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adverse events tracking for enhanced compliance

A challenge for corporate regulatory affairs is to maintain and continually improve their level of regulatory submissions compliance. There is a need to address regulatory concerns with a corrective action plan demonstrating their company's commitment to meeting the regulatory requirements. To accomplish this they have to:

- Identify any root cause for delays in submission of Adverse Event (AE) reports to the regulator at the local subsidiary and headquarters
- Increase the efficiency of their workflow
- Identify where AE reports are within the paper-based workflow at any given time
- Categorize AEs and determine deadlines for submission to the regulatory organizations
- Identify every action performed on the AE and the time each action took place
- Link initial AEs to follow-up reports for the same event
- Report the AEs within the compliance time

vision

TCA's solution:

- Assists the client in performing a root cause analysis of adverse event report delays and defining a corrective action plan
- Facilitates a detailed review of the client's organizational workflow
- Identifies process delays and potential improvements from both a business and technology perspective
- Determines where managers are able to shift resources to ensure higher levels of compliance
- Develops the metrics required for continuous improvement

results

End-to-end adverse event analysis system aiding in pinpointing compliance issues

value

A solution was delivered on time, within scope and on budget. Benefits were:

- Delivered a preliminary working system in less than 3 weeks
- Enabled the client to meet an immediate objective of answering questions from the regulator with a corrective action plan
- Demonstrated the client's commitment to regulators in meeting the regulatory requirements
- Ensured compliance with FDA regulations governing electronic signature and records (21 CFR Part 11)
- Generated measurements that enabled management to measure the quality of data and individual performance