APCER LIFE SCIENCES
Together for better health

BROCHURE

Together for Effective Risk Management

Risk Management Servicess

The identification and characterization of safety profile and the management of safety concerns, including the implementation of risk minimization measures (RMMs), 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 for and a risk–benefit analysis of any medicinal product are characterized

To improve the risk–benefit profile of certain medicinal products, additional risk minimization measures (aRMMs) may be implemented to address important safety issues, which may not be feasible through a routine RMM. The aRMMs may include sending direct healthcare professional communication (DHPC); hosting educational programs on website or paper or electronic dissemination of the educational materials; and controlled access programs (CAPs), such as pregnancy prevention programs (PPPs) and educational programs, which target healthcare professionals (HCPs) and patients and are based on educational materials, such as medication guide, prescriber guide, patient alert card, and pharmacist guide. These materials are delivered using a combination of tools and media (e.g., paper, audio, video, the web, and in-person training).

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

APCER Risk Management Capabilities

APCER Life Sciences can support end-to-end risk management activities, such as implementation of aRMMs or REMS and 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 RMPs for the European Union and global regions
- SME participation in safety-related discussions with regulatory authorities on behalf of MAH if required

Additional Risk Minimization Measures

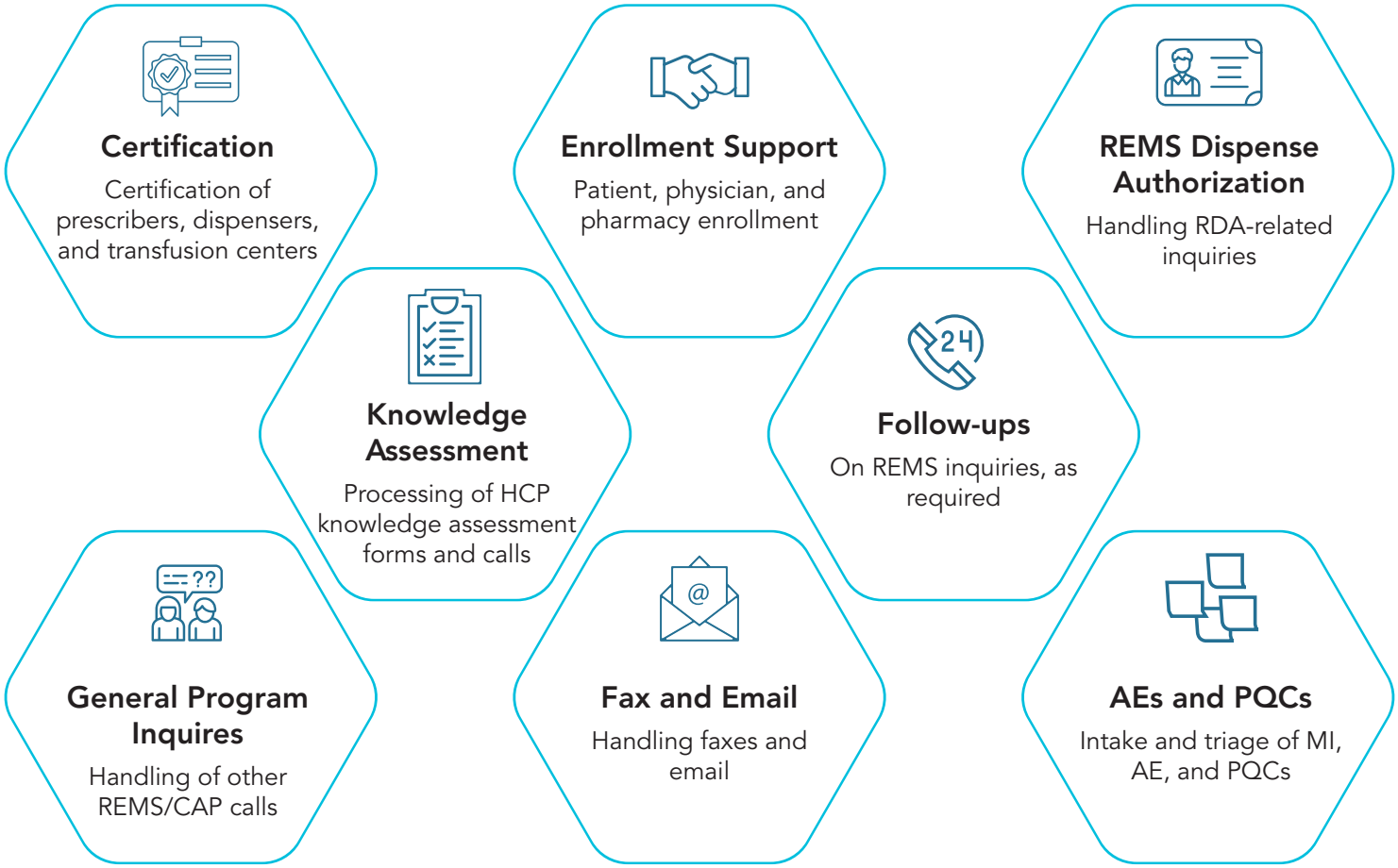
- Preparation of aRMM tools, such as educational materials including prescriber education, medication guide, patient alert card in a language customized for the target audience such as patients and prescribers
- Preparation and implementation of various aRMM tools such as DHPC and CAPs
- Training of HCPs/ prescribers
- aRMM tracking, aRMM effectiveness assessment, consortium support, targeted follow-up questionnaires, and periodic review
- Robust and efficient tracking mechanisms for compliance monitoring and notifying stakeholders regarding the upcoming regulatory submissions
- Support vendor services such as surveys and report preparation (e.g., a Knowledge, Attitudes, and Behavior [KAB] survey and user readability testing) and translations for the risk mitigation/management programs
- Well-established processes for managing requests/ inquiries from healthcare providers, patients/ consumers, sales representatives, and online website submissions
- A controlled access program/ specialized therapy program includes services to provide full support to REMS programs, including support knowledge assessment, general program inquiries, enrollment, and REMS dispense authorization (RDA) support
- Preparation of REMS documents with or without Elements to Assure Safe Use for single and shared REMS systems, REMS assessment reports, and timely submissions to the Food and Drug Administration.
- **Controlled access programs** such as PPPs are implemented for medications that may have teratogenic effects, using tools and strategies to minimize the risk of accidental exposure during pregnancy. These programs ensure that patients with childbearing potential are fully informed and take necessary precautions to safeguard an unborn child while using such high-risk medications.
- Due to the nature and complexity of certain products, such as targeted therapies or advanced therapies (e.g., CAR T-cell therapies), **specialized programs** may be required for close monitoring of serious adverse events (SAEs), such as cytokine release syndrome, or neurotoxicity with some SAEs, such as secondary malignancies, requiring life-long monitoring.

APCER's team of experts can support in setting up such programs, which includes the preparation and implementation of various RMM tools such as educational material, control access tools, and the management of a **dedicated PPP/ specialized therapy website and portal** as required.

Specialized aRMM/REMS Contact Center

- The Medical Information Contact Center (MICC) supports the implementation of aRMMs to handle enrollment queries, adverse drug reaction/pregnancy reporting, and follow-ups.
- The implementation of a 24×7 call center to support REMS with on-demand technical support (multilanguage support).

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



21-CFR-compliant websites/portals

- Setting up 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% Customizable
Ensures configuration as per program requirements

Single Platform for REMS/CAP
Country-wise login with common datasets

24×7 Accessibility
Ensures real-time data entry to prevent any data loss

Training compliance
Training assessment and records with easy access

Auto Emails
Real-time notifications, reminders, and 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

A dedicated team of HCPs with strong expertise in end-to-end risk-management program support, including effectiveness assessment

Ready to launch 21-CFR-compliant websites/portals

A specialized REMS call center with 24×7 availability

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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.

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