CHIPS REGIMEN

Drug Information News Letter
APR-JUN 2025 Volume 10, Issue 4

ARTIFICIAL INTELLIGENCE INTRODUCED INTO FDA DRUG SAFETY MONITORING

Artificial Intelligence (AI) became one of the most discussed healthcare innovations during April–June 2025 after the United States Food and Drug Administration (FDA) introduced an AI-supported platform called "Elsa" to strengthen drug safety monitoring and regulatory review processes. The initiative was launched as part of the FDA's broader modernization program aimed at improving efficiency in pharmacovigilance, scientific evaluation, and healthcare data analysis. The announcement attracted significant global attention because it marked one of the first major implementations of AI technology within a national drug regulatory authority.

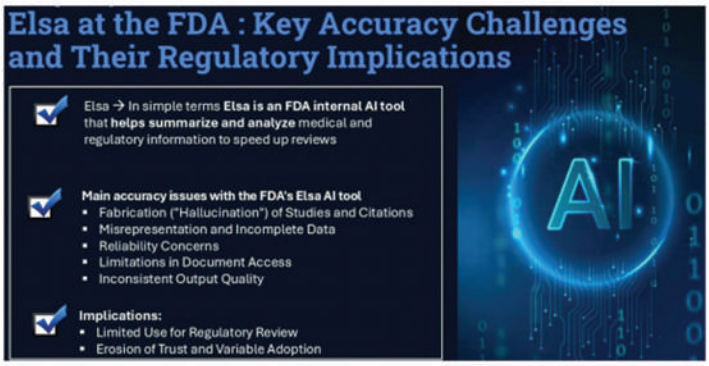
The FDA developed Elsa to assist scientists and healthcare reviewers in handling the rapidly increasing amount of pharmaceutical and clinical data generated every day. Traditionally, reviewing adverse drug reaction reports, clinical trial documents, safety alerts, and post-marketing surveillance data required extensive manual effort and time. With the integration of AI, the system can rapidly analyze large datasets, identify patterns, summarize reports, and detect potential medication safety signals much faster than conventional methods. This advancement is expected to improve the early detection of adverse drug reactions and support faster regulatory decision-making.

Experts in clinical pharmacy and healthcare technology highlighted that AI systems like Elsa could play an important role in reducing medication errors and strengthening patient safety initiatives. During various healthcare technology conferences and pharmacovigilance discussions held in 2025, researchers emphasized that AI-assisted systems may help healthcare professionals identify high-risk medications, monitor prescribing trends, and improve evidence-based therapeutic decisions. Hospitals and healthcare institutions are also increasingly exploring AI-based clinical decision support systems to optimize medication management and reduce preventable adverse drug events.

The introduction of AI into drug safety monitoring also reflects the growing digital transformation occurring within clinical pharmacy practice. Clinical pharmacists are now expected to develop skills related to health informatics, electronic health records, and AI-assisted medication review systems. Rather than replacing healthcare professionals, experts believe AI will function as a supportive tool that enhances the efficiency and accuracy of pharmaceutical care. The FDA's adoption of AI technology represents a major

Printed & Published by
Dr. R. Srinivas, President
Dr. C.N. Srinivas, Secretary & Correspondent
Edited by
Dr. S. Vidyadhara, Principal
Editorial Team :
Dr. R.L.C. Sasidhar, Dr. V. Ravi, Dr. A. Chakravarthy
Dr. M. Raghava Kalyan, Mr. N. Venkata Deepak
Mr. S. Vikas, Dr. V. Sindhu Vaishnavi

milestone in the future of pharmacovigilance and healthcare innovation. As healthcare systems continue to generate vast amounts of patient and medication data, AI-supported systems are expected to become increasingly important in improving patient safety, accelerating drug evaluation processes, and supporting precision medicine. The development highlights how technology and clinical pharmacy are becoming closely interconnected in the advancement of modern healthcare services.



New Pharmacovigilance Findings Highlight Safety Concerns in Commonly Used Medications

During April–June 2025, several important pharmacovigilance studies drew attention to medication safety concerns identified through the FDA Adverse Event Reporting System (FAERS), one of the world's largest databases used for monitoring adverse drug reactions. Researchers analyzed thousands of patient safety reports submitted by healthcare professionals, pharmaceutical companies, and consumers to identify unexpected or underreported adverse effects associated with widely prescribed medications. The findings generated significant discussion within the clinical pharmacy and pharmacovigilance communities because they highlighted potential gaps between real-world adverse event data and official prescribing information.

Medication	Therapeutic Use	Reported Safety Concerns from FAERS Analysis (2025)	Clinical Pharmacy Significance
Statins	Management of hyperlipidemia and prevention of cardiovascular disease	Increased reports of muscle pain, myopathy, liver enzyme abnormalities, fatigue, and possible neurological symptoms in certain patient groups	Requires regular monitoring of liver function tests, muscle-related symptoms, and assessment for drug interactions, especially in elderly patients
Gemfibrozil	Treatment of hypertriglyceridemia and dyslipidemia	Reports of severe muscle toxicity, rhabdomyolysis, and significant drug interactions when combined with statins	Pharmacists should carefully evaluate combination therapy and monitor for signs of muscle damage and adverse drug interactions
Levetiracetam	Management of epilepsy and seizure disorders	Increased reports of mood changes, anxiety, depression, irritability, aggression, and behavioral disturbances	Important to counsel patients and caregivers regarding neuropsychiatric adverse effects and monitor mental health status during therapy
Donepezil	Treatment of Alzheimer's disease and dementia-related cognitive impairment	Reports of bradycardia, dizziness, syncope, falls, and cardiovascular complications in elderly patients	Requires careful monitoring in geriatric patients due to increased fall risk and possible cardiovascular adverse effects

EMA Regulatory Actions on Acne Drug "Winlevi"

During April 2025, the European Medicines Agency (EMA) attracted significant attention in the pharmaceutical and dermatology communities after initially refusing marketing authorization for Winlevi (clascoterone), a topical anti-androgen medication developed for the treatment of acne vulgaris. Winlevi had already gained approval in the United States for the management of acne in patients aged 12 years and older and was considered one of the first topical hormonal therapies specifically targeting androgen receptors in the skin. However, during the European regulatory review process, the EMA raised concerns regarding the potential risk of endocrine suppression and hormonal imbalance, particularly among adolescent patients. Clascoterone works by blocking androgen receptors within sebaceous glands, thereby reducing sebum production and inflammation associated with acne formation. Although the medication demonstrated effectiveness in reducing acne lesions during clinical studies, EMA reviewers expressed concerns about systemic absorption and the possibility of hormonal adverse effects in younger patients undergoing long-term treatment. Particular attention was given to the potential for hypothalamic-pituitary-adrenal (HPA) axis suppression, which could interfere with normal hormonal regulation in adolescents. Regulatory experts emphasized that even topical therapies may produce systemic effects if absorbed in significant amounts over prolonged periods or when used extensively on inflamed skin.

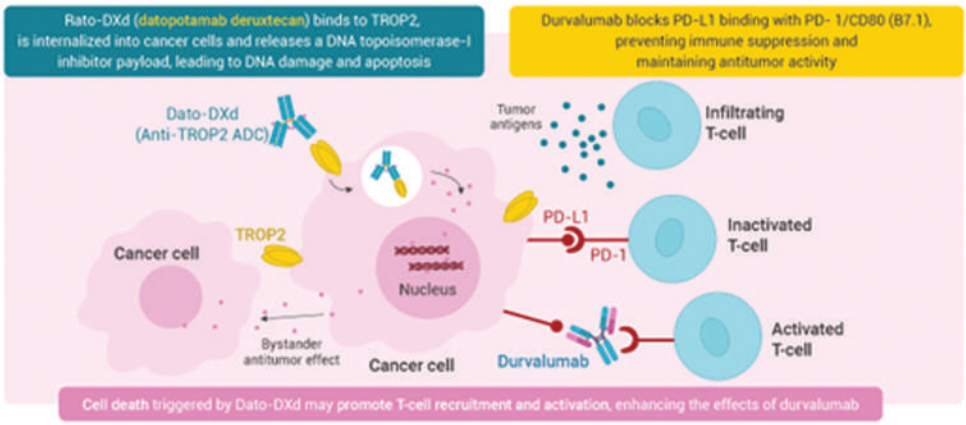
Datopotamab Deruxtecan (Datroway): A New Advancement in Targeted Cancer Therapy

One of the most significant oncology-related developments in 2025 was the approval and expanded clinical use of Datopotamab deruxtecan (Datroway), an advanced antibody-drug conjugate (ADC) developed through collaboration between AstraZeneca and Daiichi Sankyo. In January 2025, the U.S. Food and Drug Administration (FDA) approved the drug for the treatment of hormone receptor-positive, HER2-negative metastatic breast cancer in patients who had

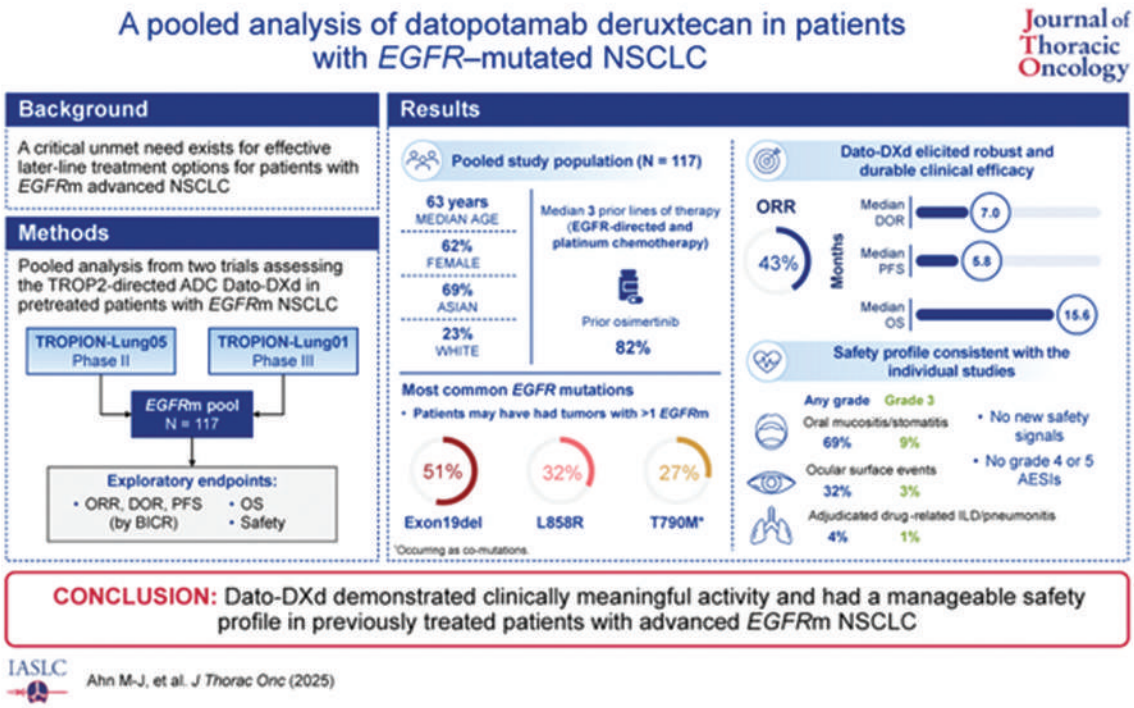
previously received endocrine-based therapy and chemotherapy. Later, in June 2025, the FDA further expanded its indication for the treatment of patients with EGFR-mutated non-small cell lung cancer (NSCLC), particularly in cases where disease progression occurred after prior targeted therapy.

The approval generated considerable attention during major international oncology meetings, including discussions presented at the American Society of Clinical Oncology (ASCO) conference held in Chicago during 2025. Oncology experts described Datopotamab deruxtecan as an important advancement in precision medicine and targeted cancer therapeutics because of its ability to selectively attack tumor cells while minimizing damage to normal tissues.

Datopotamab deruxtecan belongs to a class of medications known as antibody-drug conjugates (ADCs). These therapies combine the targeting ability of monoclonal antibodies with the cell-killing activity of chemotherapy drugs. The medication specifically targets TROP2, a protein highly expressed on the surface of several cancer cells, including breast and lung cancer cells. Once attached to the tumor cell, the drug delivers a cytotoxic payload directly into the cancer tissue, resulting in tumor cell destruction. This targeted mechanism helps improve treatment effectiveness while reducing systemic toxicity compared to traditional chemotherapy.



FDA Approves DATROWAY® (Datopotamab Deruxtecan-dlnk) for Breast Cancer Research



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Virtual Industrial Visit






Awareness programme focused on Importance of medicinal plants in oral health


20th Annual Day Celebrations



Awareness programme on Cervical Cancer and the importance of vaccination for prevention of HPV Virus