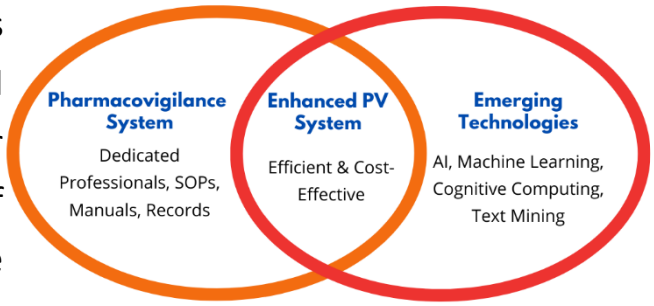
TATA ELXSI

Pharmacovigilance in the Digital Era – Know Your Safety Reporting

"As per the World Health Organization (WHO), pharmacovigilance is the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other medicine/vaccine-related problem."



All the pharma products undergo rigorous testing for safety during pre-clinical and clinical trials before they are authorized for human use. However, the clinical trials of phase I to phase III are of limited scale in the scope of population size from a pharmacovigilance perspective. There is always a possibility of long-term side effects that can only be analyzed during product maturity in the market and by the broader use of the product by the target patient population. It is imperative to have a robust pharmacovigilance system and practice to monitor these events, which can be captured through traditional event capturing processes and through social media monitoring in this modern era.

Marketing authorization holders (MAH) have to prepare authentic, legible, accurate, and verifiable Individual Case Safety Reports (ICSRs) of possible adverse reactions associated with medicinal products for human use originating. These reports can be classified as:

- **Unsolicited reports:** These are the reports arising apart from the company's organized data collection system. It can be a healthcare professional report, a report from a customer or other competing organizations to a competent authority, interviewing outcomes of some medical professionals.

  The mentions of an adverse effect of the candidate drugs on various social media platforms like general-purpose platform Twitter and health networks including PatientsLikeMe, DailyStrength, and MedHelp are also considered in such reports. However, extracting data from social media mentions poses a significant challenge as they are unorganized and informal. A machine learning framework can be of immense usefulness for extracting required information from such platforms.

Often, the medical literature is published on various platforms that can help monitor the safety performance of medical products. Therefore, authorization holders must maintain awareness of publications through a periodic literature review of major reference databases. However, these publications are enormous with over 1.8 million new articles published annually in MEDLINE alone. A typical researcher can ordinarily read about 200-300 pieces a year. It suggests that scientists can't read a significant chunk of literature mentions of their products. Big data management technologies such as cognitive computing are imperative to extract target information from such huge piles of data.

- **Solicited reports:** These reports originate from the organized data collection system of the company. The authorization holder must record all reports of suspected adverse reactions sourced from within the event's origin country or outside the country where the products are marketed, which comes from the studies being managed by that organization.

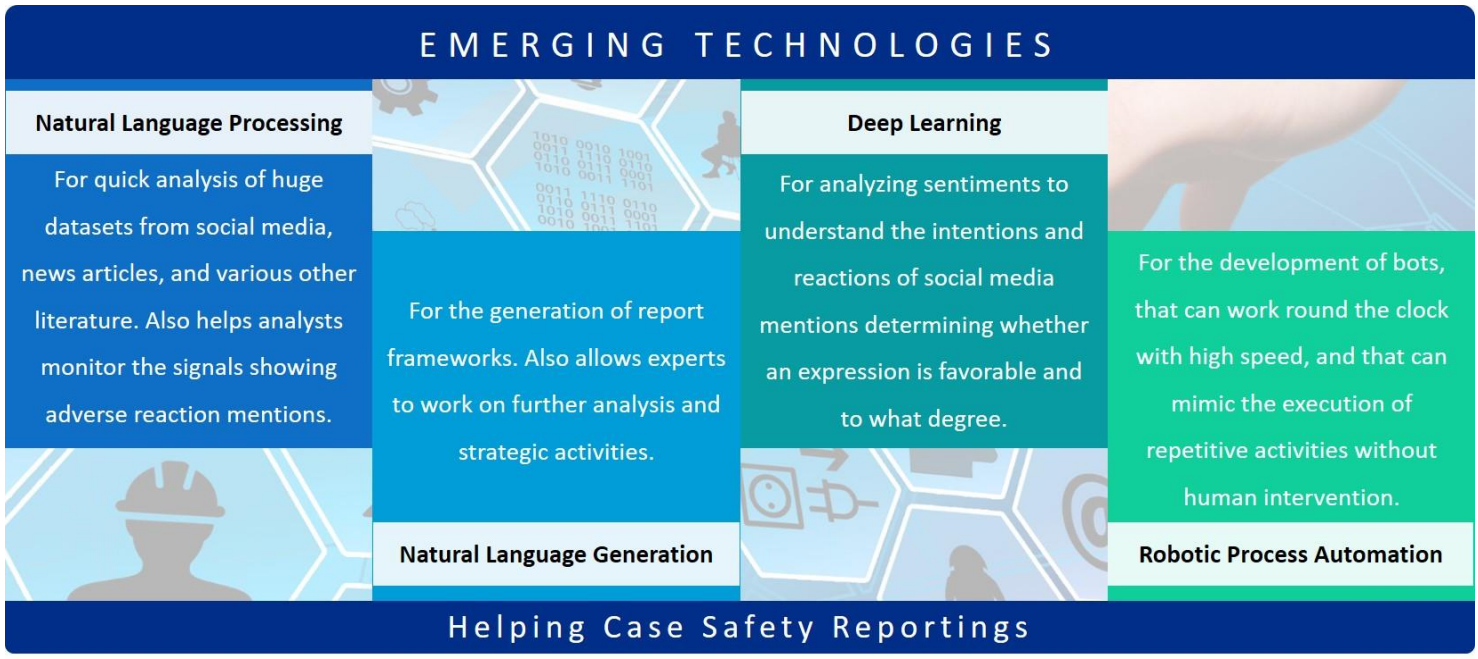
  Marketing authorization holders face some unique challenges. The challenges include inconsistent reporting of adverse events, the priority of efficacy over safety, and limitations in published case reports such as delay in publication, poorly documented literature, etc.

In addition, another major bottleneck in the digital era is establishing an effective pharmacovigilance practice for monitoring digital platforms. The increasing amount of unstructured information originating from several sources, including social media platforms, poses challenges of informal vocabulary and grammatical mistakes. Companies are looking at neural network architectures and other technological advancements such as artificial intelligence, blockchain technologies, and machine learning, as crucial tools to enhance performance by labeling the adverse drug reactions.

Emerging Technologies in Pharmacovigilance Reporting

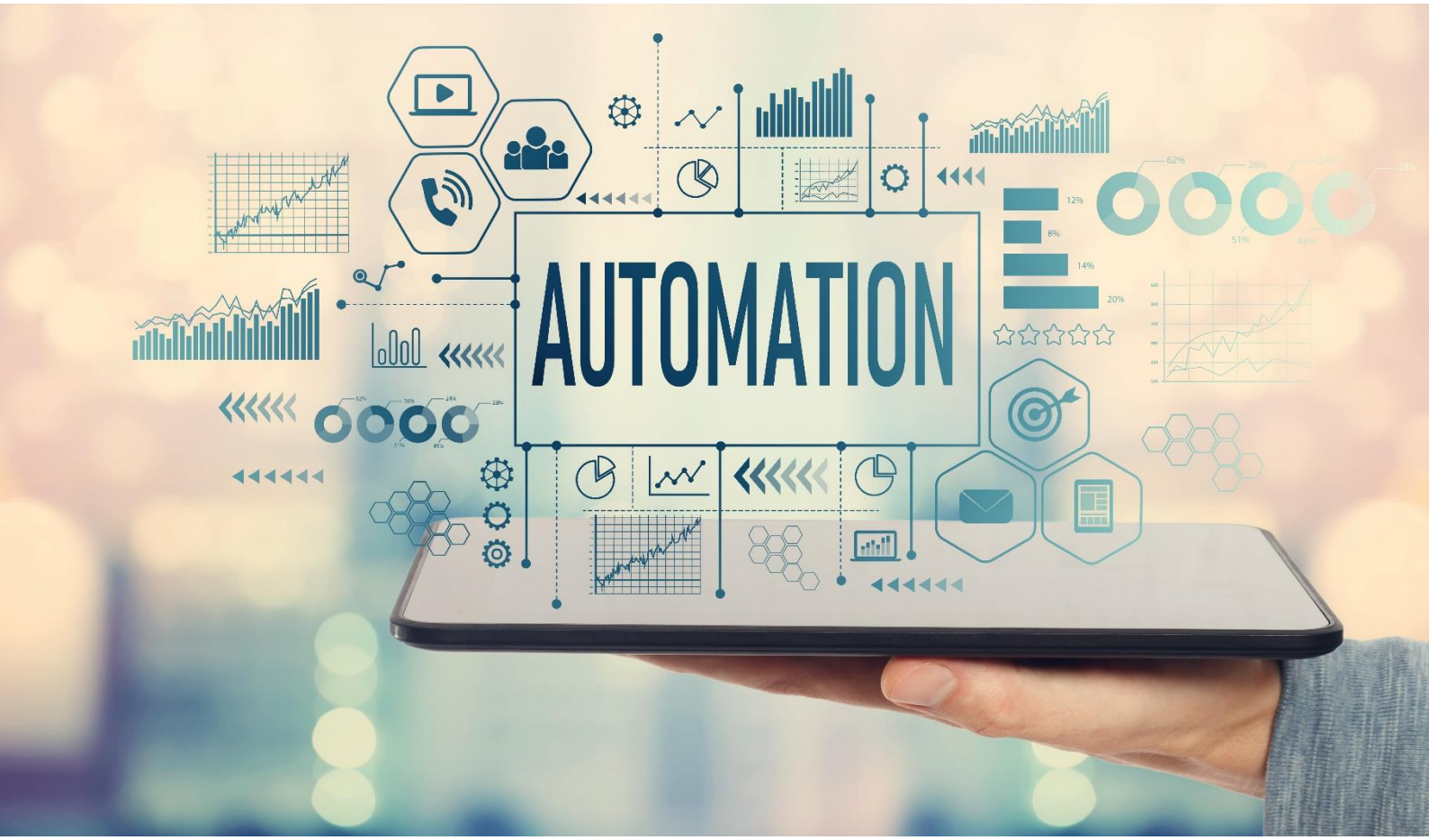
The increasing complexity and availability of a large amount of unstructured data make it the need of the hour to use the emerging technologies to increase the efficacy of pharmacovigilance in the digital era.

- **Cognitive computing:** Pharmaceutical companies can create automated IT systems capable of solving problems with little or no human assistance. These systems could be used for extracting useful information from a vast data source and in the ICSR process for literature review and social media mentions. These integrated systems could also augment the existing drug safety process to accelerate adverse events reporting to the regulatory bodies.
- **Text mining**: It is an artificial intelligence technique that uses natural language processing (NLP) to convert the unstructured text in documents and databases to structured data suitable for analysis. Text mining could be applied to various sources of pharmacovigilance data, including biomedical literature, clinical narratives, and web search logs.



An estimate suggests that the cost of bringing a new drug to market has reached $2.5 billion and >12 years of investment. Of all drug candidates, only about 14% succeed to gain regulatory approval from FDA. The most common reasons for failure include a lack of efficacy and safety at some drug discovery stages. Continuously changing market dynamics and constantly evolving regulatory requirements have increased the hurdles in developing a successful drug candidate. Today's pharmacovigilance sector must implement IT systems with the latest technologies to comply with the strict, demanding, and complex regulatory compliances while containing the cost of operations and new drug development.

Tata Elxsi has been pivoting and transforming regulatory and vigilance processes for pharma and medical devices companies in the US, Europe, Japan, and the Asia Pacific markets.



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ABOUT TATA ELXSI

Tata Elxsi, a part of Tata Group, is amongst the world's leading providers of design, engineering, and regulatory compliance services. With 15+ years of experience in catering to healthcare & life sciences companies, Tata Elxsi has built a strong services and solutions portfolio that adds value at every stage of the customer's product development lifecycle.

We offer end-to-end regulatory service portfolio for global pharma companies to help them increase agility and lower operational costs while ensuring compliance with ever-changing global industry standards and requirements. We have extensive experience with regulatory agencies like FDA, EMA, PMDA, MHRA, BfArM, and other leading health agencies.

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