



**AmerisourceBergen**

Innomar Strategies

# Drug safety and medical information solutions

**Maximizing safety and minimizing risk**

**Quality. Expertise. Trust.**

Healthcare companies have essential pharmacovigilance (PV) responsibilities to support the use of Medicinal Products, Medical Devices, or Natural Health Products throughout their lifecycle. At Innomar Strategies, we partner with healthcare companies to share these responsibilities. Whether you need to set up a new PV system or update your current PV process, our multidisciplinary team offers complete PV and medical information (MI) solutions that meet Health Canada and US FDA's legislative requirements while optimizing patient and HCP interactions. We provide customizable stand-alone PV/MI services, or PV/MI services in combination with patient support programs or third-party logistics solutions.

## Highlights

- Handling > 200,000 ICSRs annually
- Serving > 60 clients with over 200 products – Diverse therapeutic portfolio including oncology, rare disease, cardiovascular, OTC, CNS, women's health, immunology, etc.
- 100% compliance rating in all Health Canada Inspection
- >99% compliance in Individual Case Safety Reports (ICSR) reporting
- A centralized, multilingual team of medical professionals who are knowledgeable and experienced in Health Canada, FDA, and EU pharmacovigilance regulations

## We can support you with...

### Pharmacovigilance

- Global Safety Database hosting
- PV System set up
- Local PV representative
- ICSR Management
- Global and Local Literature Monitoring
- Aggregate Reports Development (PBRER, ASR, PADER)
- Risk Management Plans (RMP) and Risk Evaluation and Mitigation Strategies (REMS) development
- Vendor audit and regulatory inspection support

### Medical Information

- Multilingual call center services
- Dedicated phone lines with < 20 seconds wait time
- Creation of standard and complex response letters

### Promotional material review

- Promotional materials review to ensure compliance with Canadian advertising regulations and standards

### Quality management

- ICH E2B Standard Safety Database – Validated to CFR 21 PART 11 and Annex 11 Compliant
- Electronic Document Management System for controlled documents (SOPs, policies, and work instruction) and training

For more information visit [innomar-strategies.com](http://innomar-strategies.com), or contact:

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