

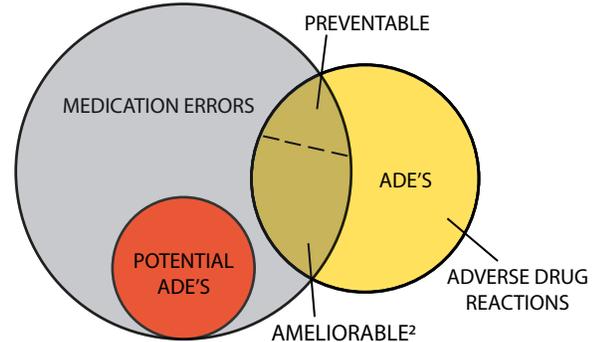


CHRYSALIS



PHARMACOVIGILANCE

Pharmacovigilance is the cornerstone of any pharmaceutical company seeking to ensure that the wellbeing of every patient is being safeguarded. Drug effects are monitored along the course of drug development and when available on general market such that patients are as best protected as possible from the potential of adverse drug reactions. The risks and benefits of these products are continuously evaluated and key decisions are taken to ensure the safety of patients. The responsibility of PV is to detect, assess, understand and prevent adverse events and any other drug-related problems¹.

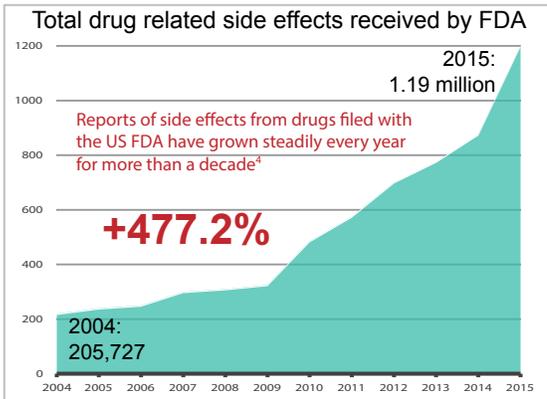


ADRs account for 4.2-30% of hospital admissions in the USA³

PHARMACOVIGILANCE IS EVOLVING

Across many industries and domains, the mechanisms for generation and consumption of data continues to evolve. As pharmacovigilance data volumes increase, our industry has been seeking new ways to leverage technology to collect, collate and evaluate this data.

CHRYSALIS



Celgene's Global Drug Safety and Risk Management function has established a series of work activities to drive innovation across the pharmacovigilance value chain. Chrysalis is built upon three pillars; people, process, and technology. Our vision is to transform pharmacovigilance to drive the new era of patient safety by introducing innovative approaches that leverage artificial intelligence and machine learning to increase operational efficiency, consistency, quality of data collection, and signal detection.

THE FUTURE OF PHARMACOVIGILANCE IS INFINITE

As regulators adopt new approaches aimed at revolutionizing digital health regulations⁵, our aim is to align with the regulators and the rest of industry to shape how these technologies can enhance pharmacovigilance in the future. Chrysalis is our blueprint for progressive pharmacovigilance innovation.

References:

1 Pharmacovigilance. World Health Organization. 2015. Available from: http://www.who.int/medicines/areas/quality_safety/safety_efficacy/pharmvigi/en/

2 Morimoto T, Gandhi TK, Seger AC, Hsieh TC, Bates DW. Adverse drug events and medication errors: detection and classification methods. Qual Saf Health Care 2004;13:306-314. Available from: <https://qualitysafety.bmj.com/content/13/4/306>

3 Howard RL, Avery AJ, Slavenburg S, Royal S, Pipe G, Lucassen P, et al. Which drugs cause preventable admissions to hospital? A systematic review. Br J Clin Pharmacol. 2007;63:136-47. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2000562/>

4 Journal Sentinel. Analysis: Reports of drug side effects increase fivefold in 12 years. Available from: <https://www.jsonline.com/story/news/investigations/2017/03/17/analysis-reports-drug-side-effects-see-major-increase/99211376/>.

5 FDA. Statement from FDA Commissioner Scott Gottlieb, M.D., on Administration's request for new FDA funding to promote innovation and broaden patient access through competition. Available from: <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm596554.htm>