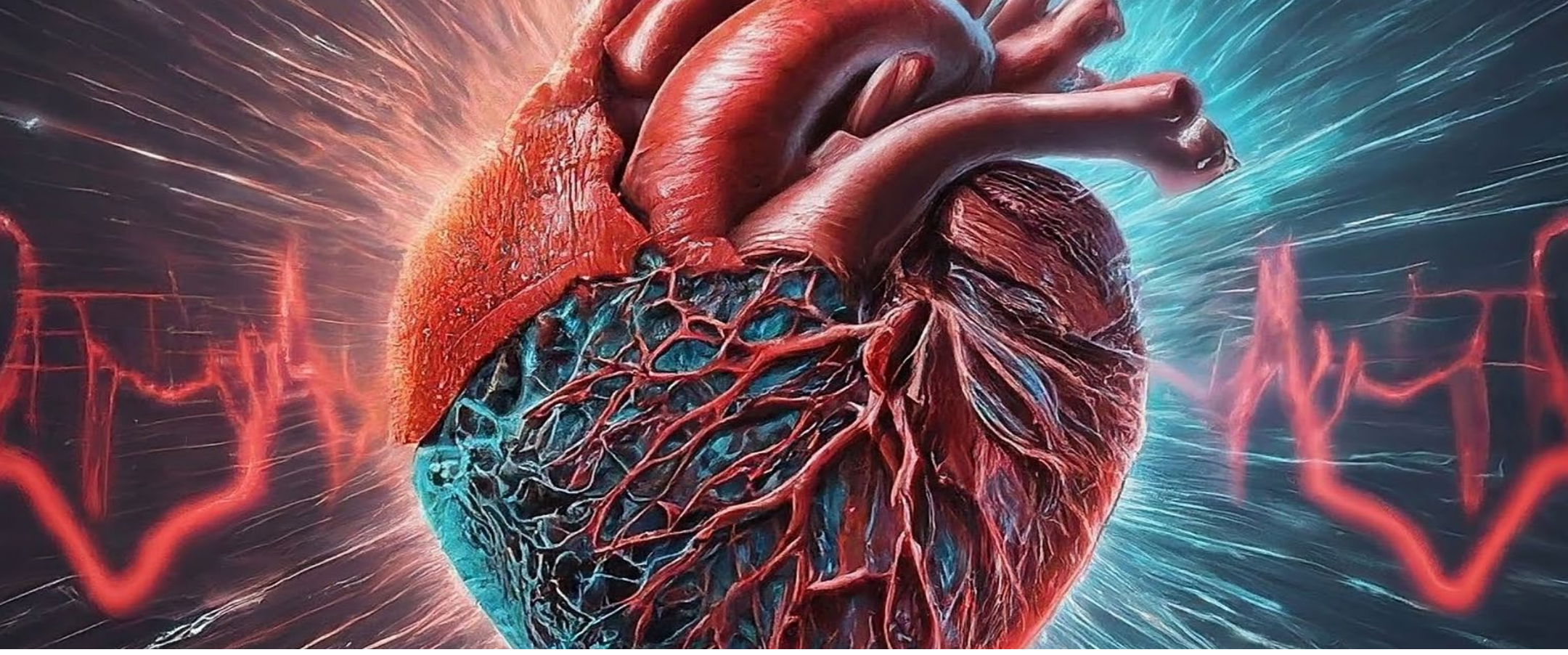

AI to Streamline Cardiovascular Clinical Trials

Clinical Need

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. For example, efficacy and safety endpoints require painstaking manual measurements of hundreds of parameters from cardiac imaging studies. Further, centralized adjudication (applying standardized criteria to participants' medical records) is costly, slow, and imperfectly reproducible.

Our Innovative Approach

Dr. Scott Solomon has pioneered the use of cardiac imaging in cardiovascular drug and device development and use of imaging in clinical trials. He and his research group have played a leading role in many international clinical trials in heart failure, hypertension, and myocardial infarction. Dr. Solomon and his team have recently been exploring how novel artificial intelligence (AI) technologies could automate and streamline the design and conduct of clinical trials. Their efforts carefully consider the risks of inaccuracy and bias in order to protect the validity of trial results.

Results

Dr. Solomon and his team applied neural network-based segmentation and measuring tools to assess trial outcome measures. The AI tool is highly accurate when compared to human readers but offers greater reproducibility and efficiency.

They also developed a natural language processing model for adjudication. The initial model was trained on MGB medical records to identify heart failure hospitalizations from discharge summary text. When the model was applied to international clinical trials, it yielded 87% agreement with human reviewers.

Commercial Potential

AI can streamline many other facets of clinical trials:

- optimizing trial design
- screening potential study participants
- answering questions during informed consent
- ascertaining physiologic parameters and clinical events ("digital biomarkers")
- monitoring participants/protocol adherence
- analyzing trial data

Dr. Solomon's group collaborates with sponsors at all stages of clinical development to integrate AI into clinical trials. These AI-based solutions can help bring new therapies to patients faster with lower costs and greater reliability.

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