POSTMARKETING SURVEILLANCE AND SERVICES

Managing risk is critical to the success of a compound both during the development process and into commercialization. The ability to manage global adverse events and product complaints requires a quality driven process, innovative technology, and robust services designed to drive a comprehensive program. Medpace can orchestrate global safety programs for postmarketing projects, taking into account necessary components covering consultation on complex safety profiles, operational excellence, data collection and analysis design, case processing, medical review and safety reporting, with an advanced understanding of regulatory requirements over the lifespan of the compound. Importantly, our team members have healthcare-related degrees to better manage the services offered.

Full-service Postmarketing Comprehensive Services include the following:

- Adverse Event (AE) and Product Complaint (PC) management
  - Includes intake, triage, case processing (Medpace or client-provided database), narrative writing, QC, medical review, and follow-up, as applicable
- Individual case safety report (ICSR) distribution
  - Global post-approval reporting to the appropriate regulatory authorities, including FDA (via WebTrader) and EudraVigilance
- Call center function
  - Trained healthcare professional staff
- Safety database services
  - Includes AE and PC safety database set-up, implementation and maintenance
  - Data migration
- Global literature monitoring and routine media monitoring search strategy and review
  - To support individual case safety report detection and signal management
- Safety signal management
  - Includes detection, validation, evaluation, and tracking of safety signals as a part of safety surveillance
- Risk Management Plans (RMPs)/Risk Evaluation and Mitigation Strategies (REMS)
  - May provide support for development of RMPs and/or REMS as per applicable requirements
- Aggregate report management
  - Includes preparation and submission of postmarketing aggregate reports, including periodic safety update reports (PSURs, PBRERs) and periodic adverse drug experience reports (PADERs)
- Region-specific pharmacovigilance management
  - Maintenance of a certified pharmacovigilance system (i.e. PSMF) for pharmaceutical companies in the EU
  - European Union-qualified person for pharmacovigilance (QPPV)
  - In-country pharmacovigilance services, including local literature surveillance and national contact persons/QPPVs EudraVigilance profile management

SCALABLE TECHNOLOGY PLATFORM

Medpace's ClinTrak® technology platform has a Safety and Pharmacovigilance (CSPV) component for electronic tracking and reconciliation of postmarketing source information received from multiple media sources. This enables effective management of case workload on a daily basis according to priority, while minimizing compliance risk. The system facilitates electronic capture of incoming and outgoing calls received/made by the call center team as well as tracking any follow-up action items requested. The system also allows for product complaint intake, tracking and data basing.

- All source information and individual case files are electronically retrievable using the CSPV search tool
- CSPV allows the postmarketing team to electronically capture and track product complaints within the system

MEDPACE CALL CENTER

Medpace provides postmarketing phone center coverage with a team that consists of healthcare professionals who manage all incoming and outgoing calls:

- Special request accommodations are available (e.g. medical inquires and litigation inquires) as requested by the sponsor
- Voicemail options are available 24/7
- Call backs are made to the reporter on, or before, the next business day, as applicable by the call center team

SAFETY EVALUATION AND MEDICAL REVIEW

A qualified and trained physician reviews adverse event cases and routinely monitors and evaluates for newly identified safety signals — closed or ongoing. The Medpace medical team assists the PMPV team in providing assessment for each potentially reportable adverse event report covering:

- Reportability
- Seriousness
- Company Causality
- Expectedness
- Necessity for follow-up
- Case closure

LITERATURE AND MEDIA SURVEILLANCE

- Worldwide scientific literature and media sources such as the lay press are screened by the postmarketing team regularly according to local regulatory requirements
- Medpace utilizes outside vendors to help manage the routine monitoring process of the scientific literature and media

AGGREGATE REPORTING

Medpace uses a collaborative approach between various teams including Clinical Safety, Medical Monitoring and Regulatory Affairs to:

- Prepare, QC, publish and submit periodic/aggregate safety reports (PSURs, PBRERs , PADERs)
- Local and global periodic reports are written and submitted as per regulations specific to each product and as requested by the sponsor

FULL-SERVICE CLINICAL DEVELOPMENT

Medpace is a scientifically-driven, global, full-service clinical contract research organization (CRO) providing Phase I-IV clinical development services to the biotechnology, pharmaceutical and medical device industries. Medpace's mission is to accelerate the global development of safe and effective medical therapeutics through its high-science and disciplined operating approach that leverages local regulatory and deep therapeutic expertise across all major areas including oncology, cardiology, metabolic disease, endocrinology, central nervous system and anti-viral and anti-infective.

MAKING THE COMPLEX SEAMLESS™