



# **DRUG SAFETY & PHARMACOVIGILANCE**

SGS provides comprehensive and flexible solutions for the active management of drug safety, pharmacovigilance and risk management during the complete lifecycle of a medicinal product. Our pharmacovigilance team consists of MDs, PhDs and Pharmaceutical scientists that are multilingual use latest powerful validated tools and work according to the latest Regulatory requirements.

# DRUG SAFETY & PHARMACOVIGILANCE SERVICES

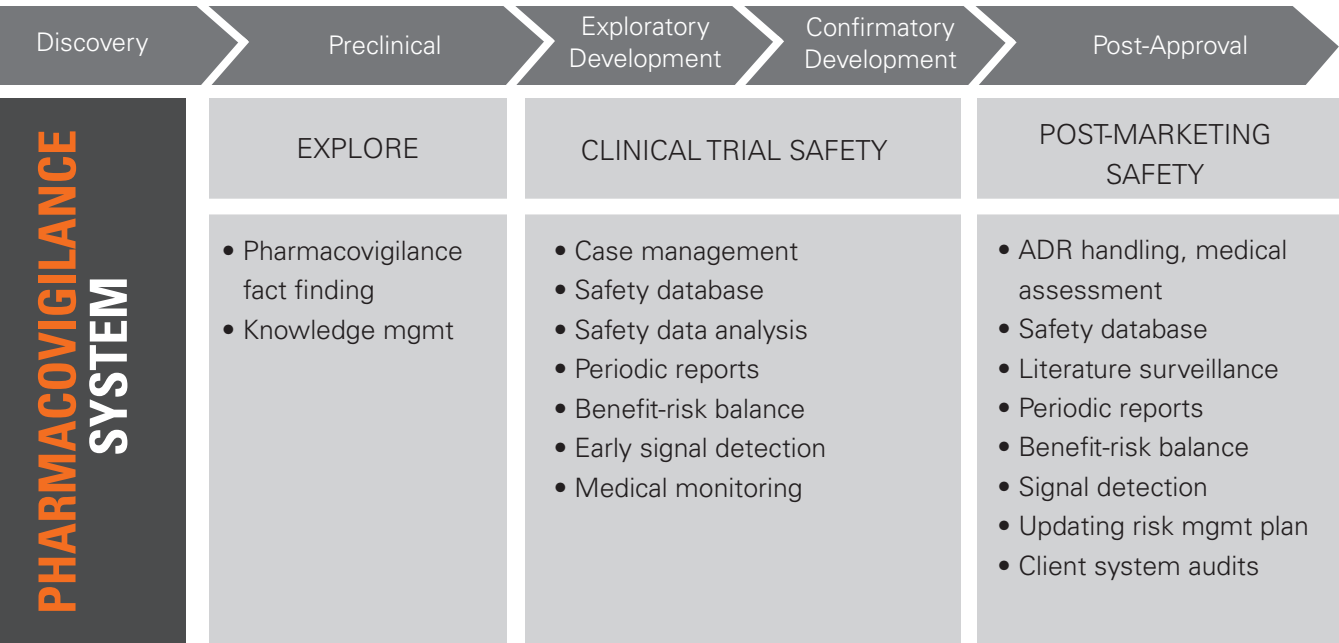
Our team of experts provides tailor-made, cost effective drug safety systems from molecule to market.

- Development and implementation of pharmacovigilance systems for investigational and registered products
- Customized Safety Plan and Safety Data Exchange Agreement
- Set-up and management of in-house Safety Database (Oracle Argus Safety):



- Individual Case Safety Report (ICSR) management
- Literature search and identification of ICSR and safety issues
- Safety related report writing such as Case Narratives, Development Safety Update Reports (DSUR), Periodic Safety Update Reports (PSUR), safety summaries, benefit/risk assessment, clinical overview...
- Medical review of safety reports and documents
- Tracking of regulatory intelligence for safety reporting and compliance
- EudraVigilance support Safety reporting to Health Authorities (HA) and Ethics Committees (EC) / Institutional Review Boards (IRB)
- Signal detection and ongoing safety evaluation
- Tailored coordination of Data Safety Monitoring Board (DSMB) activities (Independent Data Monitoring Committee (IDMC), Endpoint Committee or other)
- Pharmacovigilance consulting

## DRUG SAFETY FROM MOLECULE TO MARKET



# TEAM UP WITH SGS

Experience the ease and efficient collaboration with SGS team to bring you a complete range of international recognized services with high performance and flexible tools managed by dedicated experts. Take advantage of the:

- Senior pharmacovigilance staff
- Qualitative and comprehensive end-to-end case processing by our expert team
- Set-up and management of in-house safety database for all phases of clinical trials and post-marketing pharmacovigilance
- Expedited reporting to Health Authorities of unblinded SUSAR reports ensuring the protection of the blinding of study team
- Ongoing assessment of the drug safety profile
- Business continuity and in-time safety reporting
- Documented quality control check in order to guarantee audit proof safety reports
- Access to Elsevier Embase to support a systematic literature review of medical and scientific publications
- Direct access to safety physicians with broad therapeutic expertise for medical review and assessment of safety data
- Spontaneous reporting systems for Suspected Adverse Drug Reactions (ADR) and input to signal detection by our expert safety team
- Up-to-date information on country-specific regulatory requirements

## CONTACT INFORMATION

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WHEN YOU NEED TO BE SURE

