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ADD Patient Safety Platform

Life Sciences & Healthcare

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The life sciences industry faces increasingly stringent rules globally with regard to pharmacovigilance (PV), as drug administrators put a premium on patient safety. Ineffective PV can lead to higher regulatory penalties owing to non-compliance, including delays in authorization for product registration and marketing. With policy makers actively encouraging the migration from paper-based Adverse Drug Reactions (ADR) reporting systems to electronic ones, life sciences companies must further automate their business processes.

Tata Consultancy Services' (TCS) ADD Patient Safety platform covers all aspects of PV in a predictable, cost effective manner. Life sciences companies can leverage Patient Safety Platforms, either as BPaaS or SaaS, to optimize operating costs and achieve full regulatory compliance with regard to ADR reporting.

Overview

Regulatory requirements for electronic transmission of ADR-related information, such as E2B R3 and IDMP, continue to evolve worldwide. As regulatory bodies come up with new norms and guidelines in this regard, life sciences companies will need to undertake major upgrades to their IT landscape, including database systems. The growing complexity of their IT infrastructure, spanning multiple products, vendors and agencies in various jurisdictions, remains a major challenge for large pharma and biotech organizations. Data volumes have spiked as companies handle unstructured, case-related information across journals, articles, patents and social media, in conjunction with management of historical databases of payers and providers.

Life sciences firms, therefore, need to implement an advanced software solution that can generate actionable insights on drug safety through efficient and effective analysis of large, complex datasets. ADD Patient Safety platform, through its migration toolkit, facilitates compliance with latest regulatory norms stipulated by various regulatory agencies. The configurable BPaaS / SaaS offering enables organizations to automate different business processes, like workforce scheduling, case intake, narrative writing and analytics pertaining to pharmacovigilance.

Our Solution

- **Surveillance-cum-analytics module**- Leverages historical and other public databases to collect relevant insights on drug safety in a visually intuitive way for business users.
- **Integrated solution**: Provides standards (e.g. E2B) and service based approach to external and internal integration enabling a long term solution.
- **NoSQL Technology**: Delivers a highly scalable, resilient repository for growing AE volumes and enables rapid ingestion of wide variety of structured and unstructured data formats.
- **Ontology Support**: Offers value added manual or automated services like medical and drug coding
- **Interactive Interface**: Delivers HTML5-enabled, responsive graphical user interface facilitates for on-the-go access to PV-related IT systems.
- **AI Technologies based Decision Fabric solution**: For automation of ICSR case processing including case intake, case triaging, data entry and medical assessment

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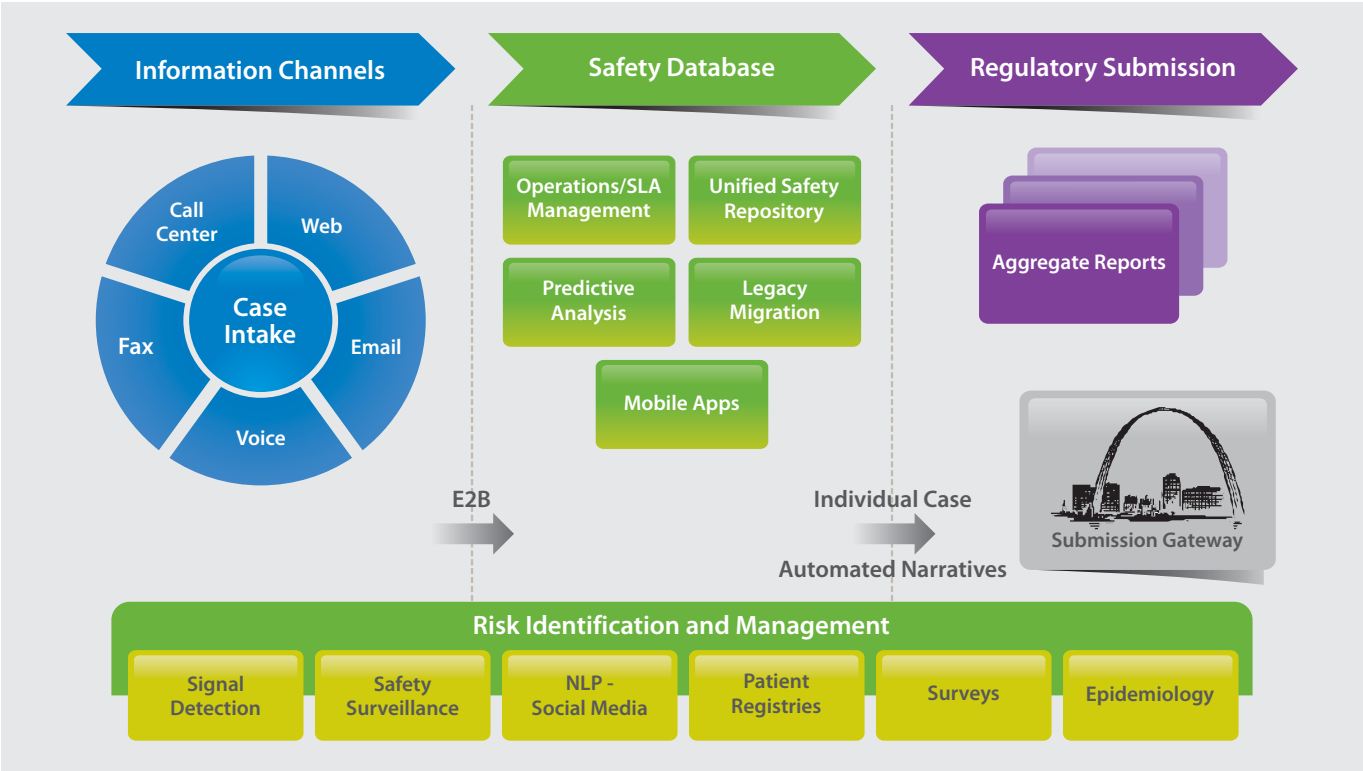

Benefits

ADD Patient Safety platform helps life sciences companies reap the following benefits:

Higher operational efficiency: Significantly reduce overheads on IT infrastructure, with regard to the pharmacovigilance function, by automating relevant safety business processes through a single window service in a predictable, cost effective manner through a cloud-based platform.

Regulatory compliance: Ensure full conformance to applicable regulations across different jurisdictions, through swift seamless and cost-effective upgrades to the latest ADR reporting requirements without disruption in regular operations.

Reduced time to market: Secure timely authorization for product registration and marketing with proactive and predictive SLA management and achieve a high degree of accuracy

Deep Insights: Showcase user group and role compliance, greater team efficiency, inflow trends, and enable real time signals with the IPS off the shelf analytics. Additionally, the multi-level filtering capability, allows intuitive data exploration sessions with drill-down support.

The TCS Advantage

By partnering with TCS, companies can leverage the following differentiators:

Scalable solution: Pharma and biotech companies can leverage the outcome based Integrated Patient Safety platform to meet dynamic regulatory standards across different geographies. The BPaaS/ SaaS platform covers various stakeholders involved in the pharmacovigilance function–patients, health care professionals (HCPs), contract research organizations (CROs), sponsors, and affiliates. TCS can customize the platform based on the unique language preferences of local enterprise users in a given jurisdiction. The platform is supported by TCS' various data centers that are compliant with relevant PV-related regulations worldwide.

Domain expertise: TCS' certified subject matter experts have knowledge of pharmacovigilance services relating to data capture, medical review, quality management, aggregate reporting, and signal detection and the experience of these SMEs is being leveraged to develop IPS roadmap.

Process maturity: TCS' well-defined and widely acclaimed quality management systems and standard operating procedures (SOPs) facilitate cost-effective optimization of business processes associated with PV.

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Awards & Recognition

To know more

Visit the **Life Sciences & Healthcare** page on **tcs.com**
Email: **ADD.Platforms@tcs.com**

About Tata Consultancy Services Ltd (TCS)

Tata Consultancy Services is an IT services, consulting and business solutions organization that delivers real results to global business, ensuring a level of certainty no other firm can match. TCS offers a consulting-led, integrated portfolio of IT and IT-enabled infrastructure, engineering and assurance services. This is delivered through its unique Global Network Delivery Model™, recognized as the benchmark of excellence in software development. A part of the Tata Group, India's largest industrial conglomerate, TCS has a global footprint and is listed on the National Stock Exchange and Bombay Stock Exchange in India.

For more information, visit us at **www.tcs.com**

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