Managing Safety more Efficiently with Business Process Management Solutions

PPD®

There are many unique needs of the pharmacovigilance (PV) industry, especially when it comes to managing the safety data of patients. Business process management solutions (BPMS) are just one great way to identify efficiencies and reduce timelines throughout the safety tracking process.

The specific solution PPD's PV team has implemented is an internally developed tool called the **safety tracking system (STS)**. This tool has been developed to meet the requirements of our PV customers and provide robust process automation functionality. **PPD's STS significantly streamlines processes** enabling us to drive efficiency and reduce overall costs for our customers through **resource management, quality control tracking, oversight and compliance**.

Specific areas where automation capabilities are used include:

Capturing incoming ICSR and follow-up information and automatically routing to the appropriate processing team members.
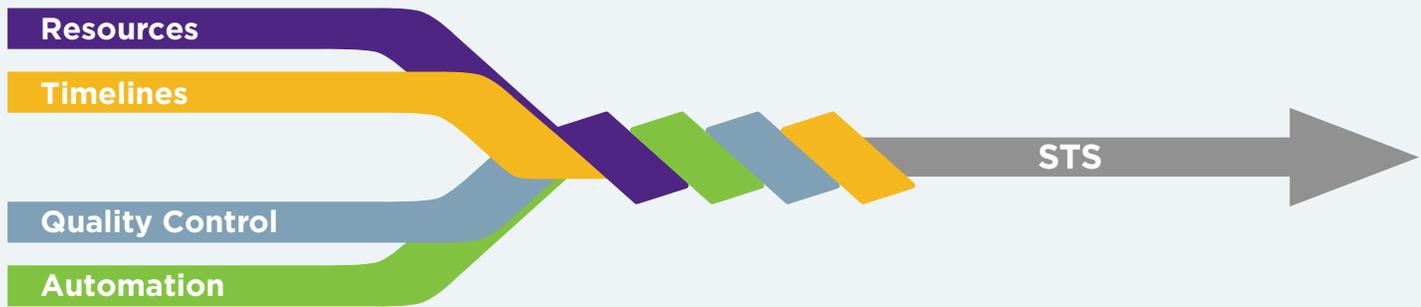
Generating and tracking of follow-up queries to ensure due diligence through multiple follow-up attempts

Collating and filing documentation to the electronic trial master file (eTMF). Documentation includes both source documentation and documentation generated during case processing activities (e.g., client notifications, draft CIOMs, site queries/responses, medical review results, etc.)

STS enables PV to compare processing metrics across all our clients to establish processing benchmarks. This information is critical in driving PPD's continual process improvement strategy and enabling us to constantly refine and improve. **Comparing benchmarks across customers enables us to identify when a client-specific process falls outside the norm. Benchmarks also enable us to identify and target specific areas for potential efficiency gains.**

Safety Tracking System (STS)

PPD's STS provides:

- Integrated resource coordination
- Deliverable management
- Workflow automation
- Task scheduling
- Timeline monitoring
- Quality control

PPD's **custom-developed**, in-house BPMS can help manage case processing/reporting, literature surveillance, aggregate report writing and signal detection activities to ensure we are able to **meet regulatory timelines**.

With our solution, handoffs and workflow organization become easy and efficient, keeping case flow on time and quality continuously monitored

- Increases processing capacity and peak volume management by keeping cases flowing across time zones; 20 hours per business day through globalized workflow management.
- Integrates safety functions including case intake and processing, medical assessment, adjudication, medical monitoring and safety reporting; ensures all information is current and accessible across all PV functions.
- Seamlessly manages multiple protocols for the same investigational medicinal product, ensuring consistent processing across all your projects.
- Better controls your processes, integrating advance quality and volume metric reporting to manage outcomes and performance.
- Workflows are easily customized to meet specific client processing needs and similarly expanded to automate additional PV business processes to provide a holistic approach to managing pharmacovigilance.

Contact us today to learn more about PPD's STS and how it can help you from case intake to final reporting to ensure you meet timelines, manage resources and case load, monitor quality and keep safety program

For more information on any of our products or services please visit us at: www.ppd.com/pv

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