



# **Tech Mahindra Pharmacovigilance Services**

Next Gen Framework for  
Maintaining Compliance

# Abstract

As a sector, healthcare and life sciences is a very unique one. Every aspect of the industry is highly regulated and needs to be continuously monitored. One such area of stringent scrutiny is reporting of drug safety or pharmacovigilance (PV). To serve healthcare practitioners and patients better, life sciences and medical devices companies need specialized PV services.

Tech Mahindra brings an end-to-end solution suite for comprehensive PV services, ensuring rigorous monitoring and reporting of drug safety.

## Introduction

TechM has a strong experience in clinical to regulatory and safety services to manufacturing and we take pride in delivering exceptional results in life-science consulting, operations, and transformation. With a focus on new age technologies like GenAI, design thinking, and hype-personalization, we deliver impactful results and offer a comprehensive solution. Our expertise and solutions help organizations improve their operations, reduce costs, and streamline their functions.



**10+**  
Countries



**7500+**  
Experts



**300+**  
Projects



**10M+**  
Patients

## Our Solution

### Next Gen Pharmacovigilance Framework

TechM has vast experience in triaging and processing adverse effect (AE) cases for global clients. Our dedicated team conducts systematic surveillance, signal detection, social media sentiment and safety analysis and regulatory compliance, fostering a proactive approach to adverse event management. With a commitment to pharmaceutical safety, we provide pharmaceuticals with robust solutions for maintaining compliance and safeguarding public health. The following diagram illustrates our integrated PV framework.



#### **Dashboard with Safety and Regulatory Intelligence -**

Patient data aggregation and visualizations for regulatory and safety requirements.



#### **Comprehensive Analytics -**

Highly personalized patient recommendations and treatment plans.



#### **Early Signal Detection -**

Near real-time AE active surveillance platform powered by AI engine.



#### **Real World Evidence -**

Health economics and outcome research through real world data collected.



#### **AI-powered Reusable Content -**

Identification of reusable components from clinical and safety reports.



#### **Literature Search and Creation -**

AI models to read and extract relevant safety information for various reports.



#### **Social Media Sentiment and Safety Analysis -**

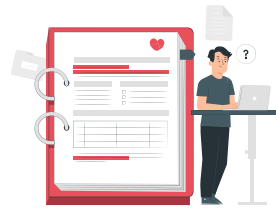
Capture safety notifications and posts from leading social media platforms.

# End-to-End Offerings for PV lifecycle



## AE Collection and Follow-up

24/7 AE collection support, AE reports, product complaints, medial enquiries, AE follow-ups, and safety communication



## Report Writing and Development

Safety narrative writing, ICSR template, PSUR template, annual safety reports, risk management plans



## Monitoring and Analysis

Early warnings, email alerts, clinical review and analysis, SAS analysis and reporting



## Case Entry and Processing

Data collection (internet, fax, email, and literatures), case entry, medical coding, and review

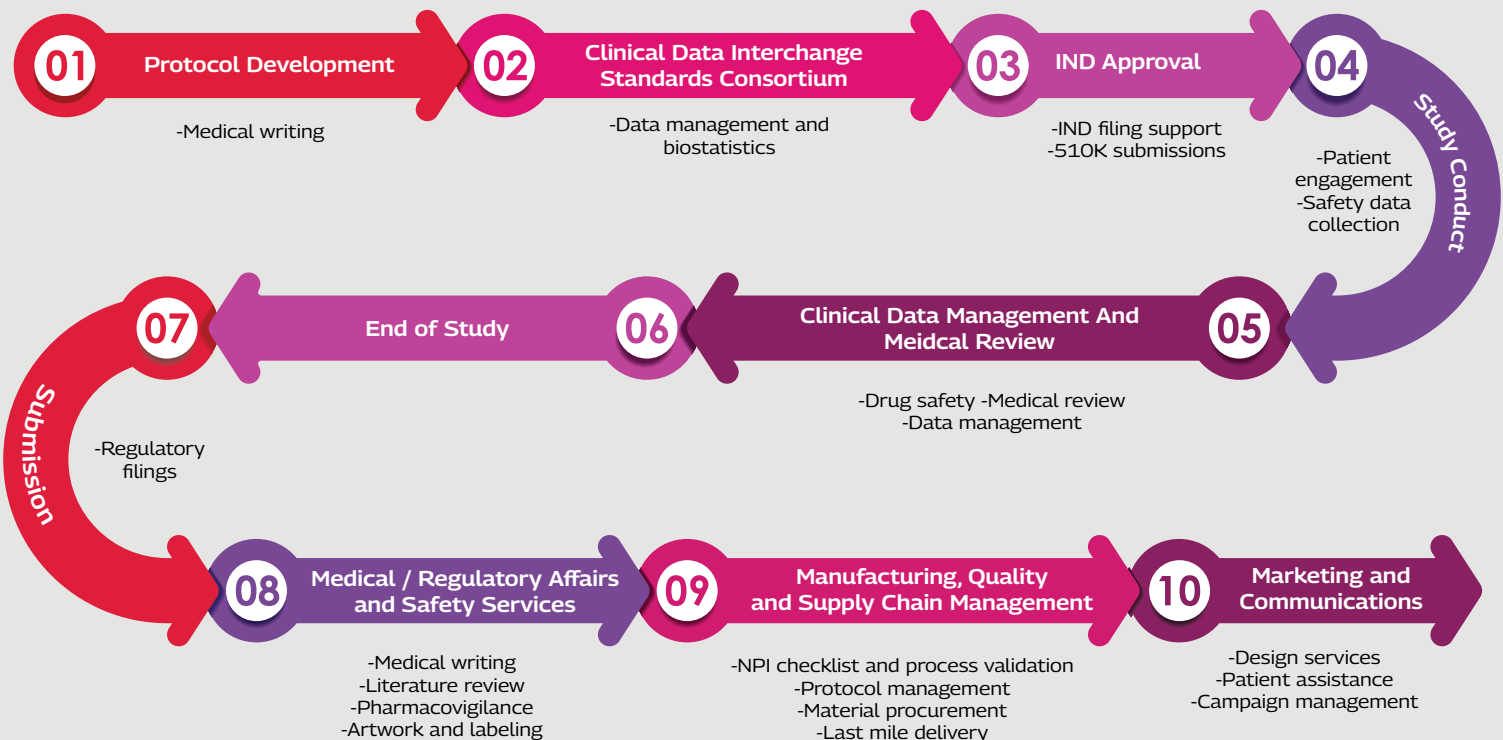


## Data and Safety Analysis

SaaS based AI-platform, regulatory compliance, signal detection, aggregate data output, interactive dashboards, AI/ML techniques for cohort/subset analytics

# Comprehensive Services for Life Sciences

Our life sciences value chain encompasses the journey of products and services from research and development to commercialization and patient care.



# Benefits

## Automated international medical device regulators forum coding for medical device



- First and only of its kind of automated solution that uses AI, ML, and LLM
- Accuracy - 95% in predicting relevant code
- Enhances IMDRF coding and information categorization across the 7 annexures

## Pharmacovigilance services and processing of live case reports for therapeutics and medical devices.



- Savings of over 7x
- >99% TAT Compliance and 80% TAT improvement
- >99% Quality Compliance

## Biomed literature screening automation and processing literature for ICSRs, aggregate reporting, and signal detection activities



- Automated literature search and classification
- AI/ML model with 97% accuracy
- 70% savings as compared to in-house processing

## Cost effective integrated (IT & BPO) drug safety solution with 6-sigma process optimization and translation services supporting 10+ channels



- 350,000+ cases processed
- 100% TAT cCompliance
- Consistent quality score exceeding 99.5%

## AE/SAE reporting under a PSP Project with CRM tool for updating patient records



- Zero deviation from agreed KPIs and SLA matrix
- 9+ regional language support

## The NXT.NOW™ Advantage

- At Tech Mahindra, we have been serving global life sciences organizations for over 20 years—catering to more than 120 leading companies of various strengths.
- We have engaged with more than 10 clients to ensure safety of the product.
- in-house solutions to capture adverse events and monitor literature.
- We have in-house solutions to capture adverse events and monitor literature. We have more than 10 life Sciences operations sites globally to support myriad requirements.

**Contact us today to learn more about Tech Mahindra  
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