

We Aid To Improve Public Health and Patient Safety

## Integrated PHARMACOVIGILANCE SOLUTIONS

Jeevan Scientific (JSTL) offers comprehensive Pharmacovigilance solutions starting from clinical trials to post-marketing product support.

Drug safety experts at JSTL continuously assess the safety of your products and define the best possible risk management to be compliant to respective regulatory authority.

### SERVICES



#### Individual Case Management

- Case Intake and Triage
- Data Entry
- MedDRA Coding
- Narrative Writing
- Quality Control & Medical Review
- Submission to Regulatory Authorities



#### Risk Management Plan

- Risk Identification
- Development of Risk Minimization
- Assessment of Risk Minimization
- Risk Communication & Implementation



#### Medical Call Center

- Inbound / Outbound calls
- 24/7 Support
- Collection of Reports
  - Product Complaints
  - Medical Information



#### Aggregate Safety Reports

- Periodic Safety Update Reports (PSUR)
- Periodic Benefit-Risk Evaluation Report (PBRER)
- Periodic Adverse Drug Experience Report (PADER)
- Annual Reports
- Developmental Safety Update Report (DSUR)



#### Signal Detection

- Signal Identification, Prioritization, Signal Assessment, Analysis & Signal Evaluation
- Statistical Analysis in Large Adverse Event Databases
- Active Surveillance



#### Support Services

- Literature Search Review & Monitoring
- QPPV Support
- Inspection and Audit support
- Archival Management
- IT Support

# Advantages

## Cross Functional Team

Our functional heads/domain expertise will provide expert solutions for your esteemed requirements



Independent CRO

Public Limited Company



## Experienced Global Project Managers

Pro-actively prepare solutions and take ownership of project and all its deliverables



## One Stop Solutions

Our domain experts will provide end-to-end Pharmacovigilance solutions of all phases of clinical development and post marketing surveillance.



## Effective Study Management

Our experienced project managers ensure consistent global procedures, rigorous oversight and easy access to integrated data.



## Regulatory Inspections

Our domain experts are well versed with different regulatory inspections/audits



## Variablize Costs and Shared Risk

Innovative partnering and alliance models reduce infrastructure costs and enhance strategic capacity planning.

# Other Services



## BA/BE Services

- Healthy & Patient Based Studies
- Bioanalytical Services
- Statistical Analysis & Data Management



## Clinical Development

- Patient based BA/BE
- PK/PD Studies
- Early & Late Phase Clinical Trials
- PMS and Observational studies
- Clinical Trial Management



## Clinical Data Management

- Clinical Data Management
- Electronic Data Capture (EDC)
- SAS and WinNonlin
- CDISC

GLOBAL OPERATIONS - INDIA  
Plot#1&2, Sai Krupa Enclave  
Near Lanco Hills, Golconda (PO)  
Hyderabad 500 008

CLINICAL PHARMACOLOGY CENTRE - INDIA  
B-17, TIE, Phase II, Balanagar  
Hyderabad-500 037

+91-40-67364700

+91-40-67364707

bd@jeevanscientific.com