GLOBAL PHARMACOVIGILANCE SERVICES

inVentivHealthclinical.com

LEADING INTEGRATED OR STANDALONE SERVICES SUPPORTING PRODUCT SAFETY

In today's biopharmaceutical product landscape, companies must be aware of crucial safety information regarding their portfolio in order to evaluate product benefit/risk profiles. Pharmacovigilance is important at every stage of a product's lifecycle, from preclinical studies through post-approval stages including the first few years after launch, when knowledge of the safety profile expands based on exposure to a much wider range of patients than is possible during clinical trials. inVentiv Health Clinical provides comprehensive pharmacovigilance services to help you address these concerns with confidence.

EXPERT, GLOBAL TEAM

Our pharmacovigilance team is comprised of industry professionals with deep experience in both direct patient care and industry-specific pharmacovigilance services, enabling us to deliver safety data of the highest quality. Working globally, inVentiv Health Clinical can provide integrated or standalone services to support product safety monitoring in compliance with regulatory requirements for safety surveillance in pre- and post-approval settings.

We have the unique capability to submit expedited and aggregate reports globally. Our global, integrated staff is experienced in all varieties of global submission requirements, whether electronically, fax, courier or hand delivery, such as in Argentina.

SEAMLESS SERVICE, DELIVERED YOUR WAY

Whether our clients' needs are best met on a project-by-project basis, through a functional service provider or consultative relationship, inVentiv Health Clinical has the flexibility and experience to deliver. Currently, inVentiv Health Clinical has 32 active partnerships with clients — seven of them focused specifically on pharmacovigilance.

REMS

Within inVentiv Health, we have a specialized center of excellence for REMS design, ParagonRx, which protects trial stakeholders in several ways:

- Protection of clients from REMS-related brand failures
- Protection of patients from avoidable medication risks
- Protection of brands from unnecessary restrictions to market access and commercial success
- Protection of healthcare providers from infeasible intrusions into care delivery

inVentiv Health Clinical clients have access to ParagonRx's thorough understanding of REMS element requirements and extensive experience with program elements throughout the lifecycle of a REMS program, from strategy through implementation to continuous improvement.

GLOBAL SAFETY SERVICES

- Receive, assess, process and follow-up of SAE and ADR case reports
- Generate regulatory reports
- Submit expedited reports to regulatory authorities/competent authorities
- Safety aggregate report writing including PSURs and PADERs
- Scientific literature review for adverse events
- Global call center with multi-lingual capabilities for marketed products
- Manage and non-standard/off-label medical inquiries from consumers and health care providers
- Option to utilize lower-cost case processing services at our location in India

GLOBAL SAFETY SERVICES

- Average 8 years of industry experience
- 36% of the team with inVentiv Health Clinical for 5+ years
- 140+ dedicated safety staff

GLOBAL SAFETY DATABASE

- ARISg, supporting MedDRA and WHO Drug Dictionaries
- Experience with establishing secure connectivity and providing technical support with client safety systems

inVentiv Health clinical