Global Pharmacovigilance Readiness Checklist

Having a comprehensive understanding of your organization's readiness to tackle any or all safety responsibilities is paramount.

The right strategy to continually evaluate product safety in your clinical trials, through regulatory review and entering the post-marketing setting, is complex. Local market regulations are ever-changing. Technologies to intake, track and manage workflow are getting more sophisticated. Expectations of global regulators are increasing regarding ongoing, long-term safety assessments, signal detection and refinement. Are you ready?

UBC has assembled this *"PV readiness"* checklist to enable our clients to drive internal conversations around their safety strategies, and ensure they have a partner in place to help in any or all of these important categories of a safety organization.

Safety Systems

Are you investing in a comprehensive safety platform and need guidance on the market-leading features and functionality, as well as deployment?

- [ ] Global Safety Database
- [ ] Safety Reporting Functions
- [ ] Custom SQL Reporting Capabilities
- [ ] Support for Immediate Report Generation and User Support
- [ ] Inspection-ready Quality Management System supporting PV System

Data Migration

Do you have the expertise to efficiently integrate data from multiple sources or to migrate an existing system - into a new environment?

- [ ] Manual Migration
- [ ] Highly-Automated Case Migration
- [ ] Quality Management and Oversight
- [ ] Legacy Data Cleaning

Signal Management

How are you ensuring timely identification, investigation and validation of potential safety signals?

- [ ] Qualitative and Quantitative Signal Detection and Assessment
- [ ] EV Data Analysis System *(DAS)* Monitoring
- [ ] FDA FAERS Public Access Monitoring

UBC IS AN EXPERT IN SAFETY

- From large to small populations
- Complex cellular and gene therapies
- To mega-blockbusters

Global Case Processing

Do you have a dedicated team of trained healthcare professionals (HCPs) who understand the regulatory reporting requirements and nuances of the product safety profile?

- [ ] Clinical Trial Case Processing
- [ ] Post-Marketing Case Processing
- [ ] Workflow Management *(Intake, Triage, Data Entry, Narrative Writing, QC, Medical Review)*
- [ ] Reconciliation *(SAE, Medical Information, Product Complaints, Call Center and Partners)*
- [ ] FDA FAERs & EudraVigilance (EV) Individual Case Safety Report (ICSR) Monitoring

Regulatory Reporting

Do you have the confidence that all regulatory submissions are country compliant for your program and will stand up to a formal regulatory audit?

- [ ] Secured Gateway Setup with Regulatory Authorities and Partners
- [ ] FDA Electronic Regulatory Reporting (FDA & EMA)
- [ ] National Competent Authorities Regulatory Reporting *(MHRA, BFARM, ANSM, PMDA, etc.)*
- [ ] Partner Cross-Reporting
- [ ] Aggregate Reporting to Regulatory Authorities

Periodic Reporting/Safety Writing

Do you have key templates, best practices, operational standards and structured communication approaches to address your safety writing responsibilities?

- [ ] PADER
- [ ] PSUR/PBRER
- [ ] DSUR
- [ ] Draft Responses to Regulatory Authorities
- [ ] Benefit Risk Assessment
- [ ] Two and Six month Line Listings as required by National Regulatory Authorities

Safety Regulatory Intelligence

How is your organization addressing the ever-changing global clinical trial and post-marketing regulatory requirements in the markets you compete within to ensure reporting compliance?

- ☐ Centralized Documentation of New or Changing Regulations
- ☐ Impact Analysis & Implementation in PV system
- ☐ Weekly Monitoring & Monthly Client Newsletter

Products to Enhance Operational Delivery

Do you have the tools in place to streamline and simplify data mining and analytics?

- ☐ Oracle Argus Cloud Database
- ☐ Visually Impactful Tableau® Analytics Dashboard
- ☐ DistillerSR to Manage & Track Global Literature Review
- ☐ Case Processing Automation *(Machine Learning, AI, OCR)*
- ☐ CLAERITY® for Quantitative Safety Signal Investigation
- ☐ PV Plan® software ***(signal tracking)***

Project-Specific Plans

Are you confident in the ability to address your PV planning, communication with regulators and the quality of your training plan?

- ☐ Project Management & Communication Plan
- ☐ Operational Plans *(e.g. Adverse Event Reporting Plan, Data Entry Conventions, Signal Detection Plan, Literature Review, Periodic Reporting Plan, Expedited Reporting Plan)*
- ☐ Quality Agreement
- ☐ Training Plan

Literature Review

Is your organization and team knowledgeable about literature reviews required to meet regulatory requirement standards?

- ☐ Define and Validate Literature Search Strategy
- ☐ Global Literature Searching *(Embase and PubMed)*
- ☐ Retrospective Literature Review
- ☐ Aggregate Reports Literature Review
- ☐ Local Literature Review

Medical Information Call Center

How do you communicate essential product information in the areas of drug/device information and product safety to prescribers and consumers?

- ☐ Product Quality Complaints
- ☐ Medical Inquiries
- ☐ Adverse Event Intake
- ☐ Development of FAQ Document
- ☐ Development of Standard Response Letters (SRL)

Operational Expertise

Are you prepared to scale your critical safety responsibilities and readiness as you move toward market approval?

- ☐ Sponsor/Marketing Authorization Holder (MAH) PV System Gap Analysis
- ☐ PV Training Development & Delivery
- ☐ Mock/Global Regulatory Inspection & Audit Support
- ☐ SOP Review & Writing
- ☐ Marketing Application Dossier Support
- ☐ Safety Data Exchange Agreement/ Investigator Brochure/Package Insert Writing and Review
- ☐ Training Materials and Attendance to Investigator Meetings

EU Pharmacovigilance

Have you considered the set-up and maintenance of your safety system to ensure compliance with regulatory agencies in the EU?

- ☐ EU QPPV / Deputy QPPV
- ☐ Local PV Services
- ☐ EudraVigilance & xEVMPD Registration and Maintenance
- ☐ Pharmacovigilance System Master File (PSMF) preparation and maintenance
- ☐ EU Risk Management Plan Preparation and Update

UBC combines a depth of experience in safety / pharmacovigilance, risk management, signal detection and assessment with innovative technology systems to provide you with the insights you need to oversee the safety of your product.

In the last three years, we have helped more than 60 companies address their safety needs by implementing and managing over 84 PV programs. Our broad experience includes drug, cellular gene therapy, vaccines, medical devices and over-the-counter products.

Connect with us today to discuss UBC's solutions to meeting your patient safety and regulatory reporting needs.

3 In the past **YEARS**

60 we have supported **COMPANIES**

84 and delivered **PV PROGRAMS**