Reimagining the Pharmaceutical Life Cycle with Artificial Intelligence

From discovery to clinical trials, to marketing and managing medicinal products on the market, artificial intelligence (AI) is delivering promise and possibility to the life sciences industry. Intricate, time-consuming tasks that once took departments weeks, months, or even years to accomplish are now being reimagined, thanks to AI and other digital technologies.

At the discovery stage, machine learning and artificial intelligence are being deployed to screen compounds for those most likely to be relevant and effective. The purpose is to use virtual high-throughput screening — enabled by deep learning and other machine learning capabilities — to eliminate less-relevant compounds and push new assays into preclinical and clinical studies much more rapidly.

Once a product reaches clinical trials, AI-type technologies can be engaged to reduce time, costs, and resources, including test subjects. Toxicologists have said machine learning technologies for the analysis of chemical safety data could replace many of the standard safety studies carried out on animals.[1]

AI and Real-world Data

Lately there's been much discussion about real-world data's potential to substitute the need for at least some clinical trials. In other words, regulatory authorities and companies can assess both the efficacy and the safety of a product in a real-world setting by analysing data from large databases. In February 2019, a joint task force of the Heads of Medicines Agencies and the European Medicines Agency on big data released a report on the opportunity to use existing vast volumes of data to better understand disease, therapies, and the ways products are used in the healthcare system.[2] The task force defined big data as "extremely large datasets which may be complex, multi-dimensional, unstructured and heterogeneous, which are accumulating rapidly and which may be analysed computationally to reveal patterns, trends and associations." In the jargon of data scientists, this is referred to as the *3 Vs* (volume, variety, and velocity).

The task force highlighted distributed datasets as the most effective way to link many datasets and added that the use of AI-derived machine learning and other analytic approaches would be needed in order to gain insights from distributed data networks. Properly leveraged and analysed, those datasets offer important insights about how drugs are used and how they affect patients in the real world. For example, controlled studies show that statins can reduce reinfarction but reality shows that a large percentage of patients don't use the treatment as they should, which increases their risk.

The Next Frontier in Safety

When it comes to managing the safety of products on the market, AI capabilities – or, more specifically, machine learning – are becoming important pillars for many pharmacovigilance activities. That's because pharmacovigilance involves a lot of non-specialised, labour-intensive work, such as processing, translation, patient-narrative writing, and signal detection. Such activities can be automated by way of natural-language-processing capabilities, which not only reduces time and resources but also improves data quality and cuts down on error rates during manual entry.

It seems likely that in the near future, AI or machine learning will become the next frontier in outsourcing by replacing offshoring – whereby companies seek cheaper labour – with computer algorithms.

At a more advanced level, machine learning will enable pharmacovigilance departments to glean more insights from safety data. For example, it will become easier to identify signals indicating a potential safety risk before more serious health scares or even deaths demonstrate a problem with a drug. It will also be possible to identify trends in the effectiveness of a product and whether the product is being misused or abused.

It's likely that had AI capabilities been available and deployed on signal detection when statins first hit the market, serious health consequences and deaths could have been avoided. It's fair to say, therefore, that AI in pharmacovigilance has the potential to save lives.

A Data and Human Challenge

One of the major challenges with regard to applying machine learning to pharmacovigilance case processing is the fact that data can be either structured or unstructured, and the quality of that data varies significantly. At one end of the spectrum is clinical trial data, which is managed methodically and limited to the number of patients enrolled in a trial. Next is data from case reporting and the monitoring of medical literature, which is more wide-ranging but also less verifiable than clinical data is. And at the other end of the spectrum is the massive amount of data from digital sources such as social media and wearable devices, which is far more difficult to verify.

More advanced AI capabilities will have to be applied in order to extract and reliably analyse both structured and unstructured data from multiple different sources.

Another, perhaps less well-considered, challenge is how AI changes the role of pharmacovigilance experts. Whereas AI will mean companies will need fewer administrative officers to handle more mundane tasks and whereas AI will filter out noise to uncover the genuine safety signals, there will be a need for more specialists who can interpret and act on safety and efficacy data. Furthermore, those pharmacovigilance professionals will have to become more literate when it comes to AI, machine learning, and other data science tools.

AI won't affect only industry professionals. During a presentation in Paris in November 2018, Phil Tregunno, signal management unit manager and Innovative Medicines Initiative WEB-RADR project lead at the Medicines and Healthcare Products Regulatory Agency, said artificial intelligence will

affect how pharmacovigilance inspections get carried out. Just as inspectors auditing a production plant need to know how drugs get made, pharmacovigilance inspectors will need to know how AI, machine learning, and other advanced digital tools get made, how they work, and the ways they get validated.

It's not only inspectors' *skills* that will be tested but also how deeply inspectors will be able to go in their inspections. Many AI apps are proprietary, so it's a question of whether the authors of those apps or the software companies developing those apps are willing to have their workings assessed. Precedent for in-depth inspection has been set at production sites, where inspectors are exposed to proprietary information. However, apps typically are the properties of third parties, so some sort of agreement will have to be reached between the various companies and the regulatory authorities.

Preparing for Change

There are challenges involved with the implementation of AI in the management of the product life cycle, but the life sciences industry has confronted and overcome change-related challenges many times in the past. AI is already being deployed in some areas of the life sciences and will continue to be an important tool in advancing the industry's way of working. Companies – and specifically, pharmacovigilance departments – have to prepare for the changes that broad adoption of AI will bring.

REFERENCES

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Marco Anelli, MD

Marco Anelli, MD, is a principal consultant, a coordinator, and head of the Data, Information, Knowledge & Intelligence group at ProductLife Group. Marco leads efforts to develop and implement solutions based on digital technologies, including machine learning, artificial intelligence, and data science in the fields of drug life cycle management, pharmacovigilance, and regulatory affairs.

Email: manelli@productlife-group.com