

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 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.

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 solution reimagines regulatory activities by adopting technology to improve compliance, reporting, and operational efficiency and enables informed strategic decision making.

Overview

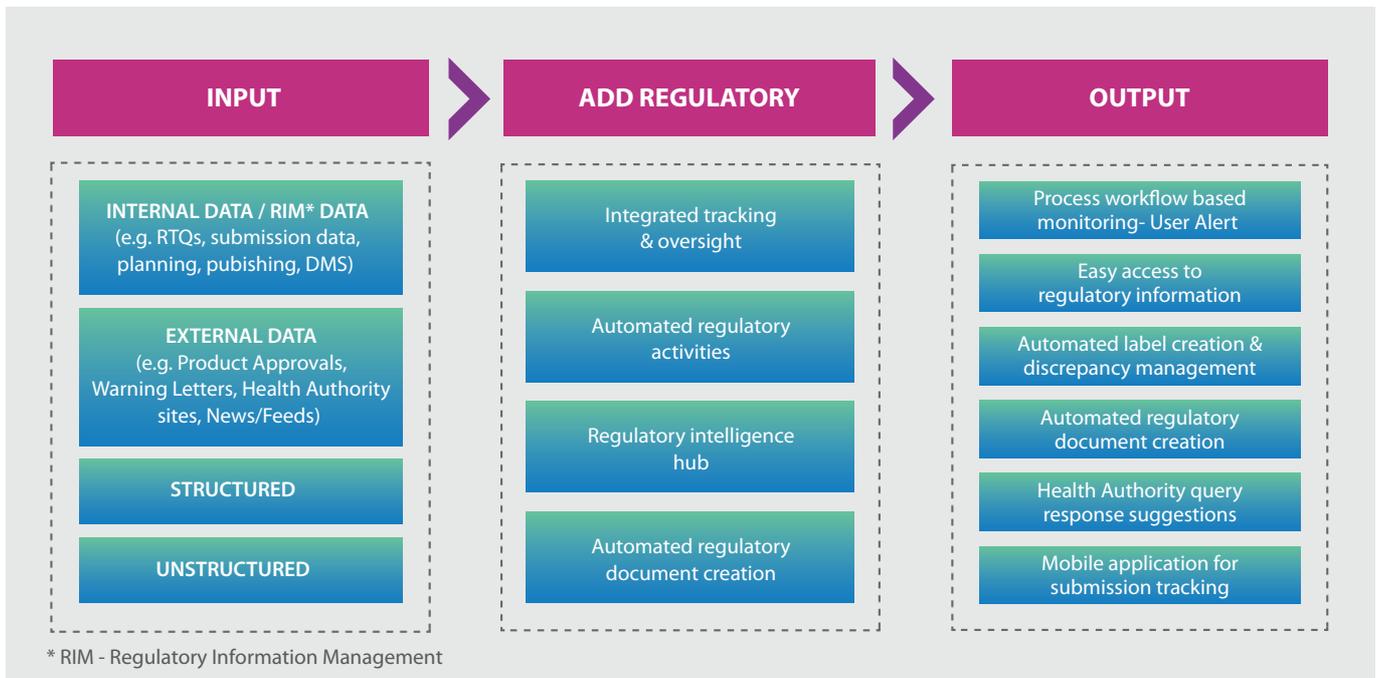
Life sciences organizations are currently facing multiple challenges within the regulatory environment resulting in a highly stretched product registration process and delayed access to medicine and treatments for patients. Lack of a technology backbone in regulatory processes causes difficulties in processing complex, big data sets essential for building regulatory intelligence. In addition, use of traditional systems limit re-use of older data and learnings thereby increasing time required to respond to Health Authority 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 or regionally, in time.

ADD Regulatory solution, with its integrated and automated functionality, offers workflow-based framework to track and oversee the data, coupled with alerts and notifications. 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 Health Authority queries, user queries, requirements etc., mines the exhaustive database and provides accurate response suggestions. Our solution also augments data reuse from past archives through the automated document writing tool. In addition, to resolve label discrepancy at Life sciences organizations, the solution provides a tool that automates label creation at a common source.

Solution

ADD Regulatory solution consists of following modules:

- **Integrated tracking & oversight:** Enables tracking of integrated and actionable regulatory processes across all operating systems including mobile apps. The solution also provides automated alerts and notifications.
- **Automated regulatory activities:** Facilitates intelligent redaction, data anonymization, review, Quality Control (QC) and formatting of regulatory content. The solution also facilitates AI enabled label discrepancy identification.
- **Regulatory Intelligence hub:** Provides a repository of internal and external regulatory data providing meaningful insights; Smart search engine 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



ADD Regulatory: Schematic Overview

Benefits

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.
 - 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.
- **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 ADD Regulatory solution, pharmaceutical companies can leverage the following differentiators:

- **Cross-Industry collaboration:** Our solution collaborates with leading global life science regulatory majors on ideas, experience-sharing and identifying trends that can be implemented. The event, referred to as 'TCS ADD-Vantage Cross Pharma for Regulatory', aims to identify the pressing challenges faced by regulatory organizations and understanding the ways technology coupled with domain expertise can help resolve them.
- **Commercial model:** The ADD Regulatory solution offers a choice of SaaS, BPaaS or in-house implementation based on the needs and preferences of life science organizations
- **Modular:** Our solution is highly modular and the components can be implemented separately or in combination, commensurate to the business need.
- **Flexible:** The solution can be implemented either as a standalone solution or in addition to existing solutions.
- **Scalability:** Life science industries can leverage our outcome-based solution that can be scaled up to any level commensurate to the business need.
- **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 & 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](https://www.tcs.com)

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