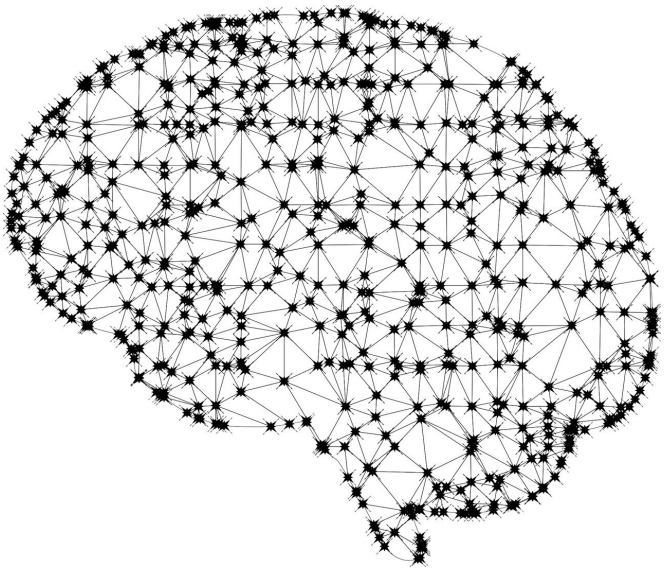
Review evaluates how AI could boost the success of clinical trials

17 July 2019



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In a review publishing July 17 in the journal *Trends in Pharmacological Sciences*, researchers examined how artificial intelligence (AI) could affect drug development in the coming decade.

Big pharma and other drug developers are grappling with a dilemma: the era of blockbuster drugs is coming to an end. At the same time, adding new drugs to their portfolios is slow and expensive. It takes on average 10-15 years and $1.5-2B to get a new drug to market; approximately half of this time and investment is devoted to clinical trials.

Although AI has not yet had a significant impact on clinical trials, AI-based models are helping trial design, AI-based techniques are being used for patient recruitment, and AI-based monitoring systems aim to boost study adherence and decrease dropout rates.

"AI is not a magic bullet and is very much a work in progress, yet it holds much promise for the future of healthcare and drug development," says lead author and computer scientist Stefan Harrer, a researcher at IBM Research-Australia.

As part of the review and based on their research, Harrer and colleagues reported that AI can potentially boost the success rate of clinical trials by:

- Efficiently measuring biomarkers that reflect the effectiveness of the drug being tested
- Identifying and characterizing patient subpopulations best suited for specific drugs. Less than a third of all phase II compounds advance to phase III, and one in three phase III trials fail-not because the drug is ineffective or dangerous, but because the trial lacks enough patients or the right kinds of patients.
- Start-ups, large corporations, regulatory bodies, and governments are all exploring and driving the use of AI for improving clinical trial design, Harrer says. "What we see at this point are predominantly early-stage, proof-of-concept, and feasibility pilot studies demonstrating the high potential of numerous AI techniques for improving the performance of clinical trials," Harrer says.

The authors also identify several areas showing the most real-world promise of AI for patients. For example:

- AI-enabled systems might allow patients more access to and control over their personal data.
- Coaching via AI-based apps could occur before and during trials.
- AI could monitor individual patients' adherence to protocols continuously in real time.
- AI techniques could help guide patients to

trials of which they may not have been aware
- In particular, Harrer says, the use of AI in precision-medicine approaches, such as applying technology to advance how efficiently and accurately professionals can diagnose, treat and manage neurological diseases, is promising. "AI can have a profound impact on improving patient monitoring before and during neurological trials," he says.

The review also evaluated the potential implications for pharma, which included:

- Computer vision algorithms that could potentially pinpoint relevant patient populations through a range of inputs from handwritten forms to digital medical imagery.
- Applications of AI analysis to failed clinical trial data to uncover insights for future trial design.
- The use of AI capabilities such as Machine Learning (ML), Deep Learning (DL), and Natural Language Processing (NLP) for correlating large and diverse data sets such as electronic health records, medical literature, and trial databases to help pharma improve trial design, patient-trial matching, and recruiting, as well as for monitoring patients during trials.

The authors also identified several important takeaways for researchers:

- "Health AI" is a growing field connecting medicine, pharma, data science and engineering.
- The next generation of health-related AI experts will need a broad array of knowledge in analytics, algorithm coding and technology integration.
- Ongoing work is needed to assess data privacy, security and accessibility, as well as the ethics of applying AI techniques to sensitive medical information.

Because AI methods have only begun to be applied to clinical trials in the past 5 to 8 years, it will most likely be another several years in a typical 10- to 15-year drug-development cycle before AI's impact can be accurately assessed.

In the meantime, rigorous research and development is necessary to ensure the viability of these innovations, Harrer says. "Major further work is necessary before the AI demonstrated in pilot studies can be integrated in clinical trial design," he says. "Any breach of research protocol or premature setting of unreasonable expectations may lead to an undermining of trust-and ultimately the success-of AI in the clinical sector."

More information: Stefan Harrer et al, Artificial Intelligence for Clinical Trial Design, *Trends in Pharmacological Sciences* (2019). DOI: 10.1016/j.tips.2019.05.005

Provided by Cell Press

APA citation: Review evaluates how AI could boost the success of clinical trials (2019, July 17) retrieved 27 September 2020 from https://techxplore.com/news/2019-07-ai-boost-success-clinical-trials.html