

TCS ADD™ Safety

A next-generation AI platform for Pharmacovigilance transformation



Manual handling of safety data is a major challenge in the Life Sciences industry, slowing progress and amplifying compliance risks. Automating the Pharmacovigilance (PV) processes can help achieve a high degree of cost-effective consistency, quality, and efficiency in case processing. Powered by TCS' proprietary artificial intelligence (AI) engine, the TCS ADD™ Safety platform creates a transformative PV model, accelerating operations and strengthening our clients' competitive positioning.

Overview

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

Current PV infrastructure is unsustainable to handle such an increased volume of data timely and accurately, increasing the risk of missing 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 platform is the most innovative and validated product in the market to handle all types of safety reports and data. The platform ensures medical context and allows submissions in customizable formats as per geo-specific regulatory requirements. Additionally, it is equipped with intelligent data analytics with actionable insights. It uses human-governed machine learning (ML) to enable AI modeling algorithms, traceability, transparency and learning management capabilities in accordance with Good Pharmacovigilance Practices (GVP).

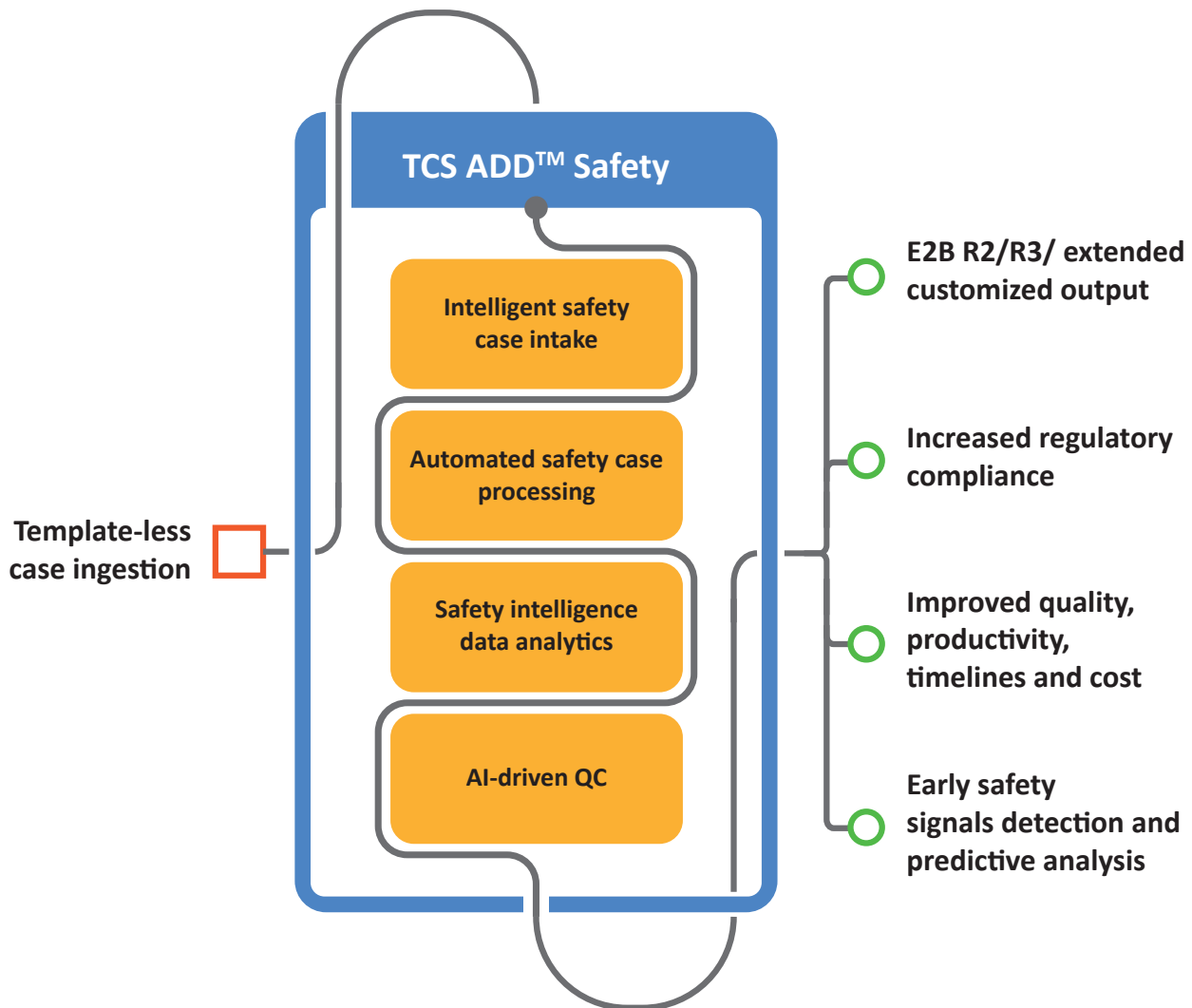
Who we are?

We are a multi-disciplinary team with decades of case processing & AI product development engineering expertise for the Life Sciences industry.

Our award-winning platform, TCS ADD™ Safety, is a transformative platform that has revolutionized the PV model, powered by Gen AI. The platform facilitates effortless configuration and 100% compliance with regulatory timelines.

Our platform

- **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 platform 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

Highlights

- **Out-of-the-Box Functionality:** Pre-built models, workflows, and rules for end-to-end Individual Case Safety Report (ICSR) automation, enabling rapid deployment.
- **Simplified Change Management:** Single UI for case intake, case processing, medical review and quality teams, ensuring best efficiency gains with minimum disruption to business.
- **Interoperability:** Open architecture and API based integrations enable interoperability with clinical, safety and quality systems.
- **Extensibility:** Supports new use cases and co-exists with other safety databases, enhancing value over time.
- **Explainability:** Human-readable business logs capture AI-driven decisions, supporting transparency and enabling responsible AI design.
- **Performance metrics & governance:** Interactive dashboard to monitor performance and accuracy of the platform and reports for audits, governance and oversight

Benefits

TCS ADD™ Safety offers the following benefits:

- **Accelerated end-to-end ICSR processing:** Significantly reduced timelines across intake, extraction data entry, and review.
- **Maximized automation:** Significantly increase the percentage of ICSR process steps completed automatically, minimizing manual intervention.
- **Enhanced data quality:** Drastically reduced errors and inaccuracies in processed ICSRs.
- **100% Regulatory compliance:** Ensured adherence to all pharmacovigilance regulations and reporting timelines.
- **Augment human expertise:** Strategically embed talent within an intelligent digital automation strategy.
- **Maximized operational efficiency:** Achieved significant throughput gains and resource optimization.
- **Elevate business visibility:** Access new and enhanced reports/dashboards with critical data points for superior decision-making.
- **Automated validation & audits:** Implemented automated checks and generated transparent process reports for immediate visibility and audit readiness.



TCS ADD™ LitGPT

TCS ADD™ LitGPT leverages advanced Generative AI to consolidate the entire literature search and monitoring process onto a single, intelligent platform. It delivers significant efficiency and accuracy gains through its unique capabilities:

- **Customized article retrieval:** Execute highly targeted searches tailored to specific needs (e.g., product, geography, adverse event, compound name).
- **Customized & reusable search strategies:** Build, save, and efficiently reuse sophisticated search strategies from centralized libraries.
- **Intelligent article triage & processing:** LitGPT automatically classifies articles into actionable categories that include ICSR, Potential ICSR, and Non-ICSR and extract data from all relevant fields.
- **Automated regulatory outputs:** Seamlessly generate regulatory-compliant reports (e.g., E2B outputs) directly from identified articles.
- **Enhanced accuracy:** Deliver superior performance and reliability compared to traditional manual processes.
- **Governed AI workflow:** Operate with assurance using a framework of human review and oversight for critical decisions.

The TCS advantage

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



Patented technology:

The TCS ADD™ Safety platform - leveraging the AI engine (Patent -#10558746) uses automated processing to ingest, extract data, and make decisions



Scalability:

Our AI and GenAI platform can be scaled up to any level to the business needs providing an optimal solution without compromising the performance metrics



Tailored solution:

The platform can be configured based on customer preferences, product type, local enterprise users, and local regulatory requirements



Flexibility:

Flexible integration with other applications that can be implemented either as a standalone solution or in combination with the existing data capture system



Technology and domain expertise:

Our certified SMEs combine AI with domain expertise in clinical research, platform solutions, and system integration to deliver strategic solutions tailored to customer requirements



Cost-optimized solution:

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



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 (TCS) (BSE: 532540, NSE: TCS) is a digital transformation and technology partner of choice for industry-leading organizations worldwide. Since its inception in 1968, TCS has upheld the highest standards of innovation, engineering excellence and customer service.

Rooted in the heritage of the Tata Group, TCS is focused on creating long term value for its clients, its investors, its employees, and the community at large. With a highly skilled workforce of over 607,000 consultants in 55 countries and 180 service delivery centres across the world, the company has been recognized as a top employer in six continents. With the ability to rapidly apply and scale new technologies, the company has built long term partnerships with its clients – helping them emerge as perpetually adaptive enterprises. Many of these relationships have endured into decades and navigated every technology cycle, from mainframes in the 1970s to Artificial Intelligence today.

TCS sponsors 15 of the world’s most prestigious marathons and endurance events, including TCS New York City Marathon, TCS London Marathon and TCS Sydney Marathon with a focus on promoting health, sustainability, and community empowerment. TCS generated consolidated revenues of US \$29 billion in the fiscal year ended March 31, 2024. For more information, visit www.tcs.com

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