

SYNTEL'S PRESCRIPTION FOR AUTOMATING PHARMACOVIGILANCE ADVERSE EVENTS MANAGEMENT

It's no secret that drug and device safety is of the utmost importance in today's competitive life sciences marketplace, and pharmacovigilance (PV) is a major component of an effective drug regulation system for evaluating and monitoring adverse events (AEs). The importance of PV to the healthcare industry is underscored by a few striking facts:

- Adverse events reported to the FDA increased at 13% CAGR from 2006-2014¹, and serious AEs increased by 15% during the same time period²
- According to the Centers for Disease Control (CDC), adverse drug reactions account for 100,000+ deaths per year, making them one of top ten causes of death in the U.S.
- The growing number of ADRs and chronic diseases will increase the global PV market size, which is expected to reach \$8.2 billion by 2022.³

Pharmaceutical and medical device manufacturers face a number of AE-related challenges, including:

- High cost of managing AEs in-house
- Lack of internal resources to manage the huge AE workload
- Evolving and un-harmonized regulations
- Stringent reporting timelines
- Increased reporting of adverse events in social media and literature

Syntel is here to help, with pharmacovigilance services that balance innovation and risk, while providing the fastest case processing and the highest quality. Syntel's PV offerings for adverse events include:

- **RPA-driven Case Processing**

Syntel's automated case processing takes AE cases from multiple sources and feeds data directly into your safety database, with integration and real-time information exchange between stakeholders. It also eliminates manual data entry for higher productivity, quality and efficiency.

- **Pharmacovigilance Center of Excellence (CoE) Services**

Our PV CoE provides end-to-end adverse event case processing, including case intake and triage, medical coding and narrative writing and aggregate reporting.

- **Safety Analytics, Risk Management, Signal Detection and Analysis**

- **Safety Data Management**

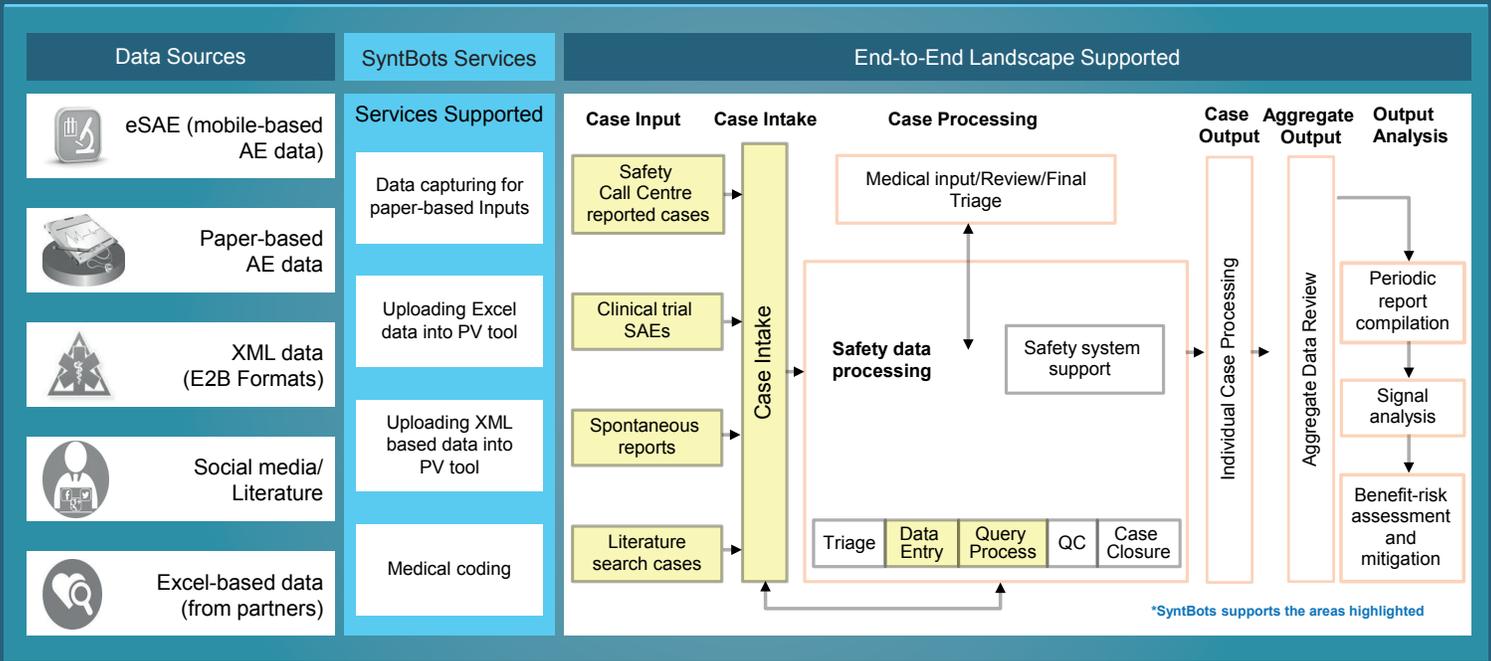
Global safety database migration, implementation and validation

- **Social Media Integration with SAP HANA**

Screens social media, performs text and sentiment analysis, and reports on tweet density, trend analysis, and ADR severity analysis.



How the SyntBots automation platform powers the Pharmacovigilance (PV) process:



The benefits of Syntel's PV services include:

- Automated AE case processing through the SyntBots automation platform. SyntBots shortens processing time by as much as 30%, reduces cost and manual effort, improves quality by reducing human error, and enhances operational efficiency.
- Reduced costs enable you to fund new technology investments and optimize R&D processes such as clinical trial discovery and reporting.
- Unique factory-based operational model that balances efficiency, compliance, quality and effectiveness.
- Deep process experience in Individual Case Safety Report (ICSR) processing from sources including spontaneous, clinical trials, literature, solicited and social media for drugs, OTCs and medical devices.
- Robust experience in support, implementation, migration and customization of safety databases like Argus and ARISg
- Syntel's scalable, knowledgeable global workforce enables more flexible engagement and pricing models.
- Delivers an audit-ready PV service platform that supports MHRA, EMA and FDA audits.

References:

- <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm070434.htm>
- <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm070461.htm>
- <http://www.researchandmarkets.com/research/5b972c/global>

About Syntel

Syntel (Nasdaq:SYNT) is a leading global provider of integrated information technology and knowledge process services. Syntel helps global enterprises evolve the core by leveraging automation, scaled agile and cloud platforms to build efficient application development and management, testing and infrastructure solutions. Syntel's digital services enable companies to engage customers, discover new insights through analytics, and create a more connected enterprise through the internet of things. Syntel's "Customer for Life" philosophy builds collaborative partnerships and creates long-term client value by investing in IP, solutions and industry-focused delivery teams with deep domain knowledge.

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