

Achieving Efficient Pharmacovigilance

The Imperative

Pharmacovigilance, the monitoring of the quality, safety and efficacy of marketed medicines, is essential to the long-term success of every drug. Pharmaceutical and biotech companies need to have intelligent systems and processes to pre-empt the current time-consuming practice of paper transmission of Serious Adverse Events (SAEs) to regulatory authorities. This practice duplicates data entry and becomes vulnerable to inaccuracies, thus defeating the objectives of adaptive trials.

An effective Pharmacovigilance, especially in an innovative adaptive clinical trial environment, is the ability to capture, analyze and evaluate data (from disparate sources) such as signal detection in real time and to make rapid decisions on the appropriate courses of action thus reducing the risk and improve the time to market of a New Chemical Entity (NCE).

Mahindra Satyam in Life Sciences

Mahindra Satyam has been helping life sciences companies monitor the safety and efficacy of their products while working towards solving some of their most challenging Clinical Safety issues. Our solutions help customers oversee safety issues with respect to their pharmaceutical products.

This is achieved through our technology solutions, which provide the scalability and consistency when handling the massive increase in amount of safety data (on account of increase in the variety of drugs, number of patients, number of Adverse Events, etc.). Leveraging over two decades of experience, Mahindra Satyam has been supporting customers with intelligent IT systems and enabling processes in the area of Pharmacovigilance/Safety Systems.

Mahindra Satyam is a global leader in providing consulting, innovation and change management for Life Sciences industry with strategic relationships with 6 of the top 10 pharmaceutical companies. Mahindra Satyam's key strengths in life sciences industry stem from strong business process know-how and relevant technologies for enabling processes across the value-chain.

Solutions in Pharmacovigilance

Mahindra Satyam addresses the following key challenges in Safety & Pharmacovigilance:

- End-to-end adverse event case processing
- Adverse event litigation case processing including solicited and unsolicited cases
- Aggregate reporting including PSURs, Clinical study report, etc.



- Case distribution, ICH E2B, 21 CFR Part11, and MedDRA
- Safety Signal detection and analysis 24X7 support with multi-lingual capabilities
- Literature searches, follow-up, regulatory reporting and PSURs
- Safety system implementation, hosting and maintenance such as ARISg, ARGUS and Oracle AERS

Value Proposition

- Singular focus on life sciences business processes
- Demonstrated experience in complex rollouts in Pharmacovigilance
- Strong subject matter expertise in Pharmacovigilance
- Process rigor; predictable, high quality delivery

Our Experience

Mahindra Satyam provides Drug Safety and Case Processing Support, and Safety Narrative Writing Services to a top 3 global pharma major.

Drug Safety and Case Processing

Business Challenge

The customer was faced with the challenge of consolidating operations, improving productivity and gaining cost and process efficiencies. The challenges spanned across three distinct areas: Full Assessment of Non-Serious Adverse Event (AE) Reports, Serious and Non-serious Litigation Adverse Event Processing, and Data Entry.

All processing and reporting was being done using ARISg. A secondary challenge was to continue regulatory compliance with increased product pipeline.

Solution

Mahindra Satyam established an offshore delivery platform customized to customer needs within the business context. Within 8 weeks, process and knowledge transition was achieved by the Mahindra Satyam transition team. The application was scaled up and went live with AE Product litigation case processing,

supporting more than the 9000 AE case volumes/year. Mahindra Satyam's offshore team comprises 21 healthcare professionals, team leads and managers.

Results

Mahindra Satyam's solution is delivering services consistent with internal service levels prior to the new system. Quality of output clocks 99.8% with 100% TAT. In addition to training plan and SOPs, Mahindra Satyam also developed a quality verification plan for cases processed. The new system currently processes around 1000 cases per month and the volume is expected to ramp up to 1500 cases per month.

Safety Narrative Writing for PSURs and NDAs

Business Challenge

The customer was faced with the challenge of consolidating operations, improving productivity and gaining cost and process efficiencies. The primary challenge was Safety Narrative Writing for PSURs & NDAs.

All processing and reporting was being done using ARISg. A secondary challenge was to improve turnaround times.

Solution

Mahindra Satyam established an offshore delivery platform customized to customer needs within the business context. Within 8 weeks, process and knowledge transition was achieved by the Mahindra Satyam transition team. The application was scaled up and went live with Safety Narrative Writing, supporting more than the 1500 narratives volumes/year.

Results

Mahindra Satyam is currently delivering more than 75 narratives/week while the actual SLA is 25 drafted narratives/ week. Mahindra Satyam also delivered more than 1500 drafted narratives and 2000 QC narratives last year. 95% of narratives were delivered within 24 hours (minimum time taken was 2 hours for 1 pack) and the remaining 5% within 48 hours of receipt.

Process Improvements

Accuracy of Narratives and QC are maintained at 100%. Prepared safety narrative writing, quality check, training SOPs and delivery plan. Mahindra Satyam also created a training plan and quality check sheet based on initial training experience.