TCS ADD™ Safety

An AI platform for pharmacovigilance

Manual handling of safety data in clinical trials and commercial settings is a major challenge for the life sciences (LS) industry. While safety data from diverse traditional and non-traditional sources (e.g., social media) has increased exponentially, there has also been a rise in the number of submission standards and requirements across various regulatory authorities and regions. This has led to increased risk of non-compliance and higher costs. LS firms need to automate the business processes to achieve a high degree of cost-effective consistency, quality and efficiency.

Powered by TCS' proprietary cognitive intelligence AI engine, the TCS ADD™ Safety platform envisages a transformational and holistic change in safety case processing and helps pharma companies bring safe and effective medicines faster to market. Life sciences firms can leverage this people centric solution to 1) automate intake and processing of safety data from structured/unstructured sources, 2) integrate and automate safety case management, and 3) use predictive analysis and signal detection for novel actionable insights.
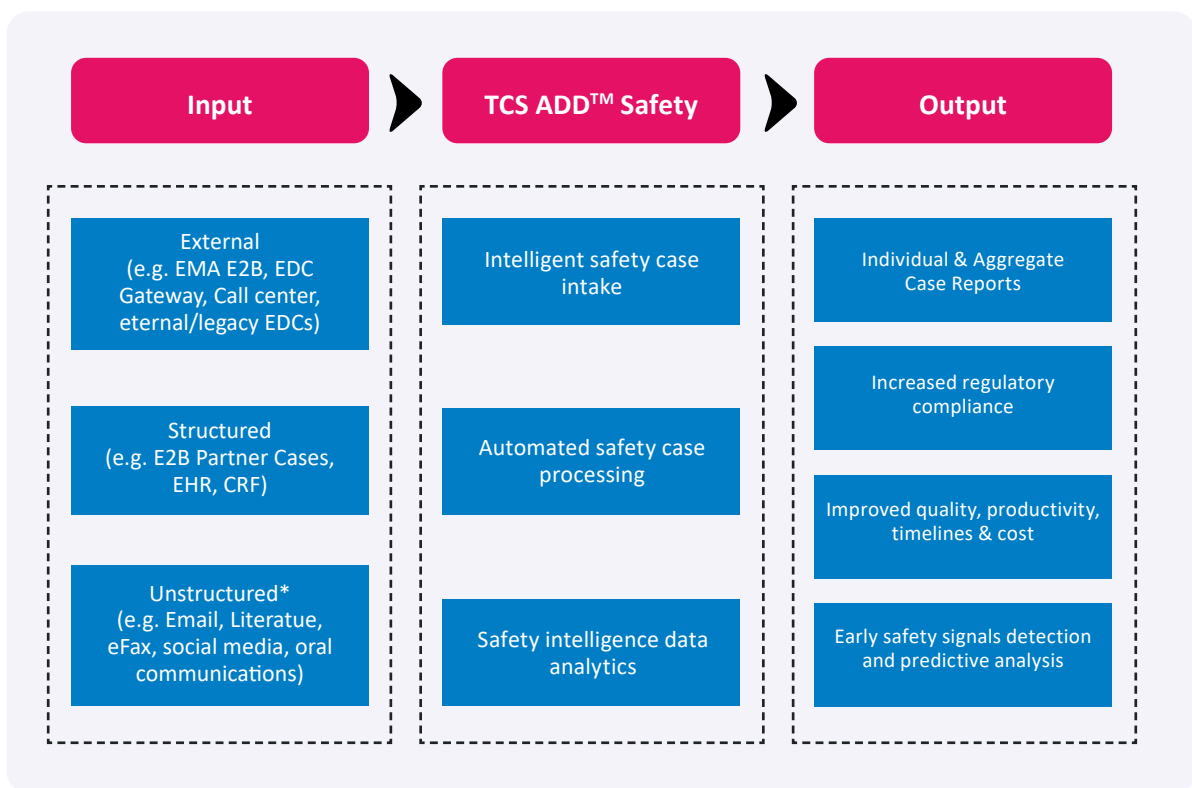
Overview

Safety cases have risen across the world in both clinical trial, and commercial settings. Further, increasingly safety cases are also being generated through multiple unstructured sources like journals, articles, patents, social media, etc. This trend is expected to further continue considering safety cases would rise by 18-20% Y-o-Y in the next 5 years globally. Existing manual processes are not equipped to handle such increased volume of data accurately and in time. This has also increased the risk of missing important safety information and face non-compliance. LS companies have also been extremely slow to respond to the changing paradigm of safety and have been unable to create proactive safety systems for actionable insights or evidence-based decisions. Our end-to-end AI platform for Pharmacovigilance has been developed to mitigate the above challenges.

TCS ADD™ Safety is an agile, cognitive platform that supports the entire product life cycle from early phase clinical trials to commercialization. To handle unstructured data, in the ingestion phase, TCS ADD™ Safety uses Natural Language Processing and AI technologies to ensure medical context. The proactive pharmacovigilance platform also allows submissions in customizable formats per geo-specific regulatory requirements and is equipped with safety-intelligence data-analytics with actionable insights. TCS ADD™ Safety uses human-governed machine learning to enable decision traceability and learn management capabilities to map new ontologies in accordance with good pharmacovigilance guidelines.

Our solution

TCS ADD™ Safety is a first-of-its-kind, AI-led cognitive automation platform for touchless case processing that leverages human governed machine learning and enables audit readiness with transparent algorithms. The solution includes:

- **Intelligent safety case intake:** Facilitates automated safety data collection directly from patients, physicians or social information channels (e.g., mobile app, website, call center)

- **Automated safety case processing:** Provides automated validity and duplicate check, data entry, medical coding, case assessment including seriousness, causality & listed ness. The solution also helps with automated narratives and report generation

- **Safety Intelligence data analytics:** Equipped with predictive analytics and signal detection, the solution empowers LS organizations with deep actionable insights and evidence-based decisions

Input	TCS ADD™ Safety	Output
External (e.g. EMA E2B, EDC Gateway, Call center, eternal/legacy EDCs)	Intelligent safety case intake	Individual & Aggregate Case Reports
Structured (e.g. E2B Partner Cases, EHR, CRF)	Automated safety case processing	Increased regulatory compliance
Unstructured* (e.g. Email, Literatue, eFax, social media, oral communications)	Safety intelligence data analytics	Improved quality, productivity, timelines & cost
		Early safety signals detection and predictive analysis

TCS ADD^TM Safety: Schematic Overview

Implementing first-of-its-kind cognitive automation solution:

A leading global pharmaceutical firm wanted to achieve end-to-end automation for safety case processing operations. Additionally, the customer wanted to understand the effectiveness of cognitive automation technology for evidence-based justification of medical device complaints.

TCS ADD™ Safety helped implement the industry-validated solution and achieve the fastest ever end-to-end Go Live of the patented offering. The client reported 96% industry leading accuracy in field processing, 40% Industry leading efficiency gain in case processing efforts, 97.5% Quality of cases automated, 30% Cost savings in end-to-end case processing and 100% compliance to Regulatory timelines.

Benefits

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

TCS ADD™ Safety is designed to help LS companies maintain a high level of safety surveillance for investigational and commercial products. Organizations can experience the following benefits:

- **Industry-leading efficiency and turn-around time in safety case handling**
  - Reduced case processing efforts to same day due to automation, leading to improved safety analysis and regulatory compliance
  - Ability to handle volumes spikes, product launches and acquisitions
  - Ability to automate all processing from case intake to submission ready report

- **Improved data quality**
  - Reduction in errors and increased consistency of case processing (manual process error rate ~4%)

  - Increase in extraction of relevant high-volume information due to automation, leading to better quality data

- **Meaningful insights and prevention**
  - Ability to identify novel trends on safety signals and business conventions
  - Ability to create predictive models and enable evidence-based 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 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 widely acclaimed solution offers a much higher return on capital investments to a LS firm and delivers a superior customer experience with its Intuitive user interface

Awards and accolades

About TCS ADD Platforms

TCS ADD™ is a suite of 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 artificial 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

Visit https://www.tcs.com/tcs-add on www.tcs.com

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About Tata Consultancy Services Ltd (TCS)

Tata Consultancy Services is a purpose-led transformation partner to many of the world's largest businesses. For more than 50 years, it has been collaborating with clients and communities to build a greater future through innovation and collective knowledge. TCS offers an integrated portfolio of cognitive powered business, technology, and engineering services and solutions. The company's 469,000 consultants in 46 countries help empower individuals, enterprises, and societies to build on belief.

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