Docket #: S19-153

Virtual Control Arms for Clinical Trials using Deep Learning

Researchers at Stanford University have developed a deep learning software algorithm that allows physicians running clinical trials to predict control patient outcomes using virtual control arms. Patients' outcomes without treatment can be predicted using historical control data, letting these same patients to undergo treatment instead of placebo.

Clinical trials are expensive endeavors that enroll many patients, a large fraction of which will not receive the experimental therapeutic. Some patients are deterred from participating in clinical trials because of the chance they will not receive treatment. In addition, some physicians find it unethical that patients are being denied treatment when they believe it will benefit them. To solve these issues, researchers have developed a software that employs deep learning to predict patient outcomes based on pre-clinical patient data and generate virtual control data. The software is trained on data from historical control patients and generates a likely outcome in the form of biomarker status or a clinical endpoint. This allows all patients in the clinical trial to undergo treatment. In addition, each patient serves as their own control, allowing the use of paired statistical tests. This technology has the potential to decrease the cost and complexity of clinical trials while permitting more patients to undergo potentially life-saving treatment.

Applications

- Multi-armed clinical trials

Advantages

- Reduces the size and cost of clinical trials

- Allows more patients to undergo treatment
- Treatment group acts as its own control

Patents

- Published Application: 20200381096
- Issued: 12,136,473 (USA)

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