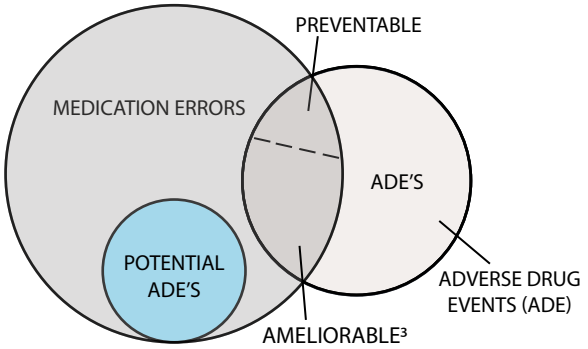
CHRYSALIS

Bristol Myers Squibb™

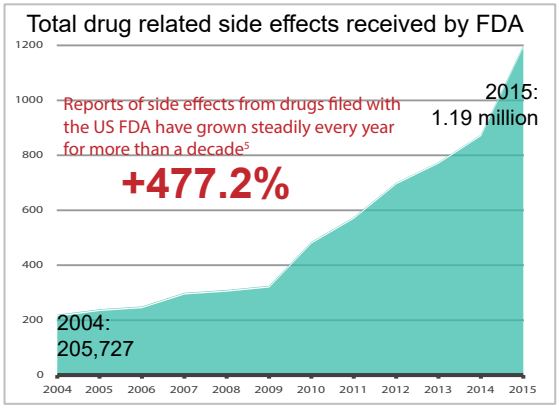
PHARMACOVIGILANCE AND RISK MANAGEMENT

Pharmacovigilance (PV) 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 commercialization 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 problems[1]. Risk Management (RM) seeks to address uncertainties in a product's safety profile throughout the product lifecycle in order to ensure its benefits outweigh its risks for the target population.[2]



ADEs account for an estimated 1 in 3 of all hospitals adverse events in the U.S.[4]

CHRYSALIS IS OUR BLUEPRINT FOR PROGRESSIVE PV AND RM INNOVATION



In many industries and domains, the mechanisms for generation and consumption of data continues to evolve. As our data volumes increase in PV and RM, our industry is seeking new ways to collect, collate, evaluate and act on these data.

BMS' Worldwide Patient Safety function is leading a series of initiatives to drive innovation across the pharmacovigilance and risk management value chain. Chrysalis is built upon three pillars; people, process, and technology. Our vision is to transform pharmacovigilance and risk management to drive the new era of patient safety. This will be achieved by harnessing novel methodologies and technologies including artificial intelligence, machine learning and digitization to enhance safety science and evidence-based decision making to enable development and optimal use of BMS medicines.

THE FUTURE OF SAFETY IS INFINITE

As regulators adopt new approaches aimed at revolutionizing digital health regulations[6], our aim is to align with the regulators and the rest of industry through external collaboration and knowledge dissemination to shape how these technologies can enhance pharmacovigilance in the future.

References:
1 Pharmacovigilance. World Health Organization. 2015. Available from: http://www.who.int/medicines/areas/quality_safety/safety_efficacy/pharmvigi/en/
2. Risk Management. European Medicines Agency. https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/pharmacovigilance/risk-management
3 Morimoto T, Gandhi TK, Seger AC, Hsieh TC, Bates DW. Adverse drug events and medication errors: detection and classi cation methods. Qual Saf Health Care 2004;13:306–314. Available from: https://qualitysafety.bmj.com/content/13/4/306
4. https://health.gov/our-work/health-care-quality/adverse-drug-events#1
5. 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/.
6. 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