

tcs ADD™



TCS ADD™ Regulatory





The Life Sciences industry has stringent compliance and reporting requirements specific to regulations around drug development. This invariably means staggered access for patients to new medicines and treatments. Traditional systems and processes have data in silos and are thus unable to achieve operational efficiency in responding to the different Health Authority (HA) queries and requirements. In addition, the system lacks cognitive intelligence due to fragmented management resulting in gaps in tracking and oversight. There is need for a single unique platform that can automate all the regulatory processes and enhance compliance.

TCS ADD™ Regulatory makes use of state-of-the-art technologies such as Artificial Intelligence (AI), mobility, blockchain, and data-driven smart analytics to automate regulatory processes and address limitations in the traditional Regulatory Information Management (RIM) systems. The platform reimagines regulatory activities by adopting technology to improve compliance, reporting, and operational efficiency and enables informed strategic decision making.

Overview

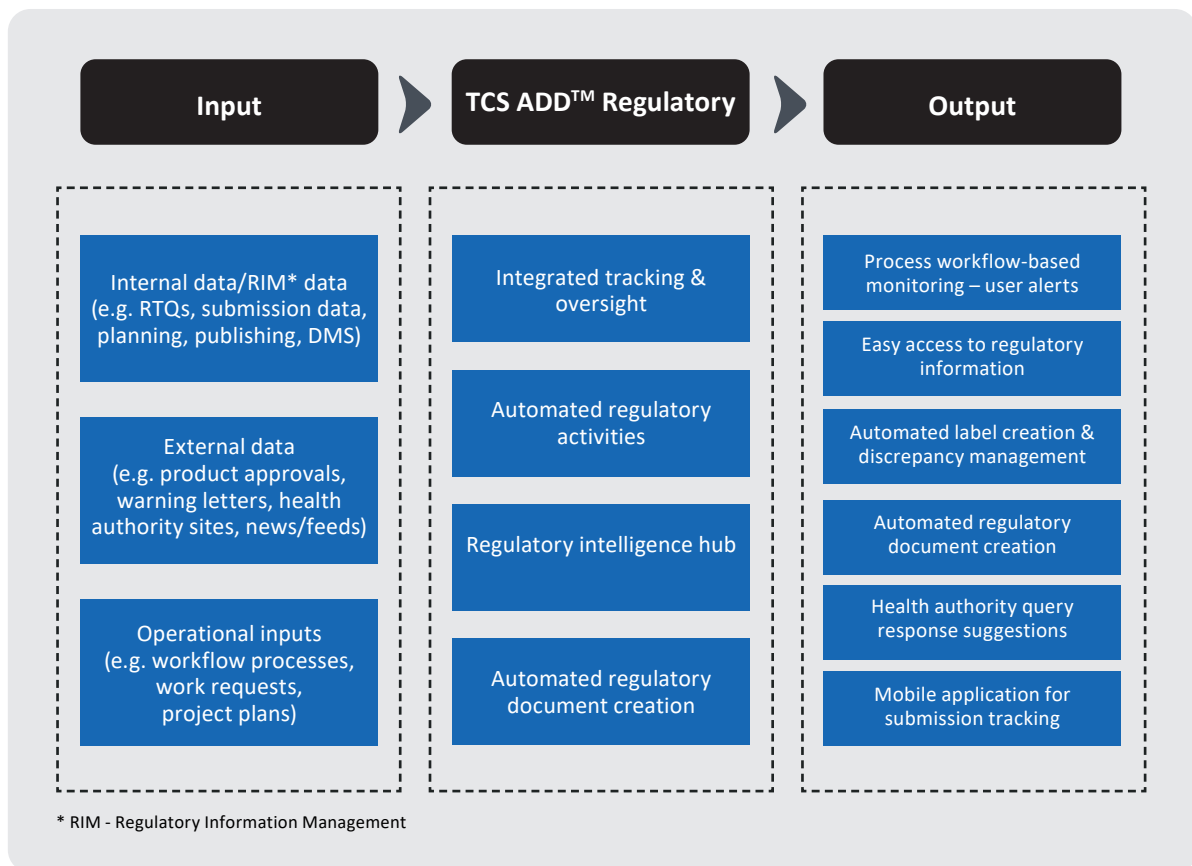
Life sciences organizations are currently facing multiple challenges within the regulatory environment resulting in a highly stretched product registration process. Lack of a technology backbone in regulatory processes causes difficulties in processing complex, big data sets essential for building regulatory intelligence. Use of traditional systems limit re-use of older data and learnings thereby increasing time required to respond to HA queries. With limited capability to perform ongoing screenings in the regulatory environment, the existing process is unable to mitigate the gaps arising from label discrepancies both locally and/or regionally, in time. The challenge further extends to submission planning with complex nature of project planning tools, lack of end-to-end traceability across projects and an inability to reuse existing submission components.

TCS ADD™ Regulatory platform, with its integrated and automated functionality, offers workflow-based framework to track and oversee the data. It leverages the power of AI to interpret big data sets to enhance the capability of the regulatory intelligence hub. The hub along with a smart search engine interprets HA and user queries, mines the exhaustive database, and provides accurate response suggestions. The platform also augments data reuse from past archives through the automated document writing tool. To resolve label discrepancy, the platform enables automation of label creation at a common source.

Our solution

TCS ADD™ Regulatory consists of the following modules:

- **Integrated tracking and oversight:** Enables tracking of integrated and actionable regulatory processes across all operating systems including mobile apps. The module also provides automated alerts and notifications. In addition, it provisions a rich and easy-to-use reporting dashboard and visualization as well as facilitates a template driven submission planning and customization that allows precise planning at milestone-task-component level.
- **Automated regulatory activities:** Facilitates intelligent redaction, data anonymization, review, Quality Control (QC) and formatting of regulatory content. The module also facilitates AI enabled label discrepancy identification and provides region and country-specific archival analytics and reports.
- **Regulatory intelligence hub:** Provides a repository of internal and external regulatory data providing meaningful insights; provisions a smart search engine for RTQ and market intelligence that comprises a centralized repository of domain ontologies and accelerates creation of regulatory responses and submission
- **Accelerated regulatory document creation:** Integrates and re-uses data, documents, and templates from multiple sources through SmartAuthor, automating document creation and reducing submission discrepancies.



TCS ADD™ Regulatory: Schematic overview



Benefits

TCS ADD™ Regulatory helps life sciences companies expedite the product registration process and patients gain faster access to better and safer medicines and treatments. Organizations can experience the following benefits with the solution:

Increased efficiencies & reduced workload

- Enhances process efficiency (e.g. publishing, CPP ordering) by enabling better monitoring, alerts and notification helping in 50% reduction of submission management efforts.
- Enables 60% reduction in the time spent on market intelligence data search
- Wields better control over processes through real-time monitoring and reports

Improved data quality and oversight

- Leverages technology to enable information search spread across websites/health agencies.
- Provides novel insights such as reason for rejection, types of studies enabling approval leading to strategic decision-making towards market and type of studies.

Increased user engagement

- Offers easy to interpret dashboards and information that is also easy to access and understand using mobile apps.
- Upto 20% increase in stakeholder collaboration due to automating the regulatory submission planning activities

Faster drug registration process

- Automation and optimization in authoring process expedites filing process and reduces the time taken for regulatory submissions by 20%.

The TCS advantage

With TCS ADD™ Regulatory solution, pharmaceutical companies can leverage the following differentiators:



Cross-Industry collaboration: Through 'TCS ADD™-Vantage Cross Pharma for regulatory' meets, TCS ADD™ Regulatory collaborates with global life science regulatory majors on ideas, experience-sharing and identifying trends that can be implemented via a technology-led approach.



Commercial model: The platform offers a choice of SaaS, BPaaS or in-house implementation based on the needs and preferences of life science organizations



Modular: TCS ADD™ Regulatory is highly modular and the components can be implemented separately or in combination, commensurate to the business need.



Flexible: The platform can be implemented either as a standalone solution or in addition to existing solutions.



Scalability: Life science industries can leverage our outcome-based platform that can be scaled up to any level commensurate to the business need.



Industry recognized solution: TCS ADD™ Regulatory platform won the India Pharma Awards 2021 under the category "Excellence in Ancillary Pharma Services" for exemplifying innovation leveraging AI and data-driven analytics to efficiently track and govern key regulatory processes with minimal efforts.



Technology and domain expertise: Our certified subject matter experts combine the capabilities of clinical research services provider, platform solution provider, and global systems integrators to deliver strategic solutions fulfilling all customer requirements.





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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