PHARMALEX

SMARTVIGILIT - SMART LITERATURE SURVEILLANCE SYSTEM

WHAT IS SMARTVIGILIT?

SMARTVIGILIT® is a web-based solution with a quality-assured environment that accomplishes all the functions related to your legal obligations for global and local literature surveillance. It independently performs weekly automated searches within PubMed or other databases. Also, safety-relevant medical and scientific literature for your products can be extracted from system by product name and time period to support all your pharmacovigilance processes at any given point in time. e.g., signal detection and PSUR(s) / PBRER(s) preparation and eventually benefit-risk evaluation (BRE) of medicinal products.

FEATURES OF SMARTVIGILIT

- Global coverage, end-to-end service for all your substances.
- Web-based access, no install / update required for customers, easily scalable.
- No user license limitations. You can assign as many users as needed.
- Management of literature references from global and local literature databases with individual designed search strategies.
- Artificial Intelligence (AI) enabled system for quality review.
- Automated email notification services for:
  - Identified literature abstract(s) with different technical segregation.
  - Case reports (ICSRs) in CIOMS I or E2B-compatible (R2 & R3) format.
- Competent integration with all Pharmacovigilance setup(s).

BENEFITS OF SMARTVIGILIT

- Successfully inspected by MHRA and BfArM.
- A validated solution in line with GAMP 5, compliant with US Title 21 CFR part 11.
- One-stop solution for the entire literature aspect of PV-related activities.
- Profound pharmacovigilance expertise paired with consulting activities.
- Drastically reduces the effort required in eliminating duplicate references as well as the load on the screening.
- Export of segregated references in the required format (PDF and CSV) with adequate information.

SMARTVIGILIT® is a web-based solution with a quality-assured environment that accomplishes all the functions related to your legal obligations for global and local literature surveillance.

300+ clients providing PV services

85+ Global end-to-end PV projects
200+ Local PV systems

Subject Matter Experts Worldwide

InnoPHLEX
DISCOVERY / NON-CLINICAL
CLINICAL DEVELOPMENT
MARKETING AUTHORIZATION / APPROVAL
PRODUCT MAINTENANCE
SourcePHLEX

DELIVERING SUCCESS WITH CONFIDENCE

PHARMALEX IS A LEADING PROVIDER OF SPECIALIZED SERVICES FOR THE PHARMA, BIOTECH AND MEDICAL DEVICE INDUSTRIES

KNOWLEDGE.
ACCELERATED.
confidence *beyond* compliance

We guide you from early strategic planning activities and non-clinical requirements through clinical development, regulatory submission processes and post-approval / maintenance post-launch activities.

Our experts use **technology-enabled solutions** to support you through the entire product lifecycle. We deliver exceptional results – going above and beyond the standard to deliver tailor-made solutions worldwide.

Stay **one step ahead** of essentials requirements needed by health agencies. Our knowledge accelerates your business success...

Knowledge. Accelerated.

CONTACT US

contact@pharmalex.com

/company/pharmalexglobal

www.pharmalex.com

@PharmaLexGLOBAL

STRATEGY & CONSULTING REGULATORY AFFAIRS PHARMACOVIGILANCE QUALITY MEDICAL AFFAIRS