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# Biovance Solutions

**CLINICAL EXCELLENCE, The full Spectrum of Safety, Medical Documentation**

Biovance Solutions is a trusted partner for end-to-end clinical, regulatory, pharmacovigilance, scientific documentation & Pre-Clinical services. With a strong commitment to quality, compliance, and operational excellence, we support pharmaceutical, biotechnology, medical device, and healthcare organizations in navigating regulatory expectations while ensuring patient safety and scientific integrity.

Our integrated service model, supported by experienced professionals and best-in-class governance systems, ensures efficient, reliable, and audit-ready deliverables across all clinical operations.

# OUR SERVICES

1

Pharmacovigilance  
Services

4

Pre-Clinical  
Services

2

Regulatory Affairs

3

Medical Writing



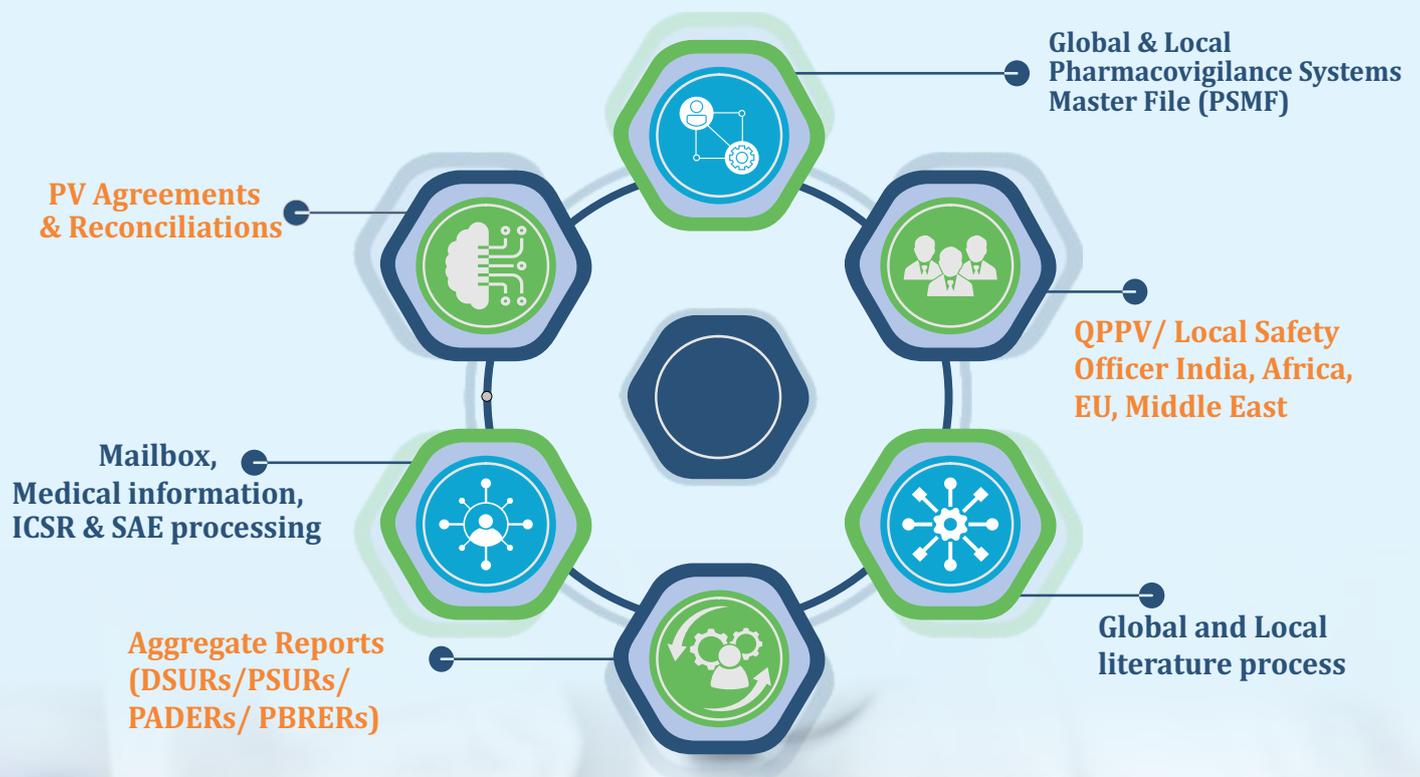
# PHARMACOVIGILANCE

Biovance offers full-spectrum Pharmacovigilance services to support pre-approval and post-marketing safety requirements.

## CORE PV SERVICES

- Case intake, triage, and data entry
- ICSR processing (serious & non-serious cases)
- Medical review and medical assessment
- Quality review and coding (MedDRA/WHO-DD)
- Literature screening and evaluation
- Periodic safety reports (PSURs, PBRERs, DSURs)
- Signal detection, trend analysis & risk management

Safety database management and compliance monitoring



## NICHE AND SPECIALIZED PV SERVICES

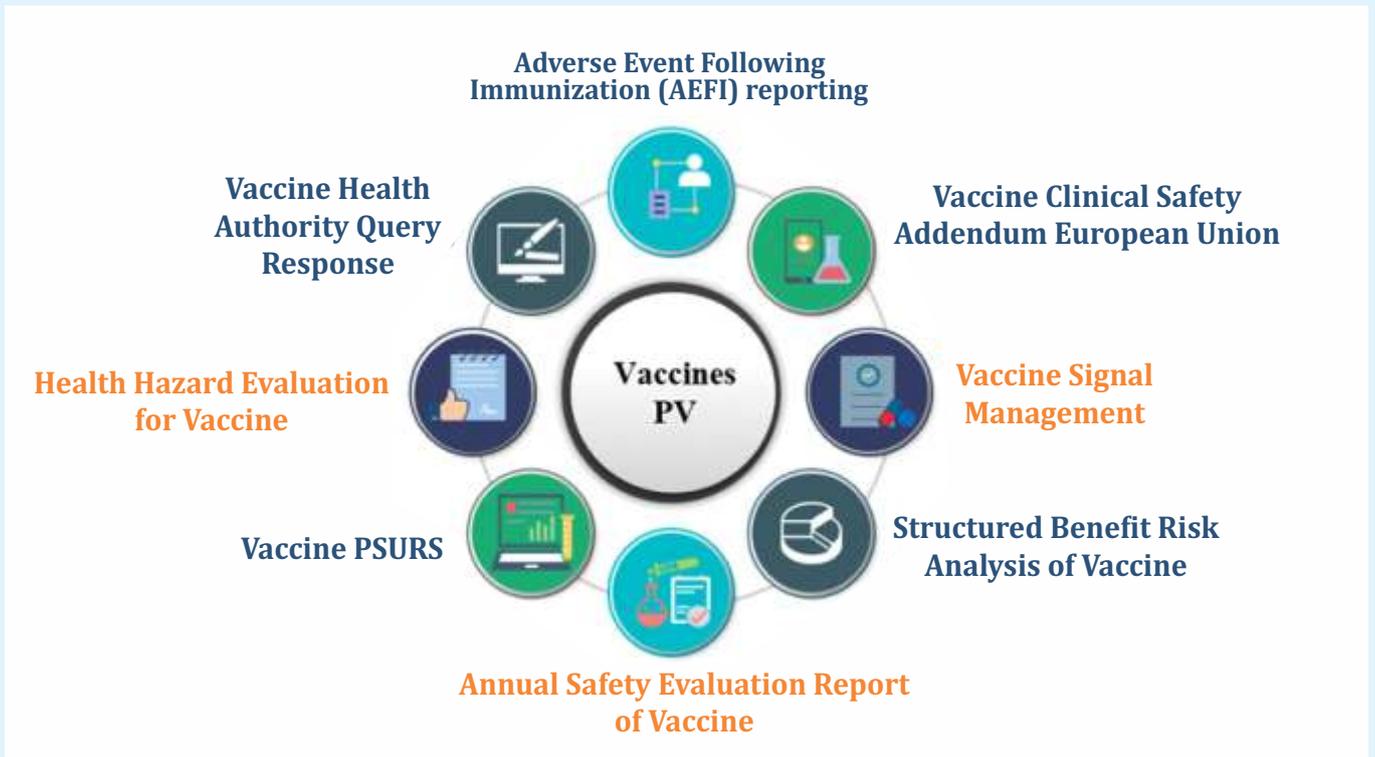
- MICC (Medical Information & Call Center) support
- Vaccine Safety monitoring and adverse event tracking
- Medical Device Safety (MDR, vigilance, PMCF)



Biovance ensures global compliance across the FDA, EMA, PMDA, TGA, Health Canada, & other agencies.

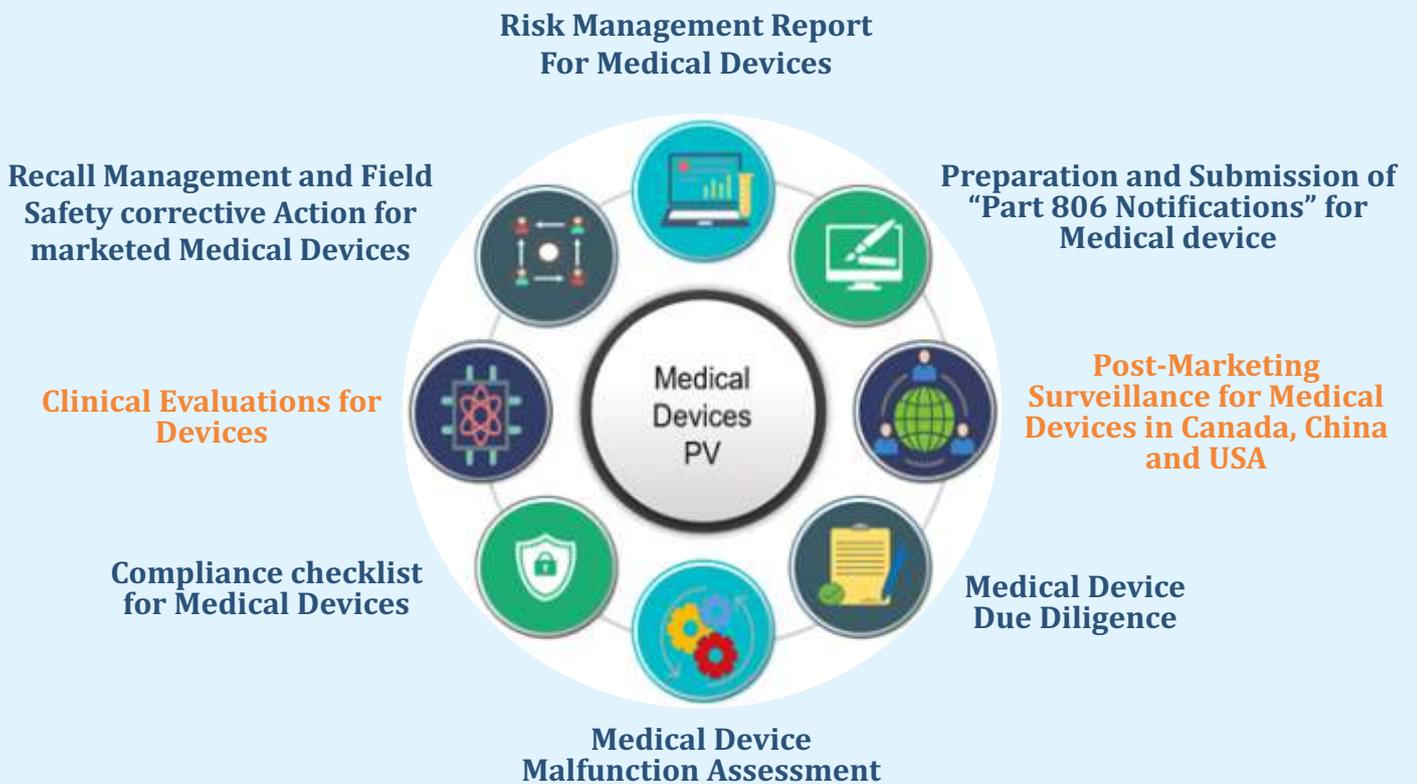


# VACCINE SAFETY - Vaccine Safety Monitoring & Adverse Event Tracking



## MEDICAL DEVICE SAFETY

Medical Device Safety (MDR, Vigilance, PMCF)



## **REGULATORY CAPABILITY**

**A comprehensive regulatory services portfolio covering product lifecycle—from development to post-market.**

### **Regulatory Services**

- Regulatory strategy and intelligence
- Dossier authoring, compilation & submissions (CTD/eCTD)
- Lifecycle management (variations, renewals, amendments)
- CMC regulatory support
- Health authority interactions (FDA, EMA, MHRA, DCGI, etc.)
- Support for fast track, Orphan Drug, Breakthrough Therapy applications

### **End-to-End Regulatory Support**

**We manage all aspects of regulatory operations including tracking, documentation, submission planning, and cross-functional coordination to ensure smooth approvals.**

### **Technology & Compliance Tools**

- eCTD submission platforms
- Regulatory information management (RIMS)
- Electronic document management systems (EDMS)
- Audit readiness support and compliance documentation

### **Specialized Expertise**

- Small molecules & biologics
- Biosimilars
- ATMPs, gene therapies, cell therapies
- Medical devices & IVDs
- Combination products

## **MEDICAL WRITING CAPABILITY**

Our medical writing team brings strong scientific, regulatory, and communication expertise.

### **Regulatory Writing**

- Clinical Study Protocols & Amendments
- Investigator Brochures (IBs)
- Clinical Study Reports (CSRs)
- CTD Modules (2.5, 2.7, 5)
- Risk Management Plans (RMPs)
- DSURs, PSURs, PBRERs
- Summaries for IND, NDA, BLA, and MAA submissions

### **Safety & Pharmacovigilance Writing**

- Case narratives
- Aggregate reports
- Signal detection documents
- Literature review summaries

### **Publications & Scientific Communication**

- Manuscripts, abstracts, posters
- Advisory board reports
- KOL slide decks
- White papers & newsletters

Our writing ensures scientific clarity, regulatory alignment, and audience-appropriate communication.

## **PRE-CLINICAL CAPABILITY**

Pre-clinical Services supports **drug discovery, development, and regulatory-driven pre-clinical evaluation**. Designed to bridge the gap between academic research and industrial expectations, it functions as an integrated platform delivering **high-quality, GLP-compliant and GLP-aligned pre-clinical services** to pharmaceutical, biotechnology, nutraceutical, medical device, and academic partners



### **STRONG FOCUS ON INDUSTRY-DRIVEN PROJECTS**

**This division** has already emerged as a trusted partner for **industry-sponsored research projects**, with a clear emphasis on **problem-solving, regulatory relevance, and translational outcomes**. LSRI has successfully executed **about 600 in-vivo studies and 500 in-vitro studies**, reflecting both the scale and consistency of its industrial engagement. These projects span early proof-of-concept studies, mechanistic evaluations, dose-range finding, and advanced toxicity investigations that require a high degree of scientific rigour and regulatory understanding.

### **HANDLING HIGH-COMPLEXITY AND CHALLENGING PROJECTS**

One of our defining strengths is our ability to **undertake technically challenging and scientifically demanding projects**. We routinely execute **long- and short-term toxicity studies**, disease-specific efficacy models, implantation studies, and complex multi-parameter evaluations across therapeutic areas such as **diabetes, neurodegenerative disorders (Parkinson's and Alzheimer's), oncology, cardiovascular diseases, dermatological conditions, and metabolic disorders**.

These studies often involve **customised study designs, advanced analytical techniques, multiple biological endpoints, and stringent ethical and regulatory compliance**, supported by a **CCSEA-approved animal facility** and state-of-the-art laboratories within the Departments of Pharmaceutical Technology and Biotechnology. The availability of advanced instrumentation such as **LC-MS Bio-Q-TOF, flow cytometry, HPLC, fluorescence microscopy, and ultra-low temperature storage** enables LSRI to manage projects that demand precision, reproducibility, and

# WHY CHOOSE BIOVANCE SOLUTIONS



- 100% compliance on regulatory timelines
- Zero-critical-finding principle for audits
- Highly skilled scientific & medical team
- Process excellence & strong governance
- Global regulatory and PV expertise
- Cost-effective and scalable operations
- Advanced tools and quality frameworks

**Biovance Solutions:**

**Where scientific expertise meets compliance excellence.**



**Biovance Solutions**  
— CLINICAL SERVICES OVERVIEW —

## **Punam Kumari**

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