APCER
LIFE SCIENCES
Together for better health

BROCHURE

Together for Effective Risk Management

Risk Management Services

Identification and characterization of safety profile and management of safety concerns including implementation of risk minimization measures are essential to ensure patient safety throughout the product life cycle. An efficient risk minimization system lays out a systematic framework on which the pharmacovigilance plan and risk–benefit analysis is characterized for any medicinal product.

To improve risk–benefit profile, additional risk-minimization measures (aRMMs) may be implemented for certain medicinal products to address important safety issues, which may not be practically achieved through routine RMM. The aRMMs may include educational programs, controlled access programs, and other risk minimization measures, such as pregnancy-prevention program (PPP) and direct healthcare professional communication (DHPC). Educational programs, which target HCPs and patients, are based on educational materials, such as prescriber guide, patient alert card, and pharmacist guide. These materials are delivered using a combination of tools and media (e.g. paper, audio, video, web, and in-person training).

In the United States (US), risk evaluation and mitigation strategy (REMS), a drug safety program may be required for certain medications with serious safety concerns. A REMS may also require the manufacturer to create a communication plan, which includes tools for disseminating information to educate and raise awareness in healthcare professionals about the risks addressed by REMS. This is a required risk management plan that uses tools beyond the routine measures, such as prescribing information, warnings on product labels, prescription status, dispensing quantity, or method to ensure that the benefits of certain products outweigh their risks.

APCER Risk Management Capabilities

APCER Life Sciences can support in end to end risk management activities including implementation, tracking, assessment, and modification of the implemented risk management systems.

Routine Risk Management Activities and Strategic Advice

- Marketing authorization holder (MAH)/Applicant support for oversight process build-up, stakeholder/ local affiliate training, implementation hand holding, and risk group committee workshop
- Collaborative service model covering end-to-end services and specialized support e.g. subject matter expert (SME) review and gap analysis
- Compilation, draft, review, update and submission of US REMS reports
- Compilation, draft, review, update and submission of risk management plans (RMPs) for the European Union (EU) and global regions
- SME Participation in safety related discussions with Regulatory Authorities on behalf of MAH if required

Additional Risk Minimisation Measures (aRMM)

- Preparation of aRMM tools such as educational materials such as prescriber education, medication guide, patient alert card in a language customised for target audience such as patient and prescriber
- Preparation and implementation of various aRMM tools such as DHPC and controlled access programs
- Training of health care professionals/ prescribers
- aRMM tracking, aRMM effectiveness assessment, consortium support, Targeted Follow up Questionnaire (TFUQs) and periodic review
- Robust and efficient tracking mechanisms for compliance monitoring and notification to stakeholders of the upcoming regulatory submissions
- Wide range of survey methodologies, including online portal-based survey and curated survey sessions with targeted audience
- Well-established processes for managing requests/ inquiries coming from healthcare providers, patients/ consumers, sales representatives, and online website submissions
- Specialized services for full support for REMS programs, patient support programs, post-authorization registries, and compassionate use programs
- Preparation of REMS document with or without Elements To Assure Safe Use (ETASU) for single and shared REMS systems, REMS assessment reports and timely submissions to the Food and Drug Administration (FDA)

Pregnancy Prevention Program (PPP)

Certain medicines may have teratogenic effects if exposed accidently to pregnant women. A PPP is a set of tools to minimise exposure of such products during pregnancy.

APCER's team of experts can support in set up of PPP including preparation and implementation of various RMM tools such as educational material, control access tools and management of a **dedicated PPP Website and Portal** as required.

Specialized aRMM/REMS Contact Center

- Medical information contact center (MICC) support to the implementation of aRMM to handle enrolment queries, ADR/pregnancy reporting and follow ups
- Implementation of a 24X7 call center for supporting REMS with on-demand technical support (multi-language support)

The REMS contact center is managed by a highly specialized team of healthcare professionals at APCER. We can handle all aspects of the REMS program or some of its components in accordance with the sponsor's procedures. Our MI team also manages patient support programs, post-authorization registries, and compassionate use programs.

21-CFR-compliant websites/portals

- Setting up a drug and/or Patient registries e.g. pregnancy registry, on a web-based HCP and patient registration portal
- Development and maintenance of 21-CFR-compliant websites/portals to facilitate aRMM/REMS implementation

Salient Features of APCER's REMS Web-Portal

100% Customisable

Ensure configuration as per program requirenment

Single Platform for REMS/CAP

County wise login with common dataset

24x7 Accessibility

Ensure real time data entry to prevent any dataloss

Training compliance

Training Assessment and Records with easy access

Auto Emails

Realtime notifications, reminders & escalations

Regulatory Compliance

21 CFR Part 11, EU Annexure 11 Compliance System

Data Analytics

Customizable data analytics to meet any dynamic data requirement from regulatory

Cloud Hosting

Cloud-based scalable infra with"Zero data loss"

The APCER Advantage

15+ years of rich experience in strategizing, designing, and implementing global risk-management systems

Dedicated team of healthcare professionals with strong expertise in end-to-end risk-management program support including effectiveness assessment

Ready to launch 21-CFR-compliant websites/portals

Specialized REMS call centre with 24×7 availability

APCER LIFE SCIENCES | Together for better health
Part of APC Group

APCER Life Sciences is committed to improving health in partnership with its clients. We bring together safety, medical, regulatory and technology resources to ensure that patients receive the safest, most effective therapies possible.

We are an ISO 9001:2015, ISO 27001:2022, and ISO 27701:2019 certified company.

Learn more at www.apcerls.com or contact us at one of our global offices: Americas: (+1) 609 455 1600 • Europe: (+49) 2409 725 6120 • UK: (+44) 208 326 3220 • Asia: (+91) 79 6677 8600

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