ADD Safety

Awards & Recognition

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 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 the https://www.tcs.com/advanced-drug-development page on tcs.com
Email REST.Platforms@tcs.com

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Manual handling of safety data in clinical trials and commercial settings is a major challenge for the life science 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 guidelines and requirements across various regulatory authorities and regions. This has led to increased risk of non-compliance and higher costs. Life science industries need to automate the business processes to achieve a high degree of cost-effective consistency and efficiency.

Powered by the TCS’ proprietary cognitive intelligence engine the ADD Safety solution envisages a transformational and holistic change in safety case processing and helps Life Science industries bring safe and effective medicines faster to market. They can leverage the 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 by multiple unstructured sources like journals, articles, patents, social media, etc. With an estimated 10-20% year-on-year volume increase, the number of safety cases is expected to double in three to five years. Existing manual processes are not equipped to handle the volume of data accurately and in time. This has also increased the risk of missing important safety information and face non-compliance. Life science industries 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.

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

Solution
- **Intelligent safety case intake:** Facilitates automated safety data collection directly from patients, physicians or social media (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 life science industries with deep actionable insights and evidence-based decisions.

**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.

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 85% accuracy on an average in automated coding and identification of similar cases for evidence-based analysis.

Benefits
ADD Safety is designed to help life science industries maintain a high level of safety surveillance for investigational and commercial products. Organizations can experience the following benefits:
- **Increased efficiency and turn-around time in safety case handling**
  - Reduced case processing efforts to same-day as a result of 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:
- **Open Technology:** The TCS ADD Safety platform leveraging our proprietary cognitive intelligence engine provides a modern, open, fast and a user-first architecture.
- **Scalability:** Our solution can be scaled up to any level commensurate to the business need.
- **Tailored solution:** The solution can be configured based on language preferences of the local enterprise users and local regulatory requirements.
- **Flexibility:** ADD Safety 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 have the capabilities of clinical research services providers, platform solution providers, and global system integrators and can deliver strategic solutions per all customer requirements.
- **Cost-optimized solution:** ADD Safety patented, mature and widely acclaimed solution offers a much higher return on capital investments by a life science industries and delivers a superior customer experience.
- **Analyst recognition:** The TCS ADD platform has been consistently recognized by leading analysts including Everest Group PEAK™ Matrix, IDC MarketScape, HFS Research, 451 Research and others, as a key to meeting the increasing need for commercial-off-the-shelf digital solutions for life science industries.
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