

REGISTRAT-MAPI offers safety data tracking, processing, and reporting services to manufacturers of marketed medical products, including pharmaceuticals, biologics, medical devices, and consumer health companies.

Post-launch observational safety studies provide an excellent vehicle for gathering data on the real-world safety of a product. Our Regulatory and Safety Services are a seamless part of the study development process and project lifecycle. In collaboration with sponsors, REGISTRAT-MAPI develops a project-specific Safety Plan for every study.



Our Safety Services group tracks, processes, and reports Adverse Events (AEs) within ICH/GCP and regulatory agencies' recommended timeframes for Client-sponsored clinical studies.

Safety Planning Services

Strategic design of clinical, regulatory, and safety plans for a study requires a comprehensive understanding of current regulations and the regulatory environment.

Our staff has senior level experience and existing rapport with many regulatory agency divisions enabling them to explore with Sponsors the most appropriate and expeditious regulatory strategy to achieve their objectives. REGISTRAT-MAPI offers the following comprehensive services, separately or collectively, to support regulatory and safety requirements of Sponsors.

- Protocol, CRF, and Investigator Brochure review
- SAE form and safety database development
- Scientific literature review
- Sponsor and clinical site training for project-specific safety requirements
- Design and implementation of safety studies, REMS/EU-RMP, and post-marketing requirement studies
- Clinical expertise in a variety of therapeutic areas

Management of Safety Data

The Safety group employs rigid quality control and quality assurance practices to ensure data are complete and accurate. To verify and ensure clinical data integrity of Adverse Events, follow-up is systematically performed with Investigators, Sponsors, and other appropriate personnel.

- AE/SAE collection and tracking
- Data are collected from multiple sources (e.g., phone, electronic and faxed SAE forms, electronic data transfers)
- Data are entered into the safety system and coded using standard dictionaries (e.g., MedDRA), and verified
- Data validation and query management
- Case-specific query and follow-up
- Quality control-100% verification of data against source documents
- QA compliance procedures (e.g., random sampling for compliance verification)
- Database reconciliation

Investigator Training

Training on the AE/SAE reporting process is conducted with the Investigator or study site staff. Training includes:

- Definitions as defined in the protocol
- Study-specific AE/SAE Report Form completion instructions
- AE/SAE reporting timeframes/notification process
- SAE reporting requirements and regulatory obligations of the Investigator
- Submission requirements of supporting documentation for reported SAEs/AEs
- Therapeutic area or product-specific training, as required

Medical Review and Analysis

REGISTRAT-MAPI's Safety group routinely performs medical review of cases to determine reportability, seriousness, and expectedness, while integrating feedback from Investigators and Sponsors. Aggregate analysis is performed to detect signals and evaluate trends.

- Case-specific verification
- Verification of recorded safety data against source documents
- Narratives
- Medical evaluation and preparation
- Trend analysis and signal detection
- Frequent case-specific signal review
- Aggregate data review and trend analysis
- Regulatory assessment of reporting requirements
- Assessment of causality

Regulatory Reporting

The Safety group completes sponsor-specific safety reports, including the following:

- Reporting to sponsor through sponsor-specific pharmacovigilance forms
- Safety tables and data listings per project-specific requirements
- Other reporting as required for regulatory or Sponsor needs

REGISTRAT-MAPI 

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