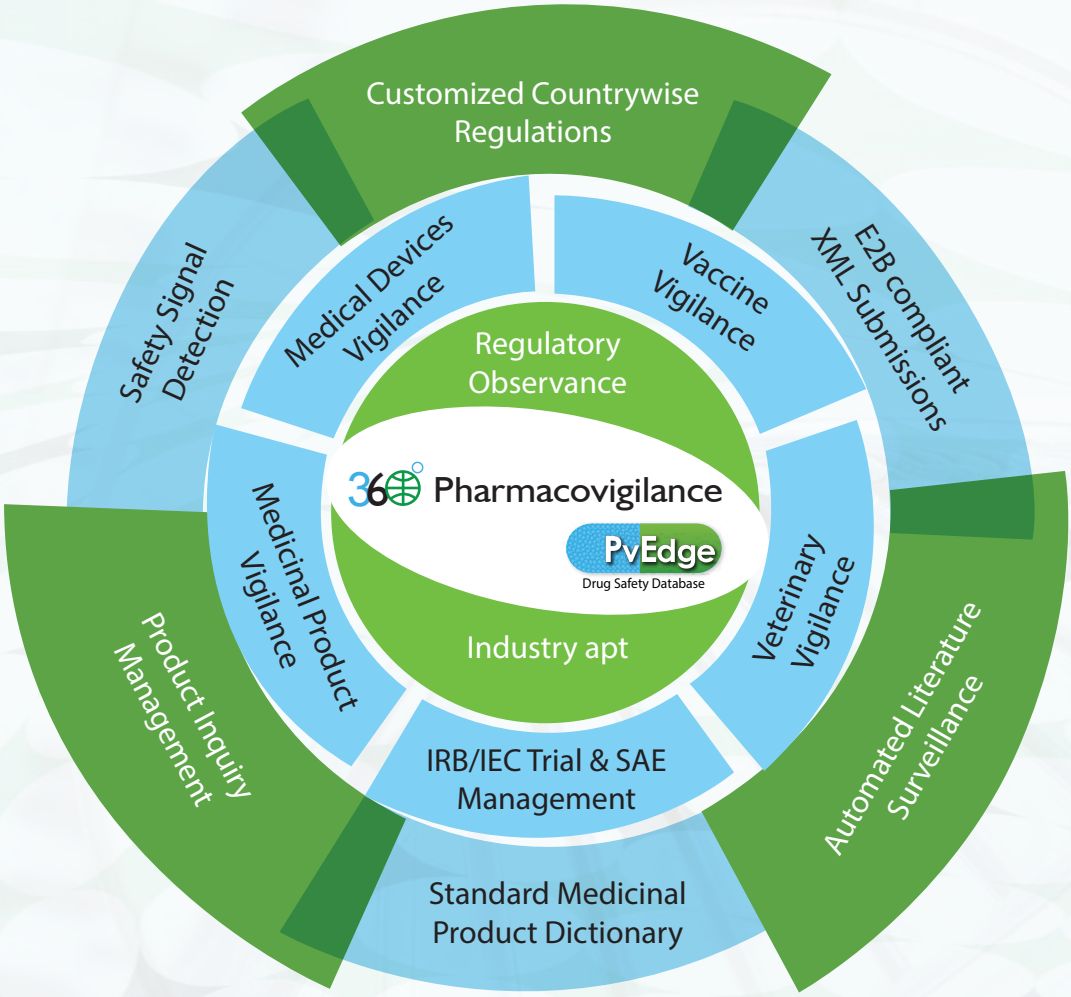
PvEdge

Drug Safety Database

360° Pharmacoviglance software solution

pvedge.sarjen.com

Benchmarked solution utilized by CROs, large scale Pharma and Biotech manufacturers and PV service providers



Unleashed strength of ePharmacovigilance

Expertise in regulatory domain submissions

Core pillars for 360° Pharmacovigilance

Exclusivity across the globe

- Mechanized literature surveillance that simplifies global scientific literature monitoring
- Reportability configuration to assure expedited ICSR submission timelines in various regions
- Integration with medical information module/software (PrITR) for preventing duplication in data entry and reconciliation of AEs
- Rationalized customization to suit varying company SOPs and practices

Benefits

- Evolved and designed by Pharmacovigilance and IT specialists
- Product-wise modules accessibility
- Regular domain knowledge sharing to stay current in day to day PV processes
- Well-timed upgradations for smooth operations
- In-built PV operational fundamentals for global adherence to product monitoring and tracking
- Open to coherent changes with ever-changing industry practices and country-wise norms
- Simplicity and ease of use with minimal hands-on training necessity

Features

- Multipurpose dashboard along with graphical representation
- Productivity calculation to improve team performance
- Clinical trial SUSARs recording and reporting
- MedDRA upgrade impact report – term comparis on in different MedDRA versions uploaded
- Identifying potential signals for better risk-benefit profiling
- Auto-narrative with multi-language – leaving users to spend more time reviewing than drafting
- Auto-scheduling of reports
- Global dictionary support (MedDRA, WHO-DD, FDA-Device/Patient problem code)
- Electronic medicinal product dictionary as per xEVMPD guidance

We believe in regulatory compliant deliverance

- Good Pharmacovigilance practices
- US FDA's guidance for industry for medicinal products, devices and vaccine vigilance
- ICH E2 Pharmacovigilance guidelines
- 21 CFR part 11 compliance
- CDSCO adherence as per PVPI and SAEs management for IRB/IECs
- Region-wise guideline implementation for submission as per standard norms

Successfully handled several Pharmacovigilance regulatory inspections including, MHRA – UK, US FDA, AIFA – Italy, Polish MOH, FAAG-AFMPS – Belgium, CBG-MEB - Netherlands and others.

Successfully cleared numerous sponsor audits.

Other Products

PharmaNET - Sales and Distribution

Sales and distribution solution with Demand, Warehouse, Financial, Purchase & Material Management…
Also, tracks Primary and Secondary sales channels to provide a consolidated picture of dispersed and complicated analysis.

pharmanet.sarjen.com

FForce - Field Sales Excellence Platform

- Distribution Management System
- Electronic Order Management System
- Sales Force Automation System
- eDetailing
- Field Sales Information System

fforce.sarjen.com

ProcEdge - Business process automation

- Processes automation
- Workflow automation
- Document management

procedge.sarjen.com

QEdge - Enterprise Quality management system

- Quality processes automation (CRF, Deviation, Investigation, CAPA, etc.)
- Document control (SOP, BMR, etc.)
- Training records keeping and management

qedge.sarjen.com

BizNET CTM - Clinical Trial management

Complete Clinical Trial management for CROs with Project tracking and monitoring, eCRF/EDC, Biometric volunteer registration, Medical screening, Medical coding, Clinical LIMS, BA LIMS…

biznet.sarjen.com

KnowledgeNET - Dossier publishing solution

KnowledgeNET is a robust, featured-packed, well established dossier submission and life cycle management solution. It has great adaptability of compiling dossiers with various global regulatory standards in distinct publishing formats like CTD, eCTD, NeeS, ACTD, GTD, vNeeS and the regional formats.

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About Sarjen

- Over 19 years' journey of IT consulting for business and technology
- Domain expertise in Pharmaceutical, Life Science and other domains
- Expertise in SCM, CRM, QMS, PV and Dossier Publishing solutions
- Client presence in 40+ countries; mainly in UK and rest of Europe
- Partnerships with Microsoft, Apple, HP, IBM
- Solutions built with own IP; adoptable to meet business challenges
- Solutions compliant with 21 CFR part 11, Annex 11 and GxP
- In-depth knowledge of Computer System Validations (CSV)

Sarjen Systems
ISO 9001:2015 certified company

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