AI to Streamline Cardiovascular Clinical Trials

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Dr. Scott Solomon's research focuses on developing therapies for heart failure and cardiomyopathies through early- and late-stage therapeutic clinical trials. His work has been instrumental in the development of several therapies in the field, including sacubitril/valsartan (Entresto), dapagliflozin (Farxiga), Finerenone (Kerendia), mavacamten (Camzyos), aficamten, patisiran, vutrisiran, inotersen, and others.

Randomized clinical trials represent the gold standard for establishing safety and efficacy, forming the basis for regulatory approval, clinical practice guidelines, and payer coverage decisions. However, early and late-phase clinical trials have become large, complex, costly, and inefficient. Dr. Solomon and his team have been exploring how novel artificial intelligence (AI) technologies could automate and streamline the design and conduct of clinical trials.

Efficacy and safety endpoints require quantification of a therapy's effects on cardiac structure and function. Such assessments typically require painstaking manual measurements of hundreds of parameters from cardiac imaging studies. The team has applied neural network-based segmentation and measuring tools to assess outcome measures. The AI-derived outputs provide high accuracy when compared to human readers but offer greater reproducibility and efficiency.

Nearly all late-stage trials require adjudication, a manual and time-intensive process of applying standardized criteria to participants' medical records, typically by a centralized group. This process is costly, slow, and imperfectly reproducible. Dr. Solomon's team has developed a natural language processing model that identifies heart failure hospitalizations from discharge summary text. Building from an initial model trained on Mass General Brigham medical records, these approaches were applied to international clinical trials and demonstrated 87% agreement with human reviewers.

AI has the potential to streamline many other facets of clinical trial operations: optimizing trial design, screening potential study participants, answering questions in the informed consent process, ascertaining physiologic parameters and clinical events in the form of "digital biomarkers," continuously monitoring participants and their adherence to protocols, and analyzing trial data. The risks of inaccuracy and bias must be carefully considered in order to protect the validity of trial results. Dr. Solomon's group is working with sponsors at all stages of clinical development to thoughtfully integrate AI into cardiovascular clinical trials. These AI solutions can help bring new therapies to patients faster with lower costs and greater reliability.

References

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