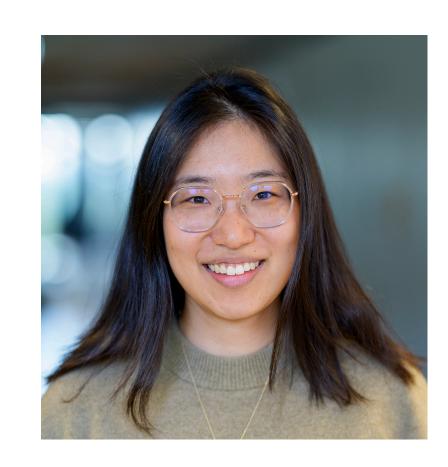


Strategic Hypothesis Testing

NeurlPS 2025 · Spotlight



Yatong Chen*



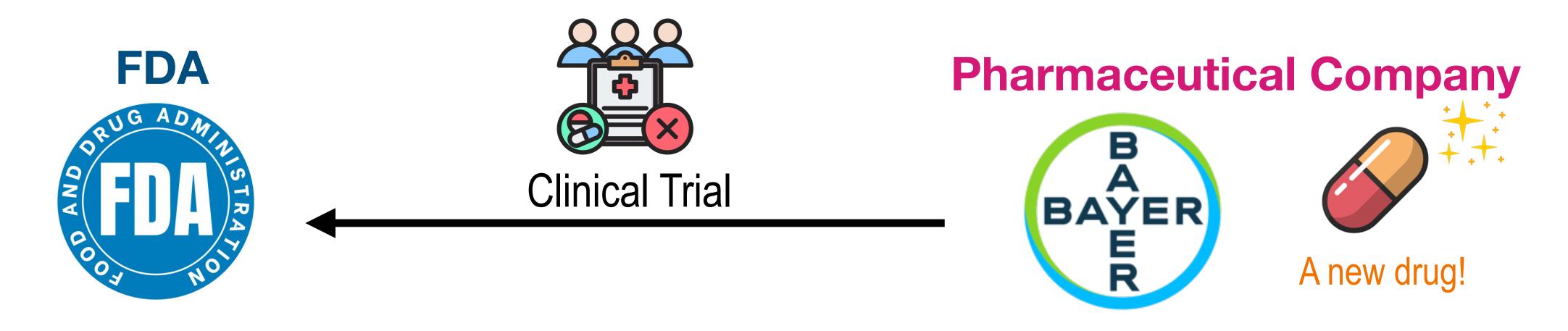
Safwan Hossain*



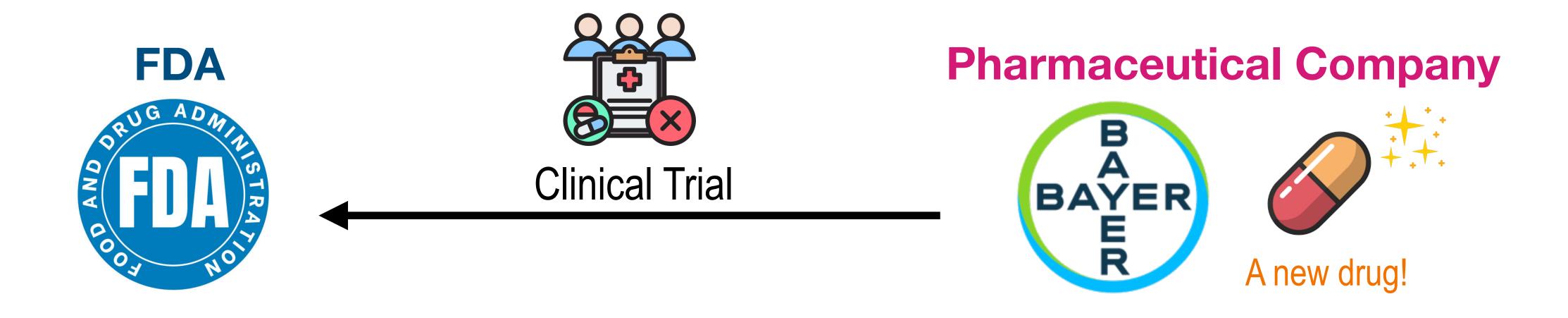
Yiling Chen

 Many real-world decisions rely on (noisy) statistical evidence when ground true is unobservable

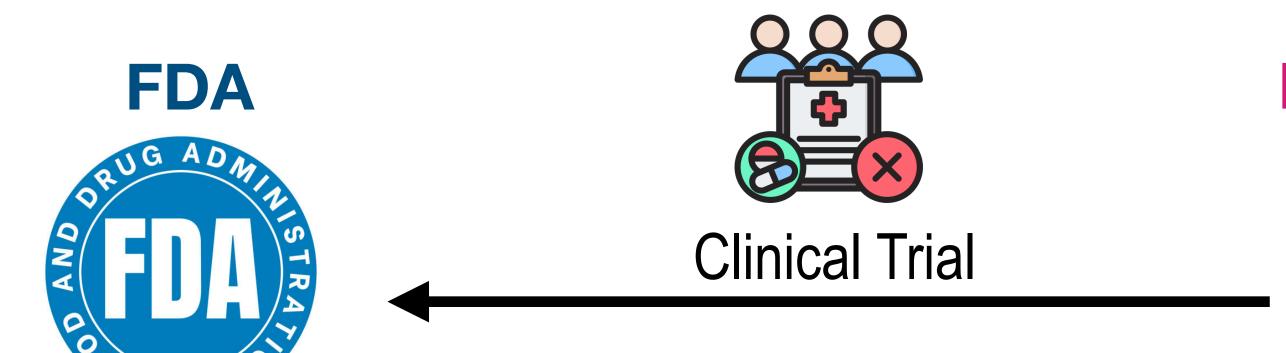
- Many real-world decisions rely on (noisy) statistical evidence when ground true is unobservable
- Example: the FDA's drug approval process



• FDA's decision (Approve or Reject X) on the drug is entirely based on clinical trial results



FDA's Testing Protocol

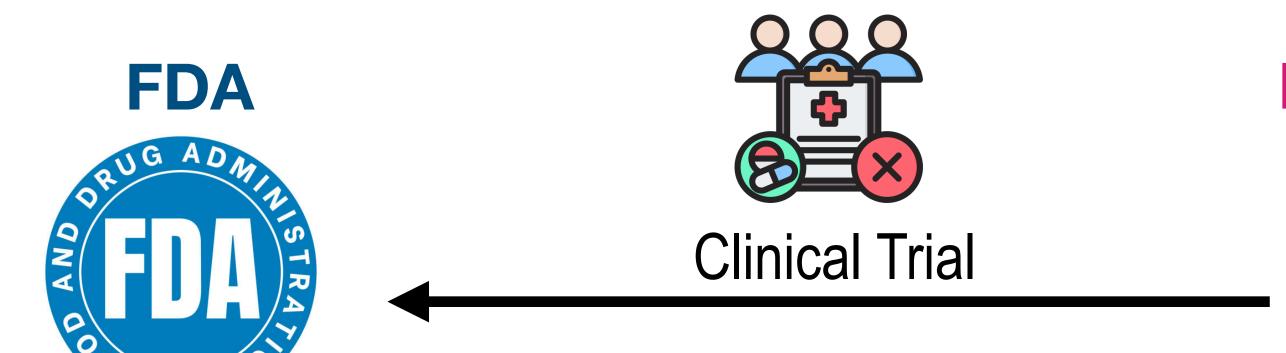


Pharmaceutical Company



FDA's Testing Protocol

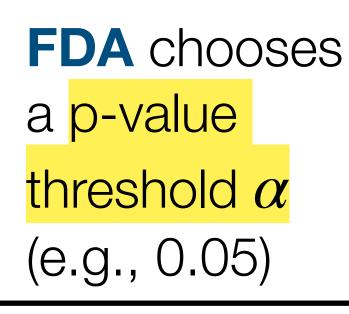
FDA chooses a p-value threshold α (e.g., 0.05)



Pharmaceutical Company

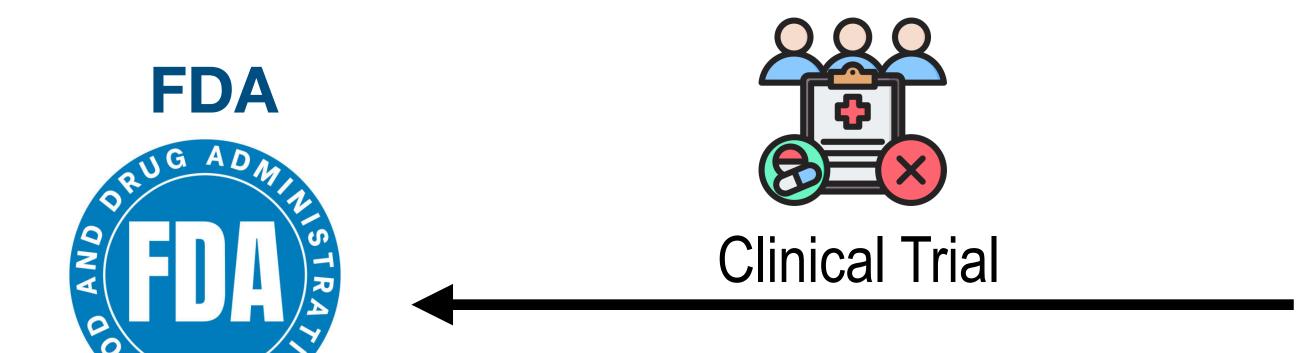


FDA's Testing Protocol



Company runs

a trial with *n* patients



Pharmaceutical Company





FDA's Testing Protocol

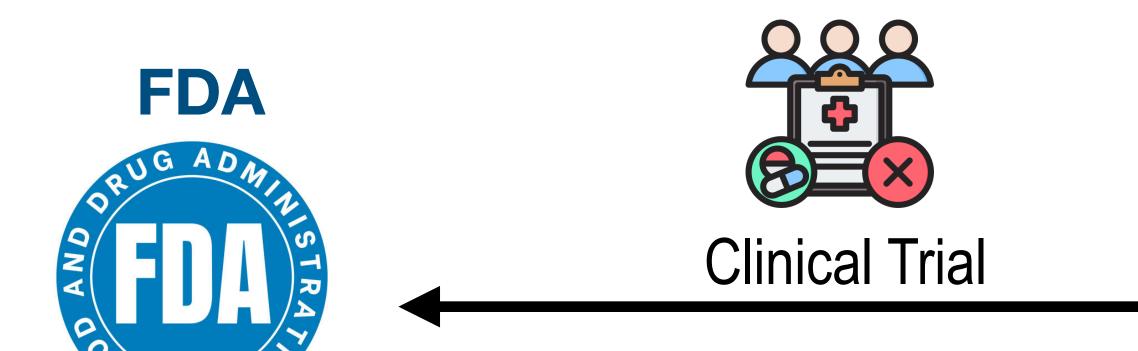
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a trial with *n* patients

FDA

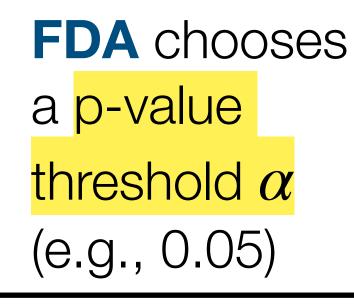
computes the p-value p



Pharmaceutical Company



FDA's Testing Protocol

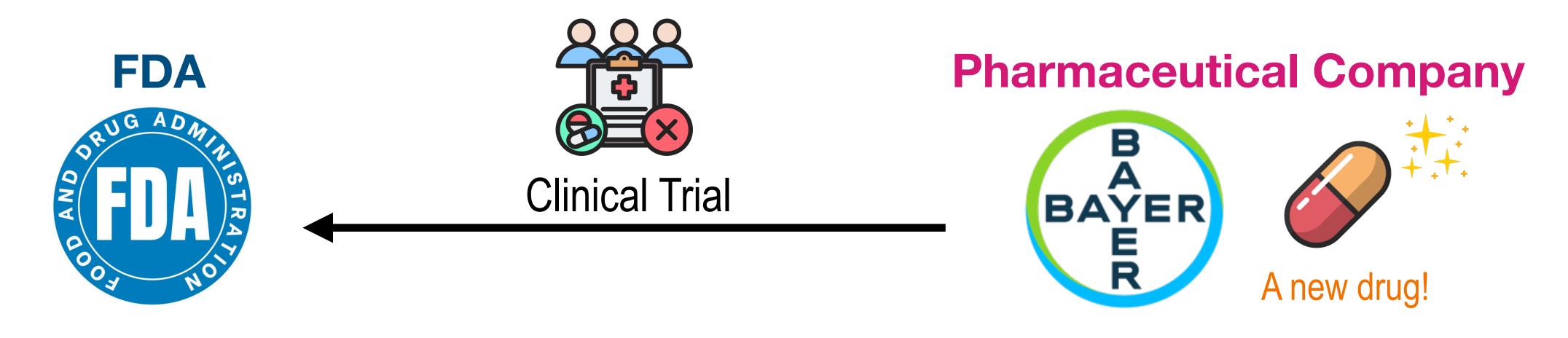


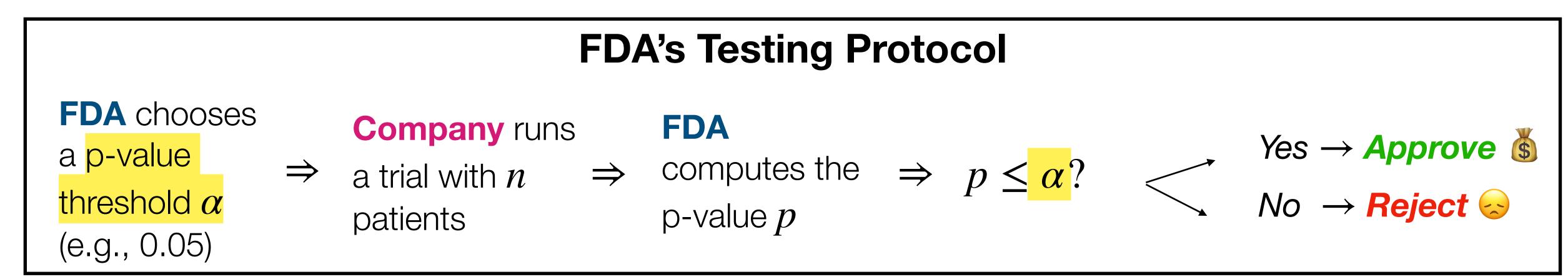
Company runs a trial with *n* patients

FDA

computes the $\Rightarrow p \leq \alpha$? p-value p

Yes \rightarrow Approve $\stackrel{\bullet}{\mathbb{S}}$ No \rightarrow Reject $\stackrel{\bullet}{\mathbb{S}}$





This setup induces a strategic interaction: each side's decision depends on the other's.

Stackelberg Game between FDA and the Company

FDA's Testing Protocol

FDA chooses a p-value threshold α (e.g., 0.05)

Company runs patients

FDA $\Rightarrow \text{ a trial with } n \Rightarrow p \leq \alpha?$ $\Rightarrow \text{ Power in the problem of th$ p-value p

Drug Company's Decision & Utility



• Company (with effectiveness μ) chooses the size of the clinical trial n^* to maximize the expected utility



Drug Company's Decision & Utility

FDA's Testing Protocol

FDA chooses a p-value threshold α (e.g., 0.05)

Company runs patients

FDA p-value p

 $\Rightarrow \text{ a trial with } n \Rightarrow \text{ computes the } \Rightarrow p \leq \alpha? \qquad \qquad \text{No } \rightarrow \textbf{Reject} \bigcirc$

• Company (with effectiveness μ) chooses the size of the clinical trial n^* to maximize the expected utility

 $u(n; \alpha) = R \cdot \Pr[\text{approve} \mid n, \alpha] - \text{Cost}(n)$ Cost of the trial Revenue once (with n samples) approved 📈 🖔 📊

For any fixed rule α , trial size $n \uparrow \Rightarrow$ Pr[approve | n, α] \(\dagger but Cost(n)\(\dagger

Drug Company's Decision & Utility

FDA's Testing Protocol

FDA chooses a p-value threshold α (e.g., 0.05)

Company runs \Rightarrow a trial with $n \Rightarrow$ patients

FDA computes the $\Rightarrow p \leq \alpha$? Yes \rightarrow Approve \Rightarrow No \rightarrow Reject \Rightarrow p-value p

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Company will do strategic self-selection: If $u(n^*; \alpha) < 0$, agent will not participate

FDA's Decision & Utility

FDA's Testing Protocol

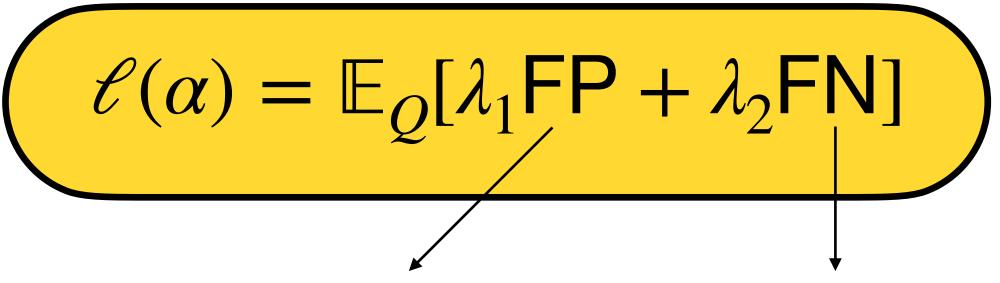
FDA chooses a p-value threshold α (e.g., 0.05)

Company runs \Rightarrow a trial with npatients

FDA computes the $\Rightarrow p \leq \alpha$? Yes \rightarrow Approve \Rightarrow No \rightarrow Reject \Leftrightarrow p-value p

• Company (with effectiveness μ) chooses the size of the clinical trial n^* to maximize the expected utility

 The FDA, knowing the company will do a strategic self-selection, chooses α^* to minimize total errors



Approve inefficient drug

Disapprove effective drug/ effective drug not participate

• We provide characterizations of **optimal behavior** of both **the principal** (selection criteria α^*) and **the agent** (optimal size of the trial n^*)

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Statistical decision rules not only determine who passes the test, but also who chooses to enter in the first place!

Thank you!

