FACT SHEET

UBC Pharmacovigilance Solutions

International, industry-leading expertise, working to enhance patient safety and manage the benefit-risk profile of your products.

Global Pharmacovigilance Domain Expertise

- 230+ Pharmacovigilance and healthcare professionals including Pharmacists, Nurses, PhDs, and 11 Medical Doctors
- 3 EU Qualified Persons for Pharmacovigilance (QPPV/deputy QPPV) and Local QPPVs/National Contact Persons in EEA countries
- Experience in 15 therapeutic areas and 7 product indications, including rare and orphan diseases, autoimmune diseases, oncology, and neuromuscular diseases, among others
- Expertise in safety for all product types including drugs, medical devices, vaccines, combined products, and gene therapy supplements
- International team including 14 nationalities (Belgium, Brazil, France, Germany, India, Italy, Netherlands, Spain, Poland, Romania, Switzerland, UK and US)
- Locations throughout Europe and the United States providing a global approach for our safety solutions

Pharmacovigilance Experience

Over the past five years, we have helped ~60 companies address their safety needs by implementing and managing over 66 PV programs.

Portfolio:
59 CLIENTS
66 PRODUCTS

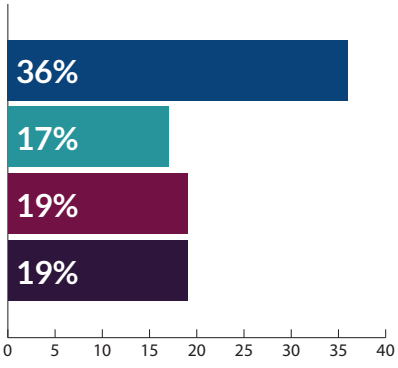
66% of all PV clients outsource to UBC in a full-service capacity

>30+ Regulatory inspections

>99% On-time regulatory submission compliance

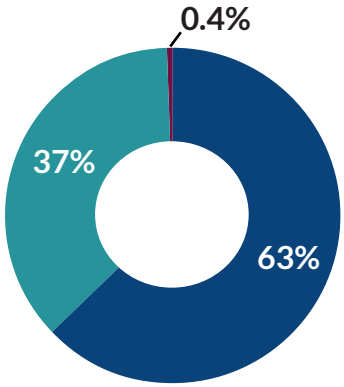
>45,000 cases processed in 2022

TOP THERAPEUTIC AREAS



Oncology / Hematology
Neurology / Psychiatry
Metabolic / Cardiovascular / Endocrine
Autoimmune / Immunology / Rheumatology

CASE VOLUME



Small case volume
Small to medium case volume
Large case volume

**Reflects UBC 2018 – 2023 year to date pharmacovigilance portfolio.*

Pharmacovigilance Services

SAFETY CASE PROCESSING	Global, technology-enabled case processing services, led by a team of highly trained HCPs with an understanding of the regulatory reporting requirements and nuances of the product safety profile, to support clinical trials, post-marketing studies, and spontaneous reporting.
GLOBAL SAFETY MANAGEMENT	Comprehensive collection, processing, and reporting of all adverse events in accordance with evolving FDA and EMA regulations utilizing the ARGUS™ 8.2.3 Global Safety Management System.
REGULATORY REPORTING	On-time reporting to regulatory agencies with an overall global reporting submission rate of above 99% in 2022.
SAFETY WRITING	Proficient assessment of global safety data and preparation and delivery of aggregate safety reports within the US and EU, including periodic adverse drug experience reports (PADERs), periodic safety update reports (PSURs), periodic benefit-risk evaluation reports (PBRERs), and development safety update reports (DSURs).
SIGNAL DETECTION	Timely identification, investigation, and validation of potential safety signals, in accordance with FDA and EMA GVP Module IX and CIOMS VIII regulations, reviewing data sets from a wide variety of sources, to ensure the submission of compliant regulatory reporting.
LITERATURE SCREENING	Global and local literature review, management, and tracking, leveraging a validated tool, guided by extensive knowledge of literature review requirements in US, EU, and ROW.
EUROPEAN PM SERVICES	Extensive experience establishing and administering global and local PV systems, guided by qualified person responsible for pharmacovigilance (QPPV) and the management of pharmacovigilance system master files (PSMF) in the exchange and processing of safety information in collaboration with affiliates, partners, and call centers.

Proactively Monitor Work in Progress

APPROACH

- Cases currently in progress by stage
- Due and overdue cases
- Two levels of due date monitoring – internal vs regulatory
- Timeliness of cases in each work stage
- Multiple filters for deep-dive analysis

BENEFITS

- Provides a command center for operational leadership
- Pinpoint serious cases for increased attention
- Highlights due dates coming up or overdue
- Breaks out regulatory delivery vs internal

LIVE CASE PROCESSING DASHBOARD

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ubc.com

UBC
Patients First. Powered by Evidence.