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16 Jul 2024 | **News**

AI And Biosimilars: Untapped Area Full Of Potential – Or Hype?

A Review Article Explores Areas For The Use Of AI In Biosimilar Development

by Urtė Fultinavičiūtė

AI could help biosimilar developers with the development and manufacture of their products, but dependence on high-quality training datasets poses potential challenges.

Artificial intelligence has already been widely used across different sections of the healthcare industry, but it might also hold potential in the off-patent sector, namely biosimilars.

A recent *journal article*, published by the Multidisciplinary Digital Publishing Institute, explored potential areas in biosimilar development where AI could be applied.

Given that biological products have a more complex development process than small molecules, the integration of AI in the R&D process of biosimilars "marks a revolutionary change in the biopharmaceutical industry," the authors suggested.

They found that various AI-based models and technologies may be used to "optimize manufacturing processes, predict the stability of molecules, and improve bioequivalence studies in more urgent times."

It could also "help to quickly identify possible structural and functional variations of molecules, ensuring that biosimilars maintain the required quality and safety throughout the study."

For example, machine learning could aid with predictive biological and clinical outcome modeling by analyzing complex datasets from bioprocessing to clinical trials, and recognize patterns in data to adapt the development process and optimize manufacturing conditions.

Meanwhile, artificial neural networks can understand the "relationship between the structure of biological molecules and their function or efficacy" by analyzing complex biological datasets. They can also analyze electron microscopy or other imaging techniques to evaluate the quality and similarity of biosimilars.

In the natural language processing realm, biosimilar developers could use NLP to analyze scientific literature or regulatory documents as it can "extract information, trends, and relevant data points to inform development strategies and regulatory considerations," and could potentially even "identify possible intellectual property problems."

Dependency On Data And Potential Bias

Despite the beneficial applications, there is also a lot of uncertainty surrounding AI in biosimilar development.

As the authors pointed out, AI needs to be trained with large, high-quality datasets, raising concerns about data privacy. Given that AI is dependent on the quality and quantity of datasets, there is a risk of bias and under-representation of certain patient groups.

Also, the acceptance of AI by regulatory agencies is evolving, "which requires continued dialogue between drug developers and regulators to ensure that AI innovations are effectively and safely integrated into regulatory standards."

The authors suggested allocating funding for R&D initiatives that focus on AI in biosimilar development. Also, biosimilar developers should foster partnerships with AI technology companies.

"Artificial intelligence is shaping a new paradigm in biosimilar development, one that promises to significantly improve the efficacy, safety, and accessibility of these essential therapies," the authors concluded.

AI Used By A Handful Of Companies

Several generics and biosimilar companies have hinted that they have employed AI technology to aid their drug development.

Earlier this year, Dr Reddy's subsidiary Aurigene introduced its AI and machine learning-assisted drug discovery platform Aurigene.AI, which combines physics-based simulation, generative AI models, and computer-aided drug design. (Also see "*Dr. Reddy's Aurigene Unit Opens New Indian Biologics Facility*" - Generics Bulletin, 13 Jun, 2024.)

During the annual J.P. Morgan Healthcare Conference, Celltrion hinted about "building an independent data bank that utilizes artificial intelligence to synthesize Celltrion's vast clinical

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and genomic data." (Also see "*Celltrion Reveals 2030 Ambition Amid 80mg High-Concentration Adalimumab Launch*" - Generics Bulletin, 19 Jan, 2024.)

Last year, Sandoz and Just-Evotec announced a "multi-year" deal to develop and manufacture multiple biosimilars, using a "proprietary AI-driven technology platform that delivers fully integrated drug substance development and continuous manufacturing" (*see sidebar*).

Just recently, both firms announced the expansion of their biosimilar partnership, potentially adding further biosimilars to the pair's development pipeline and offering "further guarantees for Sandoz's long-term commercial supply security." (Also see "*Sandoz And Just-Evotec Expand Biosimilars Collaboration*" - Generics Bulletin, 8 Jul, 2024.)

Sandoz Makes Major Moves To Bolster Biosimilars Ahead Of Spinoff

By David Wallace

10 May 2023

Sandoz has made further preparations to bolster its biosimilars business ahead of its spinoff from parent company Novartis, announcing a development and manufacturing deal with Evotec at the same time as unveiling a further investment in its Holzkirchen site to transform it into a biotech development hub.

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