tcs ADD™

Building on belief

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

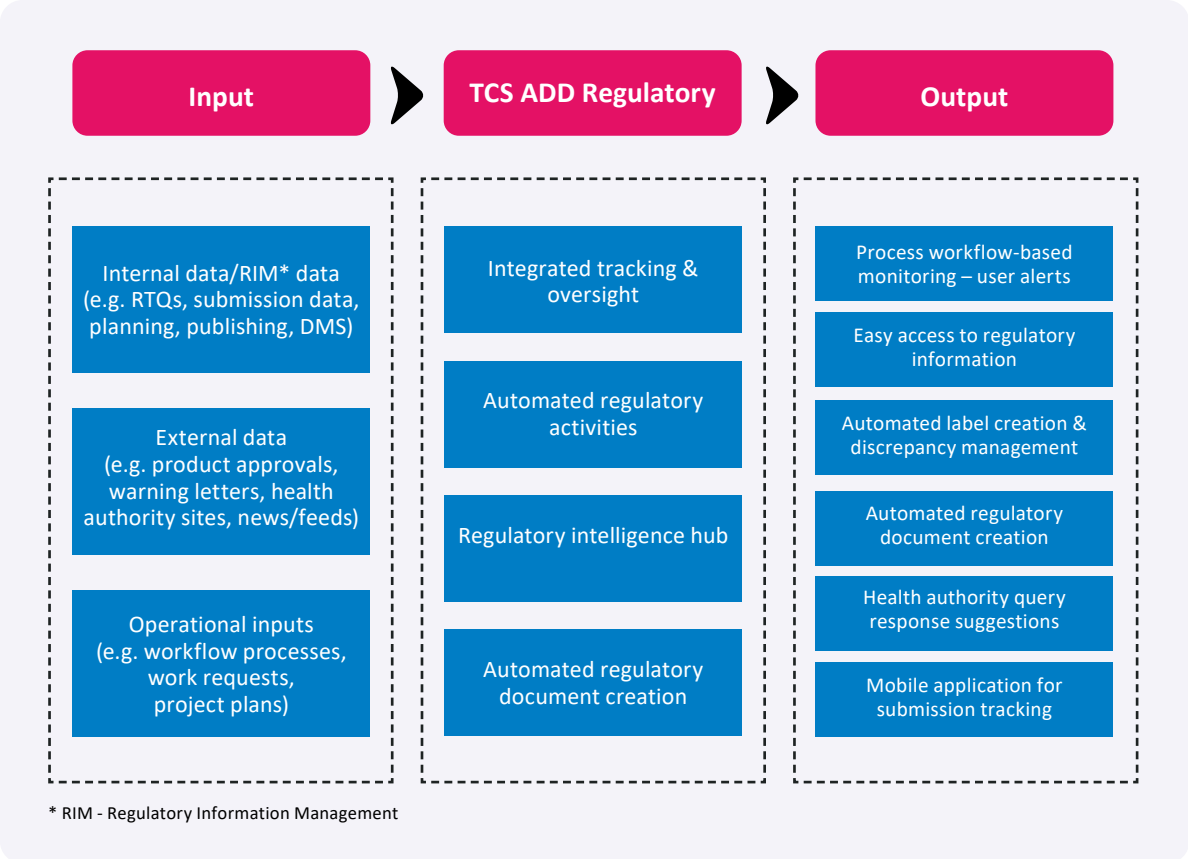
Life sciences organizations are currently facing multiple challenges within the regulatory environment resulting in a highly stretched product registration process. Lack of a technology backbone in regulatory processes causes difficulties in processing complex, big data sets essential for building regulatory 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

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.

TATA CONSULTANCY SERVICES

Awards and accolades

TOP 3
IT SERVICES
BRAND

FASTEST GROWING
IT SERVICES BRAND
FOR THE DECADE
2010 - 2020

About TCS ADD™ Platforms

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

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

Email: add.platform@tcs.com

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 500,000 consultants in 46 countries help empower individuals, enterprises, and societies to build on belief.

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