Computer-aided Clinical Trials for Medical Devices Robustness Evaluation

Kuk Jin Jang*, Yash Vardhan Pant, Bo Zhang, James Weimer, Houssam Abbas, Rahul Mangharam
University of Pennsylvania

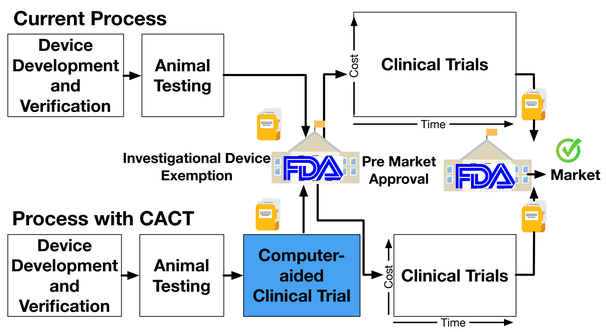
CyberCardia

Penn Engineering

Using modeling and simulation for regulatory-grade evidence and improving outcomes of medical device trials

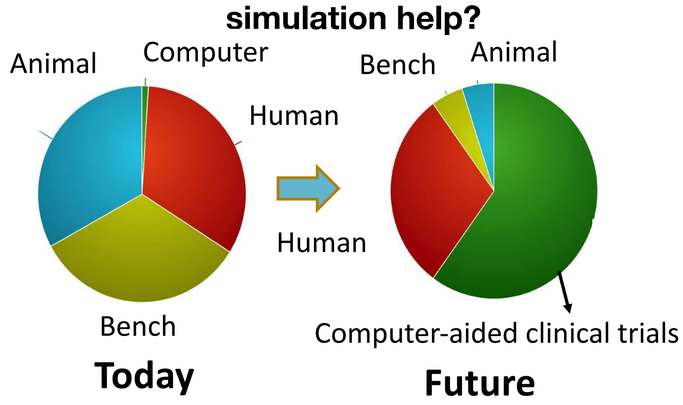
Challenge

Challenge: Device trials are a high barrier



- Cost: $10-20 million, Time: 2-6 years
- **Many trials fail to show the desired outcome**

How can computer modeling and simulation help?



Case Study

Rhythm ID Going Head to Head Trial (RIGHT)

Select Medtronic ICDs (**the control arm**)

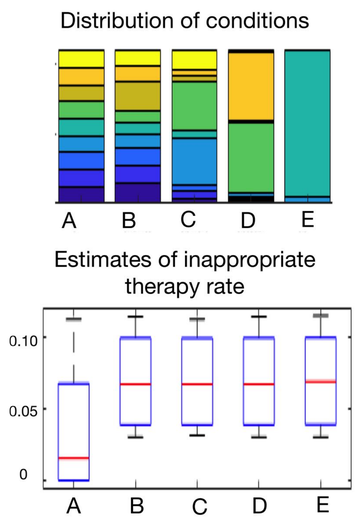
Vitality II ICD (Boston Sci.) (**the treatment arm**)

1,962 Patients
Approx. 5 years
(2006-2011)

- Assumed 25% less risk of inappropriate therapy (Vitality II vs. Medtronic)
- (Result) Vitality II had a 34% increase in risk

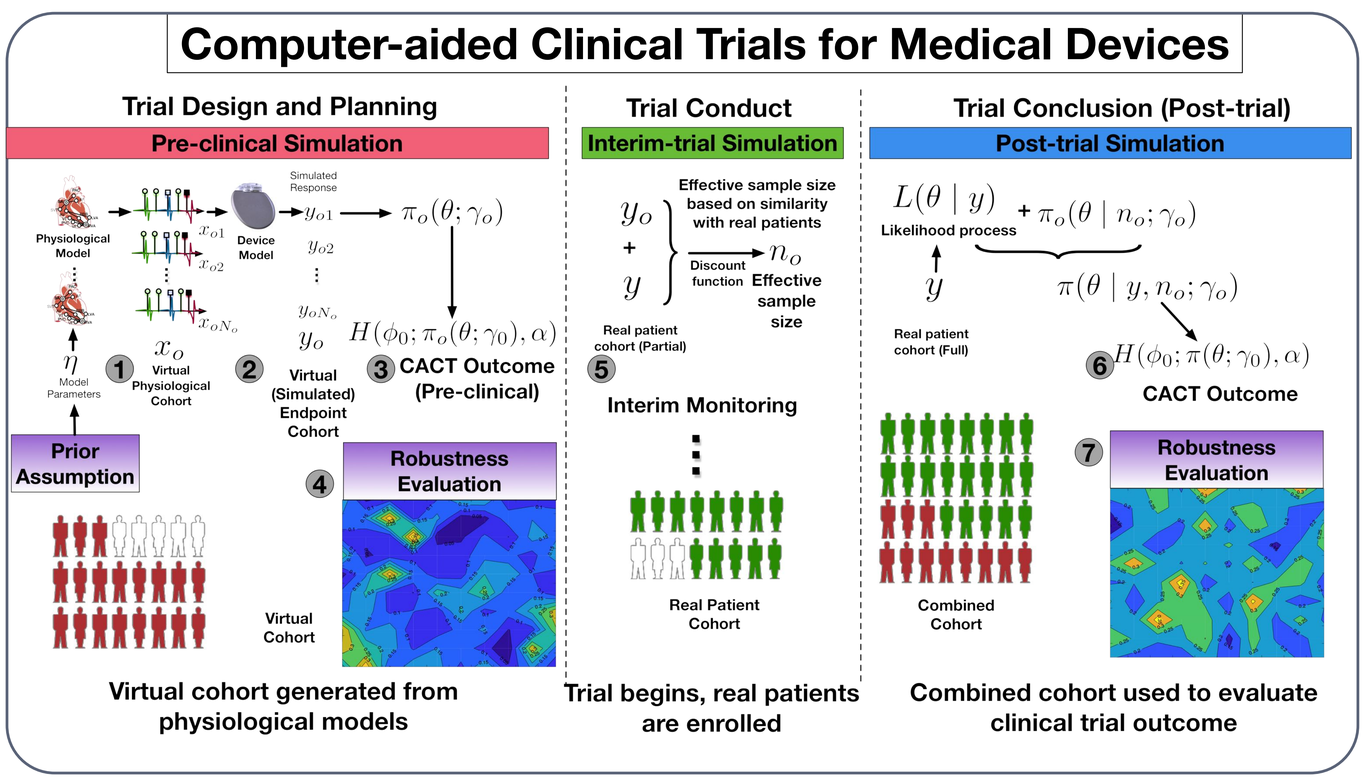
Problem

Problem: Limitations of clinical trial simulation

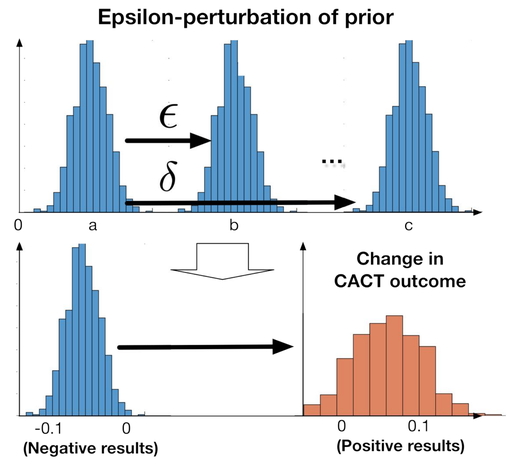


Simulation outcomes vary greatly with different assumptions

Computer-aided Clinical Trials for Medical Devices



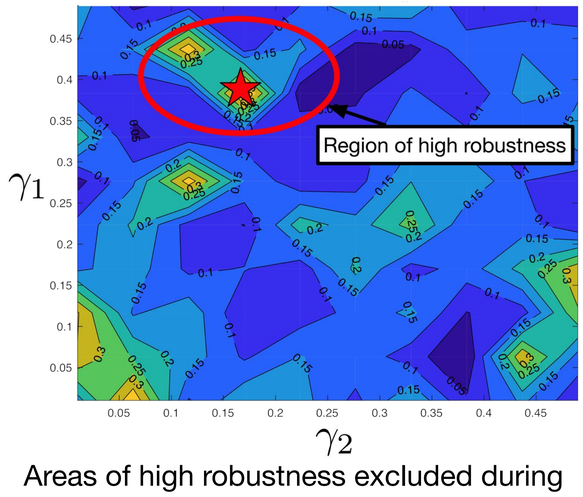
Quantifying uncertainty: Delta-robustness of CACTs



- Perturbation on prior assumption changes outcome
- *Delta-robustness* maximum perturbation before a change

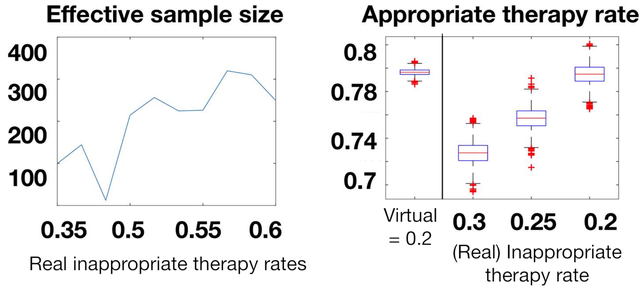
Pre-clinical Results

(1) Pre-clinical simulation and robustness plane

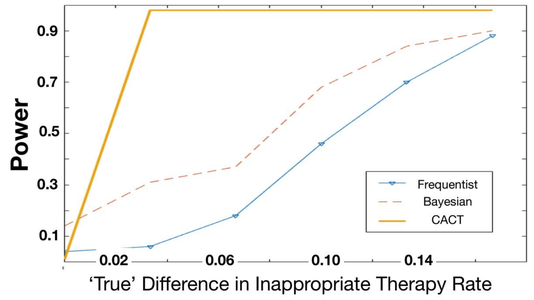


Areas of high robustness excluded during planning stages of trial

(2) Discount function and effective sample size



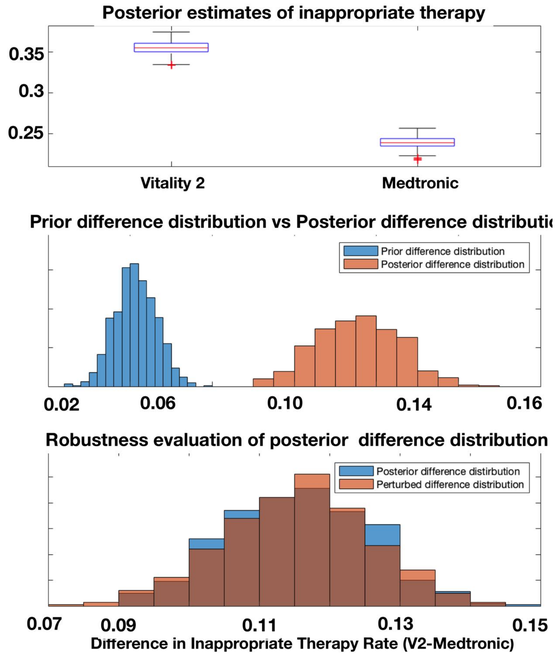
(3) Comparison of CACT vs other standard methods



CACT shows superior power

Post-trial Results

(4) Case study: Post-trial simulation results



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