Applying AI Technologies in Clinical Trials from the Perspective of Pharmacovigilance Processes

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With the advancement of artificial intelligence technology in recent years, including successes like natural language processing (NLP) and machine learning (ML), the pharmaceuticals industry has begun to realize greater benefits from data technology. AI technologies are already playing a substantive role in clinical trials, speeding the process of research, and enhancing the quality of results.

NLP is of great benefit to help extract real world data (RWD) from the treasure troves of data that are in healthcare ecosystems, such as hospital information systems, insurance claim databases, etc. Using NLP technology's ability to train computers to understand human language the same way human brains do enables the transformation of large amounts of unstructured text in clinical medical information into structured data, making it easier to analyze.

AI technology can be used with RWD on its own, or as a valuable aid in conjunction with human analysis.

For research on vaccine efficacy based on RWD, the data generation process must be taken into consideration. Advanced ML techniques, especially Targeted Learning, can be used to determine which part of the data generation process is needed to directly assess target parameters, such as **effect size estimates**.

Other areas of clinical development have begun incorporating AI in their concept phases. For **patient risk signal detection**, AI technology offers promise in overcoming the challenges of discriminating patient risk warning signals from background noise, leveraging patterns learned from a large amount of RWD across different areas of research in patients with similar characteristics.

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An important area where AI is already making a substantial impact is with **pharmacovigilance** (PV) processes. Two main components that support these PV processes are *Single Case Processing* - the collection, interpretation, and reporting of individual adverse events (AE) - and *Signal Detection* - continuous monitoring of AE data for patterns that may indicate new safety information that influences risk-benefit assessments. AI tools are particularly well-suited to help improve several key aspects of these PV processes.

Traditional, manually-based case reporting is inherently resource-intensive and repetitive. AI technologies can **automate** and scale the handling of massive amounts of data. This capability leads to better outcomes, as signals can be detected more rapidly with AI-aided review compared to manual review alone.

Another factor with case processing is that while some data comes in structured formats (data that conforms to pre-defined models, which is easier to analyze), much of it can come from **unstructured sources**, that may be difficult to interpret or analyze. This data could be in anecdotal or narrative form, like feedback from a patient-care hotline, patient-generated content from an online form, or notes from a healthcare provider. NLP and ML are able to accurately extract and classify data coming from these unstructured formats. NLP allows computers to understand, interpret, and process human language. With ML, computers are able to use algorithms and statistical models to recognize patterns and make predictions without having been specifically programmed to do so.

AI technologies are notably useful in the segment of case processing involved with **literature review**, one of the most labor-intensive tasks of the PV process. Instead of merely hunting for particular terms or keywords, NLP and ML apps are able to discern connections between specific drugs and

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known AEs, recognize their significance, and do a preliminary risk assessment. AI can even direct reviewers to the most relevant part of a particular article. All of this allows human reviewers to focus on the most significant cases, which greatly increases efficiency in terms of human resource allocation.

In the area of **signal detection**, these AI technologies also offer great benefits. Machine learning and NLP can enable computers to identify tendencies and associate them with particular phrases or keywords, allowing them to utilize RWD like electronic health records and patient registries, enabling human decision-makers to evaluate larger quantities of data from a wider array of sources. AI can also be taught to differentiate among signals, and learn how to prioritize them. By handling data faster, processing greater amounts of it, and doing so with accuracy, AI allows human reviewers to detect relevant safety signals sooner, and to intervene earlier.

Looking towards the future, we can see that in these areas where AI technologies are already being utilized, their roles will undoubtedly only increase over time. But the potential future benefits of AI in clinical trials may be even broader. Greater adoption of AI throughout

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different phases and within different segments of clinical research and operations could potentially revolutionize clinical development. AI applications have the potential to increase speed and safety while reducing risks and costs of clinical trials, and ultimately help medical researchers and professionals to realize and more-fully integrate the concept of a patient-centered approach throughout the entire research and development process.

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