Re-Imagining Drug Safety Powered by Genomics, Information Integration, and Emerging Technologies

Abstract

Scientific advancements, emerging technologies, and extensive information have created new opportunities for modernizing drug safety. Simulatenously, the pharmacovigilance regulatory landscape is shifting to ensure improved safety for patients. This is the time to reimagine the drug safety sector to transform it into an advanced, proactive and patient-centric practice.

Introduction

The global healthcare environment is undergoing transformation across the care delivery eco-system to provide more affordable and quality healthcare. Enhancements in the healthcare ecosystem have contributed to longer life spans, but at the same time, there is an increase in chronic diseases which require lifelong disease management. This has several implications on drug safety, which needs to be ensured both in the long term view (interfering with a multitude of disease conditions and other drugs) as well as in a short term view (providing immediate relief from diseases and controlling its spread).

Pharmaceutical organizations are leading the way to make personalized medicine a reality and increasingly moving towards demonstrating health outcomes. They are also undergoing constant change to ensure enhanced safety that is aligned with the shifting drug safety regulatory landscape.

Changing Context for Drug Safety

Today there is increased awareness about health due to growing adoption of digital technologies. Adoption of technology in the healthcare ecosystem is also increasing, especially the implementation of Electronic Medical Records (EMR). EMR systems facilitate care delivery and monitoring, reduce medical errors, and track health outcomes. These systems bring ease and effectiveness in sharing patient health information. The key question for drug safety is how integration with EMR can facilitate active surveillance and prevent adverse events.

Genomics has greatly enhanced our understanding of biology and presents a huge opportunity to devise genetic diagnostics and therapies. The challenge is how to enhance drug safety through personalized safety analysis and adverse event prediction for patient-subgroups.

Utilizing Genomics for Drug Safety

Today genomics, along with various tools of modern biology, allows examination of living systems at unprecedented levels of detail leading to greater understanding of biology. This understanding is further used to develop drugs that are inherently safer. There is also an increasing realization that animal models are not effective in assessing toxicity. This is

increasingly evident when predicting the impact of drugs on the Central Nervous System (CNS). Therefore, in-silico modeling of humans is essential; and in order to build good models, one needs the ability to examine human functions with great detail.

Toxicogenomics answers how numbers and levels of proteins being produced in human cells get affected when toxic side effects occur due to drug consumption. Toxicogenomics combines toxicology and genomics along with various 'omics' approaches such as transcriptomics (study of the complete set of RNAs), metabolomics (study of the unique chemical fingerprints that specific cellular processes leave behind), and proteomics (study of proteins particularly their structures) among others. There are a number of ways in which toxicogenomics can help to make safer drugs.

Small genetic differences that each individual carries can affect how he or she responds to a treatment. The study of this relationship between genetic variation and response to a drug is the subject of pharmacogenomics. It also includes the use of genomic-based approaches for discovering new drugs or re-purposing old drugs for new indications.

Integrating Information and Insights

Biological and Chemical Information

Though there are multiple information sources for safety analysis, there is no single platform for all the available biological and chemical knowhow. The next-generation drug safety program needs to be able to search and integrate insights from structured information on genes, proteins, biological function, drugs, toxicity profiles, and diseases. There is an equally critical need to include relevant insights from large amounts of unstructured information such as journal publications, articles, and patents.

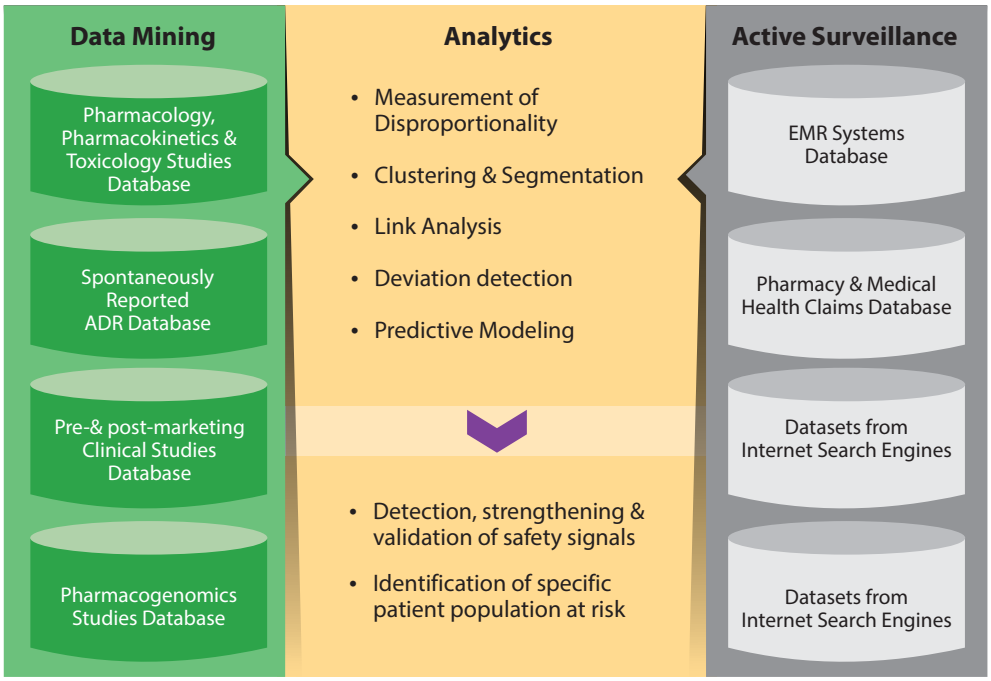
Clinical Information

Human trials are the primary source of clinical information but these represent limited scenarios with minimal information when compared to information available post drug launch. With the increasing adoption of IT in the healthcare delivery ecosystem, EMR data is being envisaged to bring many benefits by effectively utilizing patient data. Drug safety systems need to start integrating this data for safety analysis. Increasingly there has been a surge in adopting Electronic Data Capture (EDC) systems to increase and capture patient data

electronically during clinical studies. Opportunities to integrate EDC with EMR systems for clinical insights are being explored, and this approach needs to be extended to post-marketing clinical studies.

Advanced Analytics

The ability to search and combine all relevant information and insights would provide a unique opportunity to perform advanced safety analytics during the trials as well as post-marketing. This requires good algorithms to combine information from different sources with the appropriate confidence levels to draw inferences.



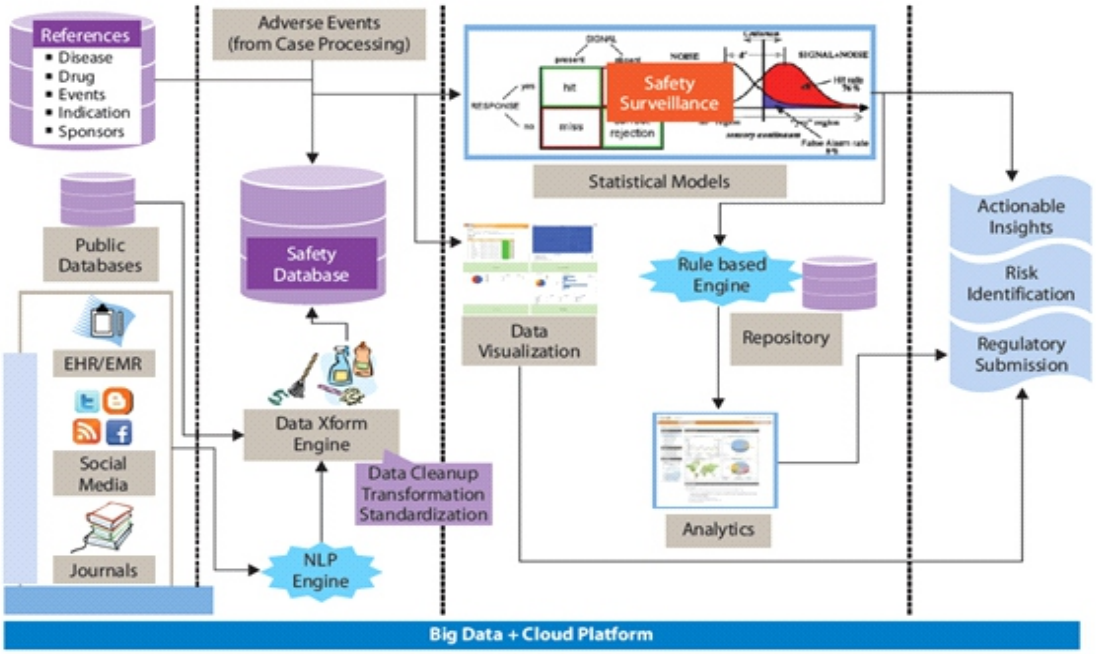
Analytics use cases for drug safety

Adopting Emerging Technologies

Emerging technologies are shifting architectural paradigms. Adoption of these technologies blurs the boundaries across systems and provides tremendous opportunities to leverage the power of information integration as never before. This also enables utilization of distributed resources to meet the computational needs of safety related processes.

Primarily, the focus of drug safety is on pharmacovigilance (case processing activities) which operates in a transaction oriented fashion. With the changing approach to drug safety due to genomics and the possibility of integrating various newer insights (generated from vast amount of continually flowing information), the entire architectural landscape of drug

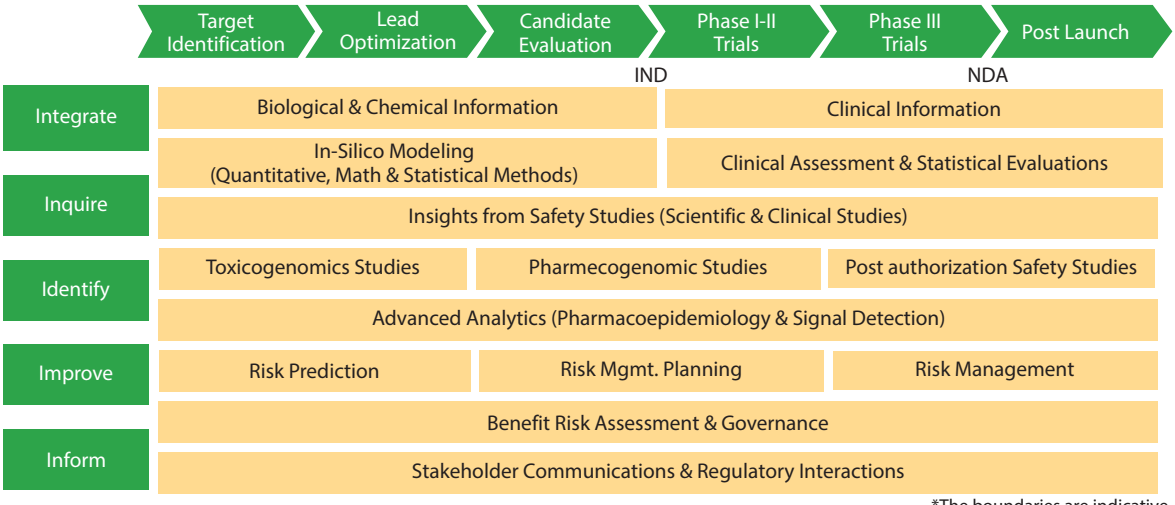
safety needs a relook. The guiding principles of the modern drug safety architecture would require the ability to integrate and analyze safety insights quickly; enable stakeholders to access relevant information and perform analysis, and ensure that proactive measures can be planned effectively to address patient safety.



Representative, next-generation drug safety architecture with seamless flow and integration of information and insights

Keeping Pace with Regulatory Expectations

The drug safety regulatory landscape is constantly undergoing changes to ensure enhanced patient safety. Understanding regulatory expectations and future direction is critical to reimagine the landscape, including benefit risk assessment and pharmacovigilance legislations.



TCS 5I Model on Drug Safety

*The boundaries are indicative

TCS 5I Model of drug safety—Integrate, Inquire, Identify, Improve and Inform represents different components of safety in the entire life cycle of a drug. The future drug safety function is expected to combine various perspectives:

- Integrate: constantly integrate information and insights needed for drug safety and be a custodian of all safety related knowledge
- Inquire: collaborating with R&D for capturing safety related insights and executing safety studies throughout the life cycle of the drugs
- Identify: perform advance analytics to predict and identify safety concerns early
- Improve: proactively address safety concerns via risk management practices
- Inform: devise safety communication strategy (including safety education to the stakeholders such as physicians, patients and care givers) and perform regulatory interactions

Conclusion

There is a strong need to develop next-generation drug safety platforms based on thorough drug safety domain insights combined with cutting-edge technology leadership capabilities and a patient-centric integrated drug safety vision. Developing a transformation roadmap and appropriate change management models, keeping in mind the current state of technology maturity in drug safety, can enable easier adoption of newer platforms.

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