

## 25 Years of Delivering Outstanding Compliant Safety Services

**300+** studies supported on an annual basis

**30,000+** clinical trial SAEs processed per year



## Value Added Clinical Safety Services

### Independent Physician Medical Monitor

- Close collaboration in patient safety monitoring
- Generating safety data for signal detection and risk/benefit balance analyses

### DSMB

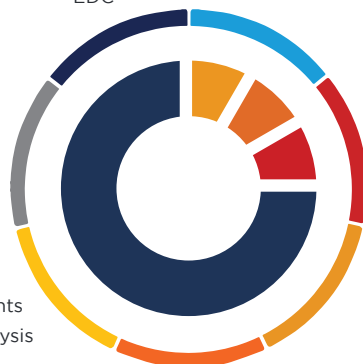
- Highly specialized PV Physicians
- Expertise in patient safety profile assessments
- Safety data listing review and signaling analysis

### CRO/Vendors

- PM/ lead
- CRAs/CTMs
- eTMF
- EDC

### Regulatory Intelligence

- Set-up of regulatory reporting capabilities: registration with EV, xEVMPD, MHRA, CTIS, etc.
- Safety Reporting



### Medical Writing

- Protocol and investigator brochure
- Safety Management Plan development and execution (including third-party CROs)
- DSUR
- SUSAR line listing
- Annual Safety and Progress Report
- Clinical Study Report scheduling and delivery in line with country-specific requirements

### Data Management

- Safety database /EDC custom-designed solutions for SAE reporting, efficient queries' resolution, etc.
- Efficient Reconciliation process
- Unblinding process

### Risk/Benefit & Signaling

- Contributing to risk/benefit analyses
- Providing result of signaling
- Advice regarding IB/protocol changes

## Signal Management in Clinical Trials Settings

### A Methodology Data Sources

- Tailored for each IP separately
- EAEs (SAEs, AEs, AESI), investigations, study discontinuations/deaths, medical history, subject exposure and demographics, literature screening results, RSI, latest DSUR and SD report

### B Analysis

- Focus on AEs/SAEs/AESIs and laboratory data
- Aggregate signal detection based on accumulating safety data from the entire clinical trial database at appropriate intervals
- Detection of any concerning patterns

### C Results & Actions

- Potential signal can have one of the following outcomes: Confirmation or rejection/ Classified as potential risk/ Classified as identified risk
- Safety actions may result in: Safety related protocol amendments including eligibility criteria / Safety revision of the ICF and the IB / Sending out a Dear Investigator letter



# Benefits of a Single Pharmacovigilance Partner

## Strategic Alignment We see the big picture

### Corporate Alignment

Governance and executive engagement to achieve mutual goals and objectives

### Capability to Support Full Product Safety Life Cycle Management

Specialized clinical, innovative, and generics units

### Data Driven Strategic Decisions

Insights from cumulative data (aggregate reports, listings, analysis) to strategically position your drug product on the market

## Standardized Quality Globalized approach

### Consistent Medical Review Processes

Product safety profile, RSI, risk/benefit assessment, and signaling

### High Quality and Excellence

Customized KPIs and tailored report

### Consistent Reporting

Harmonized reporting, coding, analyzing, KPIs, etc.

### Visibility of Industry-Wide Best Practice

Harness consolidated know-how for a competitive advantage

## Efficiency Saving time and cost

### Communication

Single point of contact driving accountability for oversight, delivery, and escalation

### Regulatory Reporting

Cross reporting efficiencies (oversight, compliance, costs)

### Budget Efficiencies

Project management, trainings, processes, and templates

### Regulatory Intelligence

Centralized surveillance and impact analysis

### Bespoke Templates

Joined Operating Guidelines, SOPs, and Working Practice Documents

## Benefits of Global PV Provider



### Efficiencies

- Budget efficiencies
- Additional resources & time to manage several partners
- Consistent approach/harmonized processes (same processing, coding, analyzing, reporting, etc.)
- Same core documents (and their maintenance)
- Access to cumulative data (=for aggregate reports, listings, analysis, less efforts with reconciliation, etc)
- Communication (one point of contact for Governance & Oversight)
- Regulatory reporting /cross reporting efficiencies (oversight, compliance, costs)
- Regulatory intelligence (centralized)

### Several PV Providers

### One PV Provider

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