

tcs ADD™



TCS ADD™ Safety

An AI Platform for pharmacovigilance





Manual handling of safety data is a major challenge in the life sciences (LS) industry that needs to automate the Pharmacovigilance (PV) business processes to achieve a high degree of cost-effective consistency, quality, and efficiency in case processing.

Powered by TCS' proprietary cognitive AI engine, the TCS ADD™ Safety platform creates a new competitive PV paradigm and holistic change in safety case processing.

Overview

Safety cases have risen across the world in both clinical trials and commercial settings. Further, safety cases are increasingly being generated through multiple unstructured sources such as journals, articles, patents, social media, and others.

Existing manual processes are unsustainable to handle such an increased volume of data accurately and timely. This has also increased the risk of missing important safety information and facing non-compliance. Our end-to-end AI Platform for PV has been developed to mitigate the above challenges.

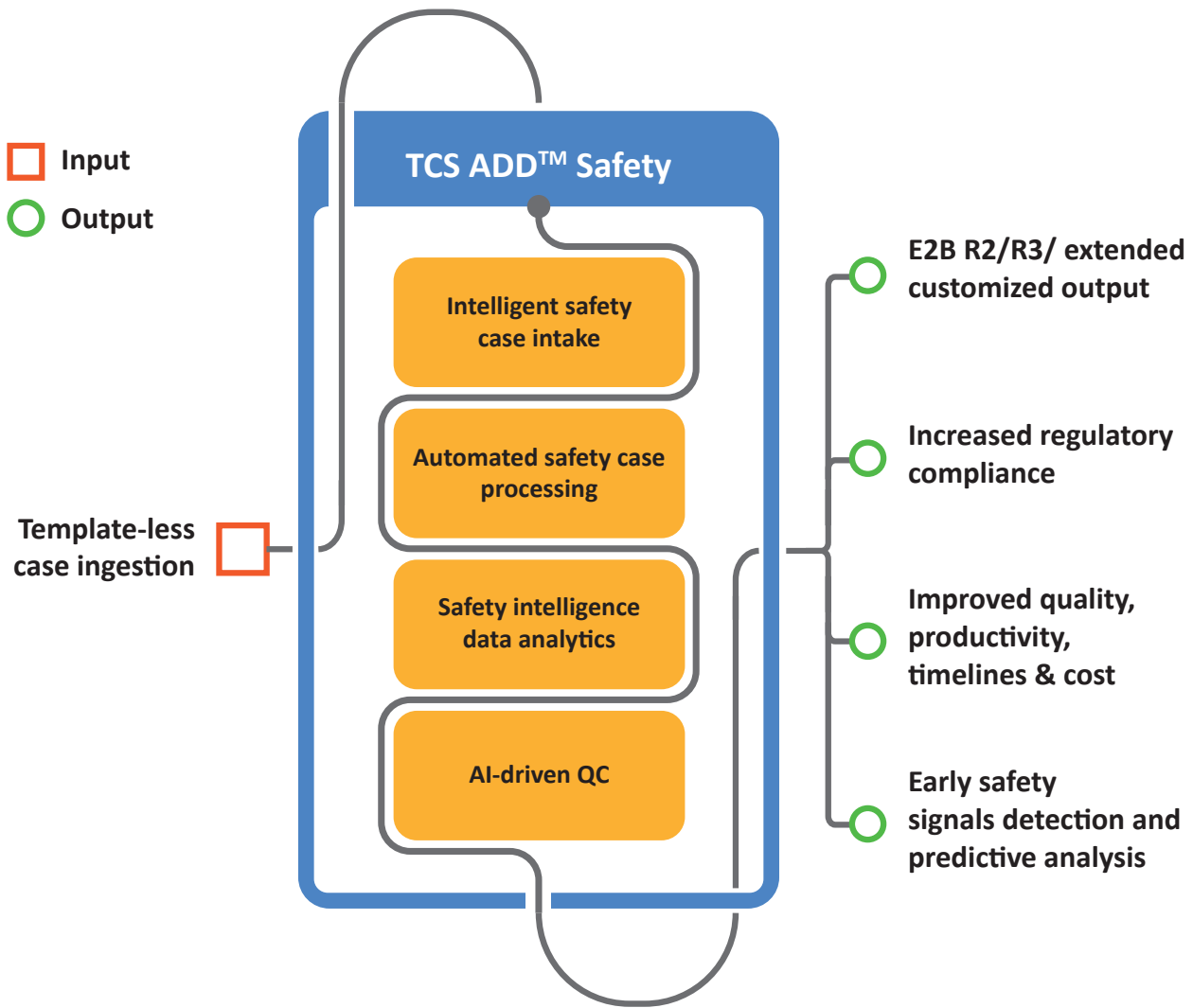
TCS ADD™ Safety is the most innovative and validated product in the market to handle all type of safety reports and data, TCS ADD™ Safety uses natural language processing (NLP) and AI technologies to ensure medical context and allows submissions in customizable formats per geo-specific regulatory requirements. Additionally, it is equipped with intelligent data analytics with actionable insights. TCS ADD™ Safety uses human-governed machine learning (ML) to enable AI modeling algorithms, traceability, transparency and learning management capabilities in accordance with Good Pharmacovigilance Practices (GVP).

Our solution

TCS ADD™ Safety is a cognitive automation platform for case processing leveraging human-governed machine learning, enabling audit readiness. TCS ADD™ Safety's transparent AI models can exponentially drive the adoption of AI/ML in PV. They help understand the nature of errors, improve quality and efficiency, and facilitate corrective actions.

The solution includes:

- **Intelligent safety case intake:** Facilitates automated safety data collection directly from any source with a template-less technology
- **Automated safety case processing:** Provides automated validity and duplicate checks, data entry, medical coding, and case assessment including seriousness, causality, and listedness. The solution also helps with automated narratives and report generation
- **Safety Intelligence data analytics:** Offers a set of performance metrics reports with deep actionable insights, improving operational governance
- **AI-driven quality control (QC):** Enhances efficiency and compliance with predictive analytics and optimizes the time and effort of the PV team



TCS ADD™ Safety: Schematic Overview

Benefits

TCS ADD™ Safety is an industry-leading proactive pharmacovigilance platform with an agile, AI-driven technology that enables touchless case processing and supports structured, semi-structured, and unstructured data source formats. We have delivered the highest levels of accuracy, quality, efficiency, and compliance.

Deliver operations and business outcomes

80%	+85%	95%	100%	40%	30%
Of volume through AI	Accuracy	Quality	Compliance with regulatory timelines	Efficiency gain	Cost saving

AI | EFFICIENCY | QUALITY | COMPLIANCE | SAFETY

Implementing the cognitive automation solution

TCS ADD™ Safety can make the PV process faster, agile, consistent, accurate, compliant, and more efficient, even though there is no viable one-size-fits-all approach to adopting an AI-based PV solution

With more than 5 years in production experience, TCS ADD™ Safety is ready to provide our customers with a phase-wise tailored implementation approach.

TCS ADD™ Safety can increase productivity, improve safety analysis, drive business growth, support budgetary responsibility, and bring innovation from day one of implementation with:

- **Template-less unstructured document extraction**
- **Reduction in safety case intake time from weeks to hours**
- **Improvement in accuracy in the extraction of medical history and indication**
- **Touchless case processing**



The TCS advantage

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



Patented Technology:

The TCS ADD™ Safety platform - leveraging the cognitive intelligence AI engine (Patent -#10558746) - uses automated cognitive processing of source agnostic data and can ingest, extract, and make cognitive decisions



Scalability:

Our platform can be scaled up to any level commensurate to the business need providing an optimal solution combining AI with skilled PV workforce without compromising on the effectiveness metrics of the solution



Tailored solution:

The platform can be configured based on language preferences of the local enterprise users and local regulatory requirements



Flexibility:

TCS ADD™ Safety provides flexible integration with other applications and can be implemented either as a standalone solution or in addition to the existing solutions to increase the efficiency of the existing data capture system



Technology and Domain expertise:

Our certified subject matter experts combine AI with contextual domain knowledge and possess the capabilities of clinical research services providers, platform solution providers, and global system integrators to deliver strategic solutions per all customer requirements



Cost-optimized solution:

TCS ADD™ Safety's patented, mature, and proven solution offers a much higher return on capital investments



Awards and accolades

- TCS named as the second most valuable brand in the “Most Valuable IT Services Brands **2024**” by **Brand Finance**
- TCS Named to World’s Most Admired Companies List 2023 by **FORTUNE® Magazine**
- TCS recognized as a most valuable global brand 2023 by **Kantar Brandz**
- TCS ranked number one for tenth consecutive year in Customer Satisfaction by **Whitelane Research Survey 2023**
- TCS Europe Listed as a 2023 Top Employer by **Top Employers Institute**

TCS ADD™ Awards and Recognition

- TCS ADD™ 7 times winner of **India Pharma Awards**
 - 2024 for “Excellence in Ancillary Pharma Services” awarded to TCS ADD™ Safety and “Excellence in the Use of New Age Technology” awarded to TCS ADD™ Risk Based Quality Management
 - 2023 for “Excellence in Ancillary Pharma Services” and “Excellence in use of Technology” awarded to TCS ADD™ Metadata Repository
 - 2022 for “Excellence in Ancillary Pharma Services” awarded to TCS ADD™ Connected Clinical Trials
 - 2021 for “Excellence in Ancillary Pharma Services” awarded to TCS ADD™ Regulatory
 - 2019 for “Excellence in Ancillary Pharma Services” awarded to TCS ADD™ Metadata Repository Platform
- Won the Global Annual AI Awards for transforming safety case processing to reduce time and increase throughput for TCS ADD™ Safety platform at Awards. **AI Awards 2021**
- Won the “Best Patient Facing Tech Initiative” award for technology excellence in clinical research & drug development for TCS ADD™ Connected Clinical Trials platform at **Citeline Awards 2020**
- Won the “European Innovation Awards” for applying thoughtful approach to solve tough industry problems for TCS ADD™ Connected Clinical Trials platform at **Scope Europe 2019**

About TCS ADD™ Platform

TCS ADD™ is a modern and open drug development platform for life sciences that enables digital ecosystems, simplifies data complexity and provides faster access to new and effective drugs for patients in need. The platform is powered by our proprietary cognitive intelligence engine data driven smart analytics and Internet of Things (IoT) that makes clinical trials more agile and safe. TCS ADD™ leverages the best of cloud architecture and personalized user experience design in compliance with quality guidelines and privacy regulations.

To know more



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About Tata Consultancy Services Ltd (TCS)

Tata Consultancy Services is an IT services, consulting and business solutions organization that has been partnering with many of the world’s largest businesses in their transformation journeys for over 56 years. Its consulting-led, cognitive powered, portfolio of business, technology and engineering services and solutions is delivered through its unique Location Independent Agile™ delivery model, recognized as a benchmark of excellence in software development.

A part of the Tata group, India’s largest multinational business group, TCS has over 601,000 of the world’s best-trained consultants in 55 countries. The company generated consolidated revenues of US \$29 billion in the fiscal year ended March 31, 2024, and is listed on the BSE and the NSE in India. TCS’ proactive stance on climate change and award-winning work with communities across the world have earned it a place in leading sustainability indices such as the MSCI Global Sustainability Index and the FTSE4Good Emerging Index.

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