



Case Study: Life Sciences

Global pharmaceutical company achieves industry-leading compliance in patient safety reporting

Regulatory compliance solutions, built on analytics and coupled with visibility into market research and patient support programs, enable a culture where patient safety takes utmost priority and reporting is never late.

Our client, a major international pharmaceutical company, faced increasing challenges with global safety reporting compliance. Working together, we identified the following root causes of late cases:

- Lack of visibility into when marketing, promotional and patient support programs commenced and concluded around the world, and the resulting forecasted increase in adverse event reports our client expected by product and geography.

At a Glance

A global pharmaceutical company was growing, and so was the complexity of regulatory compliance worldwide. Cognizant partnered with pharmacovigilance and commercial leaders across the enterprise to improve visibility into processes, market research and patient support programs to create a zero-late-case culture.

Outcomes

- Achieved industry-leading average regulatory compliance rate of 99.98%.
- Improved partner compliance rate to 99.94%.
- Maintained compliance performance while increasing ICSR volume by an average rate of 30% annually.

Eliminating the potential for late cases takes priority

Taking action

New tools improve compliance.

- Lack of visibility into licensing partners' individual case safety report (ICSR) submissions against pharmacovigilance agreement (PVA) timelines. Reports received for submission with shorter turnaround times required additional staff for on-time processing.
- Lack of predictive tools for forecasting ICSR daily patterns and volume fluctuations to ensure adequate staffing.

Eliminating the potential for late cases became a priority for our client to ensure not only that compliance deadlines were adhered to but also that any emerging signals affecting patient safety would be identified as quickly as possible.

Building a zero-late-case culture

As our valued client's strategic safety and technology partner, Cognizant identified any ICSR compliance issues as they emerged. We developed and implemented an action plan to systematically build a zero-late-case culture. Our top initiatives included the following:

- Creating a market research and patient support program (MRPSP) repository and automated notification tools to track MRPSPs. This helps our client forecast when and where

ICSR volumes are likely to increase. More than 400 clinical and commercial professionals across the company currently use the tool to view geographic regions where promotional campaigns, patient support programs and post-market surveys have been launched. The tool automatically notifies users when programs start or end.

- Building an automated case tracking tool to prioritize each case by its compliance timeline. This impressively improves visibility into the case workflow and enables effective case prioritization, effectively escalating any ICSRs with looming deadlines.
- Applying process analytics to identify which licensing partners are slow to submit ICSRs, jeopardizing our client's ability to meet reporting deadlines. We achieve this by publishing a monthly report.

Through these initiatives, our client has improved its compliance rate by 3%, achieving an industry-leading compliance rate of 99.98%. The company has consistently maintained this zero-late-case culture even as new products have been added through business acquisitions and partnerships and as ICSR volumes have increased by an average of more than 30% per year over the last two years.

About Cognizant

Cognizant (Nasdaq-100: CTSH) is one of the world's leading professional services companies, transforming clients' business, operating and technology models for the digital era. Our unique industry-based, consultative approach helps clients envision, build and run more innovative and efficient businesses. Headquartered in the U.S., Cognizant is ranked 193 on the Fortune 500 and is consistently listed among the most admired companies in the world. Learn how Cognizant helps clients lead with digital at www.cognizant.com or follow us @Cognizant.

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