes
to deliver REMS solutions quickly and effectively; cost-effective matrix approach to resourcing; commitment to quality

Full-service REMS provider

Risk evaluation	REMS design / modification and document development	REMS implementation	REMS assessment
• Identify risk • Determine likelihood of REMS requirement	• REMS document • REMS supporting document • REMS materials (e.g., medication guide, Dear HCP letter, enrollment forms)	• ETASU – HCP / HCS training and knowledge assessment – HCP / HCS certification – Patient enrollment – Manage distribution of product – Compliance monitoring • Communication plan • REMS support / contact center • REMS website / database	• Quantitative / qualitative assessments of REMS effectiveness – Program outreach – Program implementation – Knowledge and behavior surveys – Safe use behaviors – Health outcomes • Assessment report development

Single shared REMS project management office (PMO)	• Project, financial, and vendor management
Drug master file (DMF) holder	• Submission of REMS deliverables for Single Shared REMS to the FDA
REMS consulting	• Regulatory and strategy development • Review and modification of existing REMS

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REMS experience in all major therapeutic areas

Cardiology	Immunology	Opthalmology
Dermatology	Infectious diseases	Psychiatry
Endocrine & metabolic	Neurology	Rare diseases
Gastroenterology	Obstetrics & gynecology	Respiratory
Hematology	Oncology	Rheumatology

Services for 35+ REMS programs

Project management

- >35 REMS
- PMO for 2 shared REMS
  - 1st waiver-granted REMS
  - Nearly 30 sponsors combined
- DMF holder for 3 REMS

REMS design

- >10 REMS full design and document development
- Consulting for most of REMS clients

REMS implementation

- Communication plan for 2 REMS
- ETASU for 12 REMS
- Contact center for 27 REMS

REMS assessments

- >65 assessment reports
- >75 REMS surveys among >15,000 stakeholders

Learn more at **ppd.com**