PRA Health Sciences

SLIP SHEET

Literature Surveillance: Protecting Your Product Portfolio

Literature surveillance is a mandatory business process with many benefits. Literature surveillance reduces risks and long-term costs, increases safety, and enhances value for the marketing authorization holder (MAH) by evaluating and managing risk throughout a product's life cycle (pre- and post-marketing) and keeping marketed products safely on the market.

Our Services

- Automated literature searches that store and archive results electronically (available and ready for internal, client, or regulatory inspection)
- Generation of search criteria for listings of references and abstracts
- Expert screening by PV specialists to identify citations that are suspect
- Ad hoc or customized searches to meet specific needs (eg, periodic safety update reporting)
- Regulatory reporting
- Concise and timely consultation and communication of findings

Ensuring a Long & Safe Product Life Cycle

With increasing public interest in drug safety and new regulatory guidelines, it is no longer sufficient to simply collect and report adverse events. To detect safety signals across all uses, pharmaceutical companies must proactively screen and analyze published literature from initial application to suspension or withdrawal of the marketing authorization.

Medical literature is the most efficient and effective warning system for detection of new adverse reactions, rare events, or at-risk patients. This is because case reports are detailed, they are assessed for quality by reviewers (mostly independent from commercial incentives), and are open to interested parties. This published data is an important source of information for MAHs in terms of ongoing safety evaluation of their medicinal products. Many important adverse drug reactions have been detected and verified in voluntary reporting, mostly through the published literature. The success of searching published literature is measured by precision and sensitivity while not accepting any loss of sensitivity when searching for pharmacovigilance (PV).

The MAH is responsible for organizing a systematic search for information that impacts the risk–benefit assessment of the active ingredients in drugs it commercializes (ie, brand names and generics). The MAH also must ensure the adequacy of the resources who perform the search.

PRA Automates Your Searches

Automation is pivotal to keeping the process lean and affordable. It eases the knowledge acquisition bottleneck, particularly for searching large collections of legacy documents. To accommodate this, PRA has developed an automated Literature Research System to provide a user interface from which the PV experts submit their queries.

The PRA Assurance

PRA Health Sciences is an experienced partner for MAHs. We offer integrated processes and clear accountabilities to managed required weekly surveillance. We conduct qualified scientific reviews of international literature (eg, articles, manuscripts, abstracts, and excerpts) according to guidelines from the European Medicines Agency, US Food and Drug Administration, Health Canada, Therapeutic Goods Administration, and others to ensure complete and diligent product case management, expedited and aggregate reporting, and thorough risk management analysis.

Quality in People & Processes

PRA has the governance structure, people, processes, and technologies to support effective pharmacovigilance. Our team of experienced information specialists have backgrounds in the medical, healthcare, scientific, and information technology industries.

Based on the client infrastructure, PRA manages the entire process, from weekly search to regulatory reporting, or only parts of it. All records are stored and archived electronically for inspection purposes. Within agreed timelines, we provide timely summary reports that highlight search and assessment success, information about potentially interesting literature, and project progress charts. The entire process follows a strict but lean workflow to ensure performance and quality. We employ regular internal control measures and audits to deliver the highest quality services and identification rates.

Next Steps

To learn more or to schedule a capabilities presentation, please contact PRA employees: Dr Sabine Richter, Vice President, Pharmacovigilance & Patient Safety, at RichterSabine@prahs.com or Greg Chappell, Senior Technical Specialist, at ChappellGregory@prahs.com.