



Business Solutions with Technology Edge



Since 1998, we have been a trusted digital transformation and automation partner. Over time, we've developed a range of diverse GxP, business, and technical software solutions. This is a result of combining extensive industry knowledge with robust technical capabilities to effectively address various industry challenges.

CORE COMPETENCIES

DIGITIZATION



Our expertise lies in creating easily adaptable solutions and seamlessly transforming traditional processes into digital ones

SOLUTIONING



Our experience lies in understanding complex business challenges and addressing them by providing comprehensive strategic solutions with the required domain and technology knowledge

AUTOMATION



Our focus lies in data engineering through which we create robust and intelligent systems that reduce manual efforts, streamline processes, and improve efficiency

INNOVATION



Our proficiency lies in our ability to deliver pioneering innovational products through the application of advanced technology and result oriented approach





PHARMACOVIGILANCE

Experience the Power of Automation and AI in Pharmacovigilance

CHANNELS

Email / Fax / Web / Call Centre / Agency / Gateway



ADR SOURCE

- Spontaneous / Clinical Trial
- Literature Portal
- Regulatory Portal
- MICC: PQC, PQC+AE, MI
- CIOMS, MedWatch, PDF, Excel
- Auto Track Full Text Article
- Auto Valid, Non-valid Check



CASE INTAKE

- Data Acquisition
- Validate Check for Duplicates
- Prioritize / Triage
- Alert Case of Interest
- Track Local Cases
- Bulk, Structured E2B R2 / R3,
 Canada Vigilance Download
- ICSR Seriousness & Validity
 Assessment
- XML, PDF Visualizer

CASE ALLOCATION

3

CASE PROCESSING

- Full Data Entry & Follow Up
- Auto Workflow Management
- Auto Narrative and Causality
- Auto XMLs Fetching
- Auto Labeling & Causality Matrix
- Auto Aggregate Report Compilation

4

CASE SUBMISSION

- Auto Transmit Cases to Local RA
 & Affiliate Partners via AS2 Gateway
- Partner Reconciliation: Email

5

PERIODIC REPORTING

- Auto Generation of Draft / Report
- Approval Life Cycle Management
- Submission Metadata Accumulation
- SPORATIC Report
- PADER, PBRER, PSUR, DSUR etc.



PHARMACOVIGILANCE

Simplify he Complexity of Safety Data with 360° Pharmacovigilance Software

SAFETY DATABASE

- Multivigilance (Drug | Device | Vaccine | Comb. Product)
- PMS & CT, Literature, NIS, PQC+AE
- Data Privacy: GDPR & HIPAA, MFA, Data Encryption (256 bit)
- Submission Outputs: R2, R3, CIOMS, MedWatch
- Signal Detection
- Aggregate Reports
- ICSR Submission Gateway

MULTISOURCE INBOX AND TRIAGE

- Automated Structured Intake
- Literature Surveillance
- MICC: MI, PI, PQC, PQC+AE for PV Affiliates & Call Centre
- WWWConnect (Web Based ADR Form)
- Extraction of Unstructured Data (PDF, DocX, CIOMS, MedWatch)



QUALITY MANAGEMENT

- Quality Processes: Change Control, CAPA, Deviation, etc.
- Training Records: Online / Classroom Training, 52 Week Training Calendar, Multimedia Curriculum & Evaluation

CONTROLLED DOCUMENT MANAGEMENT

- Report Compilation Automation
- PADER, PSUR, DSUR etc.
- Safety Data Exchange Agreements (SDEA) / PVA
- RMPs

Cloud Ready | Pre-validated | Globally Compliant

UNLEASHING THE VALUE OF PvEdge

70+ **Regulatory Audits**

Legacy Cases Migrated

3000+

Users





CELEBRATING OUR VALUED CLIENTS & COLLABORATIVE SUCCESS



















GALDERMA





























and more...

OUR GLOBAL FOOTPRINT



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FOLLOW US ON







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