

Risk Management Plans at a Glance

Strategic RMP support for evolving global regulatory expectations

Risk Management Plans are no longer static regulatory documents. As safety data evolves, regulatory expectations shift, and local requirements diverge, sponsors need RMPs that are scientifically robust, operationally practical, and ready for regulatory scrutiny.

PrimeVigilance supports pharmaceutical, biotech, and generic manufacturers with RMP strategy, preparation, updates, and lifecycle maintenance across global and regional markets.



Three questions every RMP must answer

A strong RMP should support continuous evaluation of product safety and benefit-risk throughout the lifecycle.

Has the benefit-risk profile changed?

Have risks been adequately quantified?

Has patient safety been maintained?

PrimeVigilance helps sponsors answer these questions through structured safety evaluation, regulatory intelligence, medical writing expertise, and practical risk minimization support.

RMP support across the product lifecycle

PrimeVigilance provides flexible RMP support from development through marketing authorization and post-authorization maintenance.

Initial RMP preparation

Development of RMPs for innovative products, biosimilars, generics, and well-established use products.

RMP updates and maintenance

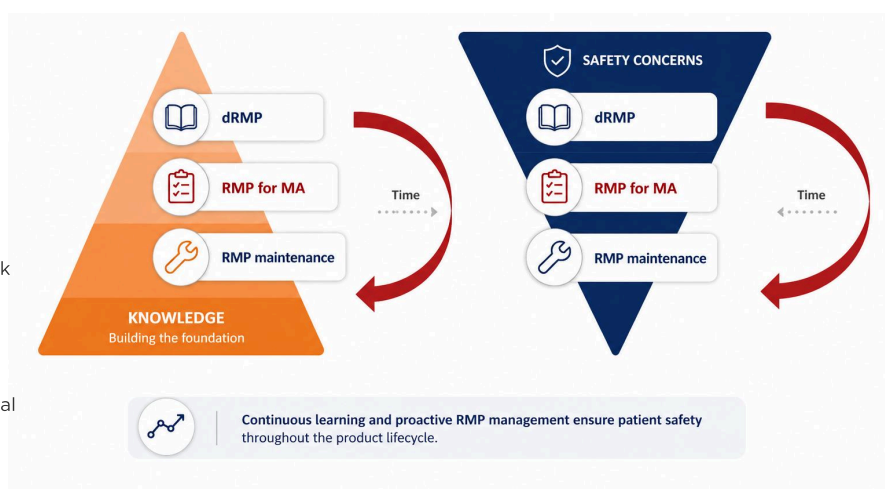
Updates driven by changes to safety concerns, additional pharmacovigilance activities, additional risk minimization measures, regulatory requirements, or new safety data.

Regional and global RMP requirements

Support for EU-RMPs, UK-RMPs, RMPs for other global territories based on local legislation, and US REMS support where required.

Risk minimization support

Development, review, adaptation, and implementation support for additional risk minimization materials, including educational materials and local market requirements.



How PrimeVigilance delivers RMP support



Our RMP delivery model is designed to support quality, continuity, and compliance from strategy through finalization.

Strategy development

Kick-off, regulatory pathway review, document planning, safety concern alignment, and timeline management.

Source data collection

Collection and review of relevant clinical, post-marketing, literature, regulatory, and cumulative safety information.

Drafting and review cycles

Medical writing supported by quality control, medical review, QPPV input where applicable, and client review.

Finalization and submission support

Preparation of final RMP documentation and submission-ready outputs.

Lifecycle maintenance

Ongoing updates as new evidence, safety concerns, regulatory expectations, or risk minimization obligations emerge.

What differentiates PrimeVigilance RMP services?



Experienced medical writing delivery

RMPs are supported by cross-functional teams that may include medical writers, PV project managers, quality control reviewers, medical reviewers, regulatory intelligence specialists, strategic advisors, and EU/UK QPPVs where applicable.



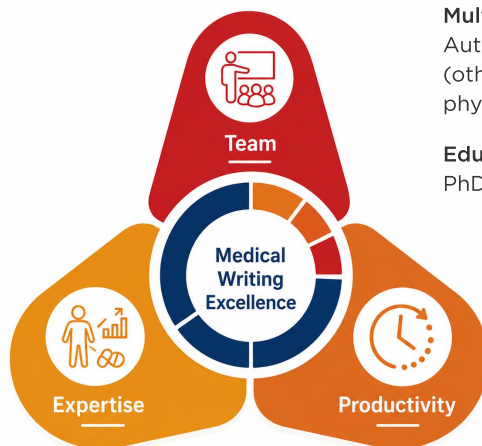
Expertise

All pre-authorization and post authorization documents:
DSURs, PBRERS/ PSURs, PADERS, RMPs, etc.

MP-specific documents
And documents required by local legislation.

Experience with the target disease(s):
Rare diseases, Oncology, Metabolic, Cardiac, Infectious, Neurology, Psychiatry

Experience with the drug class(es):
Small molecules, Antibodies, siRNA, Cell therapy, Gene therapy, Vaccines, Combination products



Team

Multifunctional Project Team:
Author (MW), PV Project Manager, QC Reviewer (other MW), Medical Reviewer (PV safety physician) and EU/UK QPPV (as applicable).

Educational background:
PhDs, MSc life sciences/pharmacists, MDs



Productivity

Over 1,500 pre-authorization and post-authorization Aggregate Reports p.a.

Experience across products and therapeutic areas

PrimeVigilance supports RMPs across a broad range of product types, including small molecules, antibodies, siRNA, cell and gene therapies, vaccines, combination products, biosimilars, generics, and innovative products.

Our teams bring experience across oncology, rare diseases, neurology, infectious disease, metabolic, cardiac, and psychiatric indications.

Common RMP challenges we help solve

PrimeVigilance helps sponsors address practical and regulatory challenges that can delay or complicate RMP delivery, including:

- Changing regulatory requirements
- Late-breaking safety data
- Legacy documents requiring alignment with current expectations
- Region-specific requirements and local appendices
- High volumes of case reports or literature
- Safety concerns requiring re-characterization
- Additional risk minimization requirements
- Regulatory authority questions or requests for supplementary information



Need support with RMP strategy, preparation, maintenance, or risk minimization implementation?

Speak with PrimeVigilance to discuss how we can support your product lifecycle, regulatory obligations, and global safety strategy.

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