

Improving Recruitment for Clinical Trials: Modeling the Impact of Coordination

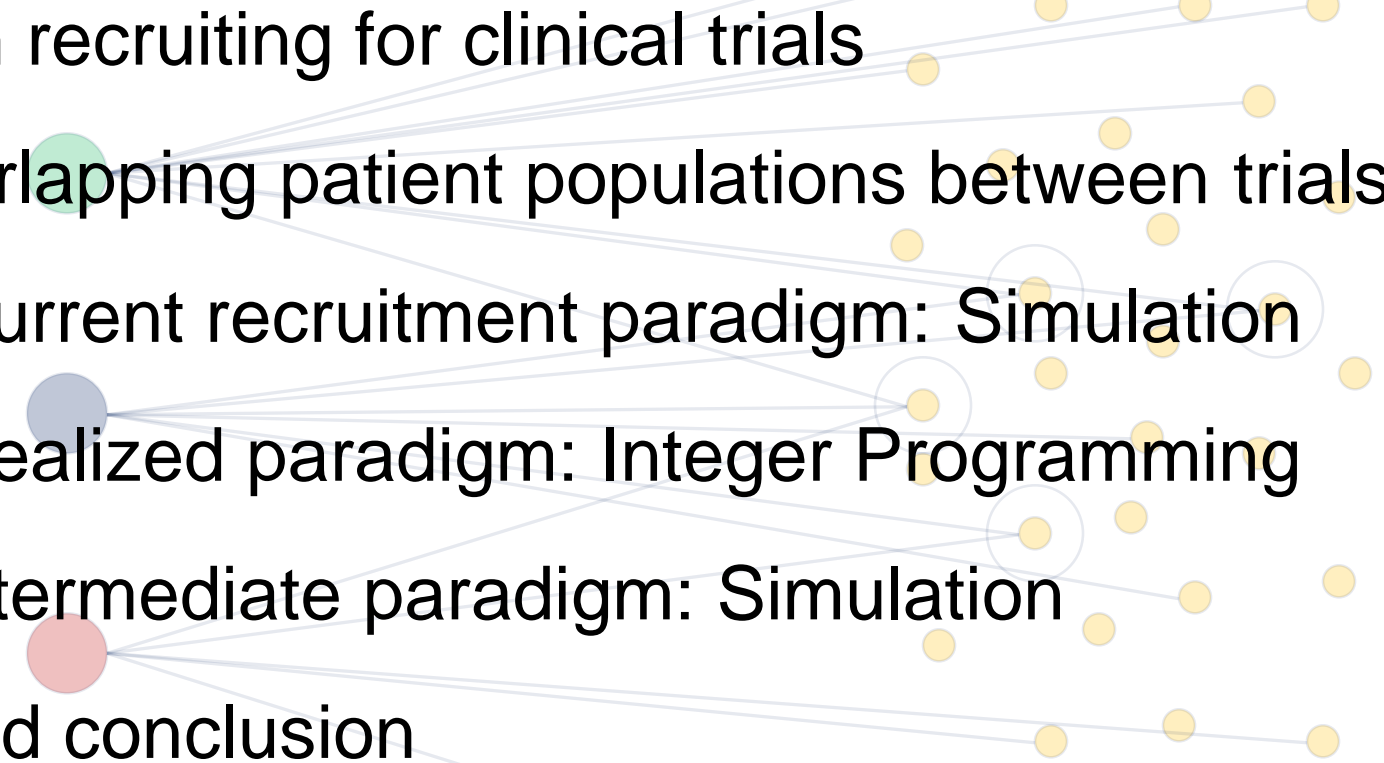
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Agenda

- Background on recruiting for clinical trials
 - Evaluating overlapping patient populations between trials
 - Modeling the current recruitment paradigm: Simulation
 - Modeling an idealized paradigm: Integer Programming
 - Modeling an intermediate paradigm: Simulation
 - Future work and conclusion
- 

Background: Challenges when recruiting for trials

16,000
Recruiting Trials ¹

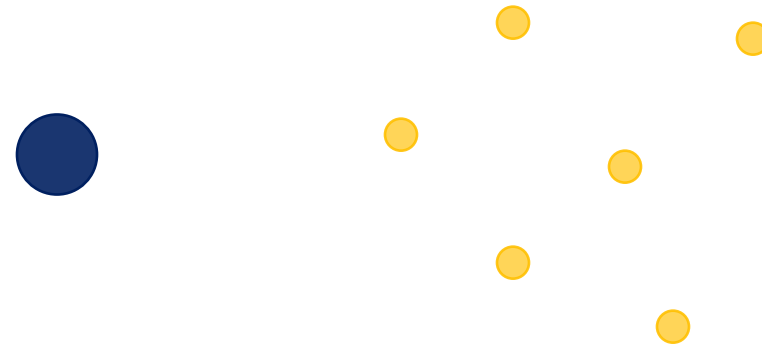
\$130 Billion/Year
US Health Research Enterprise ²

“Many clinical trials never meet their recruitment goals and others accrue patients far too slowly.” ³

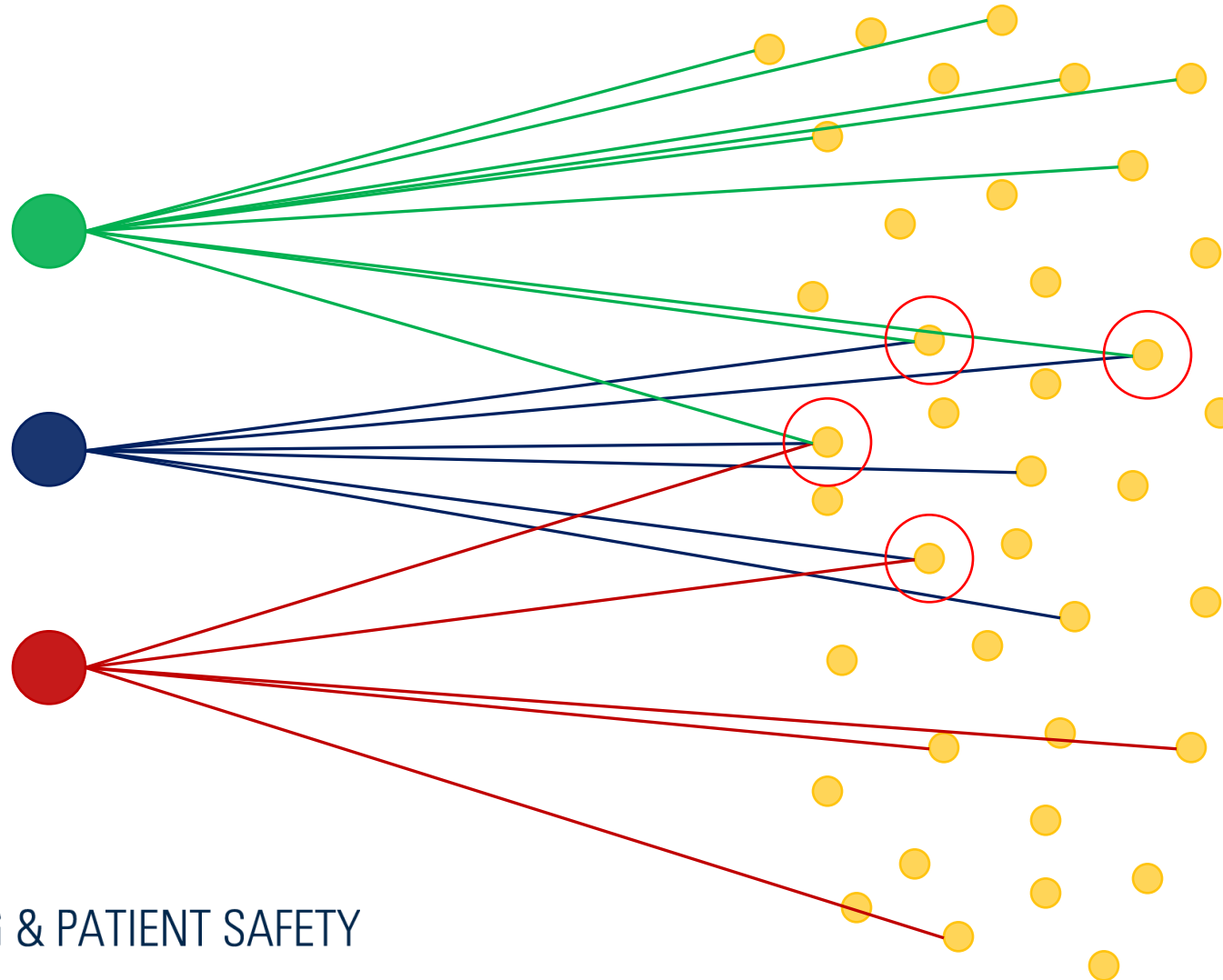
“Fifty percent of clinical research sites enroll one or no patients in their trials.” ⁴

1. Clinicaltrials.gov
2. <http://www.researchamerica.org/uploads/healthdollar12.pdf>
3. Institute of Medicine, 2011
4. Pierre C. Recruitment and retention in clinical trials: What works, what doesn't and why. 2006.

Background: The recruiting process



Background: The recruiting process



Background: The recruiting process



More effectively identify eligible volunteers

Understand overlap between patient populations

Optimize the trial a patient goes to

Background: Patient, trial registry data source

- 15,437 Patients
- 219 Trials: Only 66 had enough eligible patients to reach their goal
- Patients self report past and current medical conditions, medications, and other factors often considered for trial eligibility
- Trials identify eligibility criteria for use in automatic patient identification

Overlapping Patient Populations

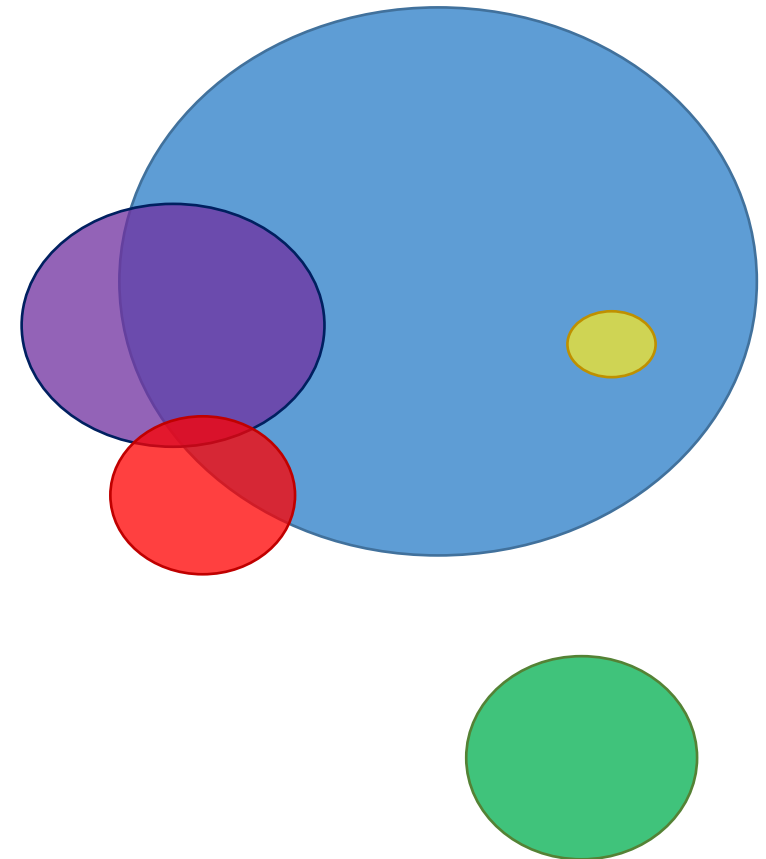
Multiple trials may seek the same patient

Number of eligible trials for each patient

Min:	0
Median:	16 (7.3%)
Third Quartile:	19 (8.7%)
Max:	39 (17.8%)

Number of eligible patients for each trial

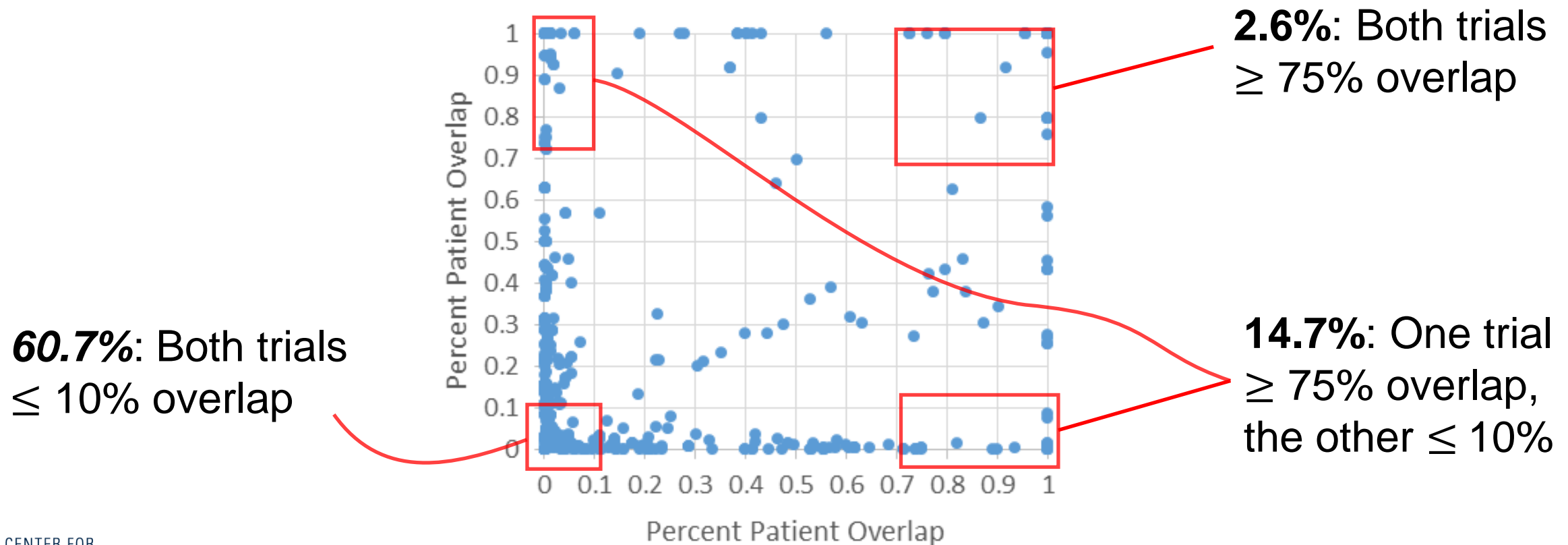
Min:	0
Median:	8 (0.52%)
Third Quartile:	86 (0.56%)
Max:	15,425 (99.9%)



Overlapping Patient Populations

Multiple trials may seek the same patient

How much do the eligible patient populations overlap?



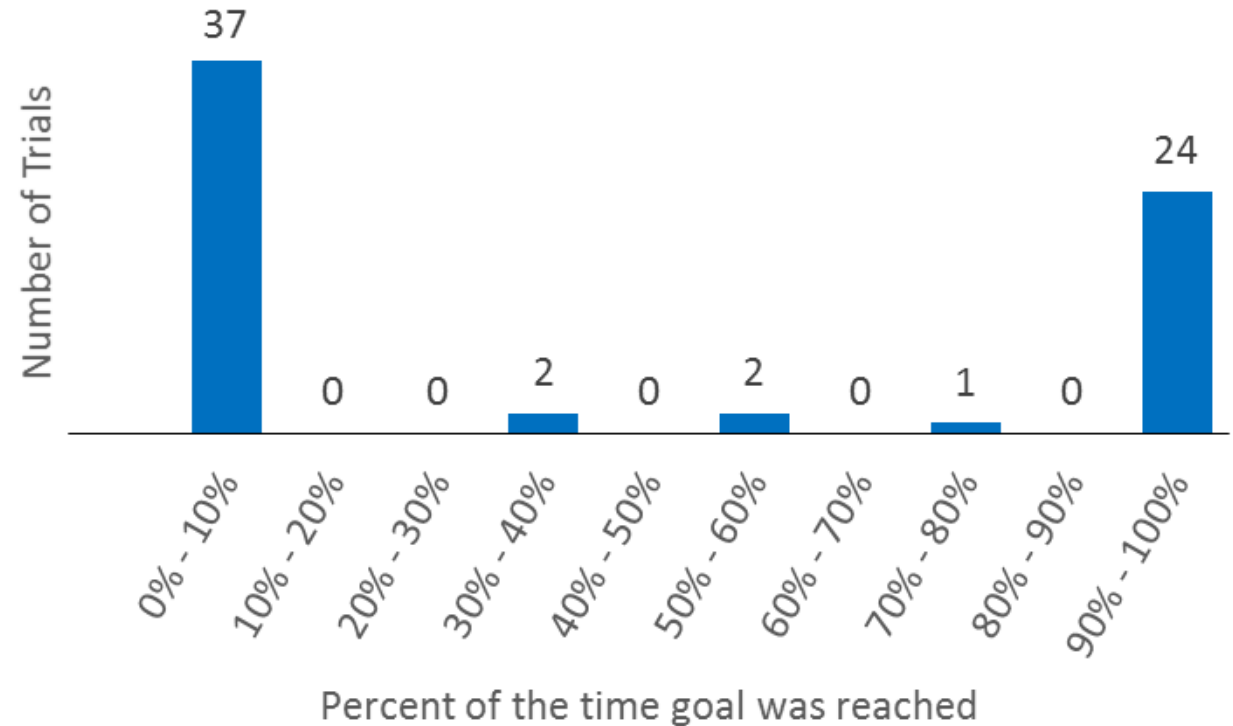
Modeling the Current Paradigm

Independent recruitment: Simulation

Methods

- For all patients, randomly select an eligible trial
- Evaluate whether each trial has reached its goal
- Simulate with 500 iterations

Results



Modeling the Idealized Paradigm

Optimized recruitment: Integer programming

Methods

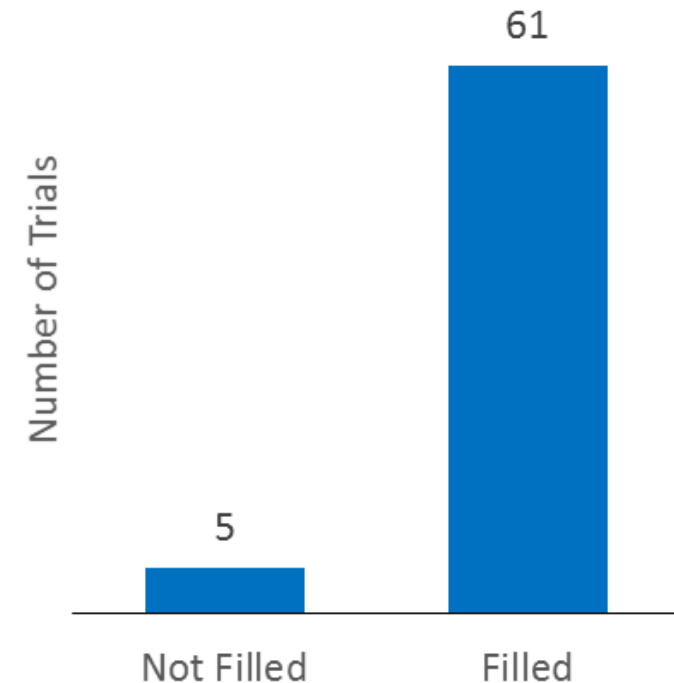
Maximize:

The number of trials selected to be filled

Subject to:

1. Each selected trial must reach its recruitment goal
2. Each patient cannot select more than one trial
3. Non-negativity constraints

Results



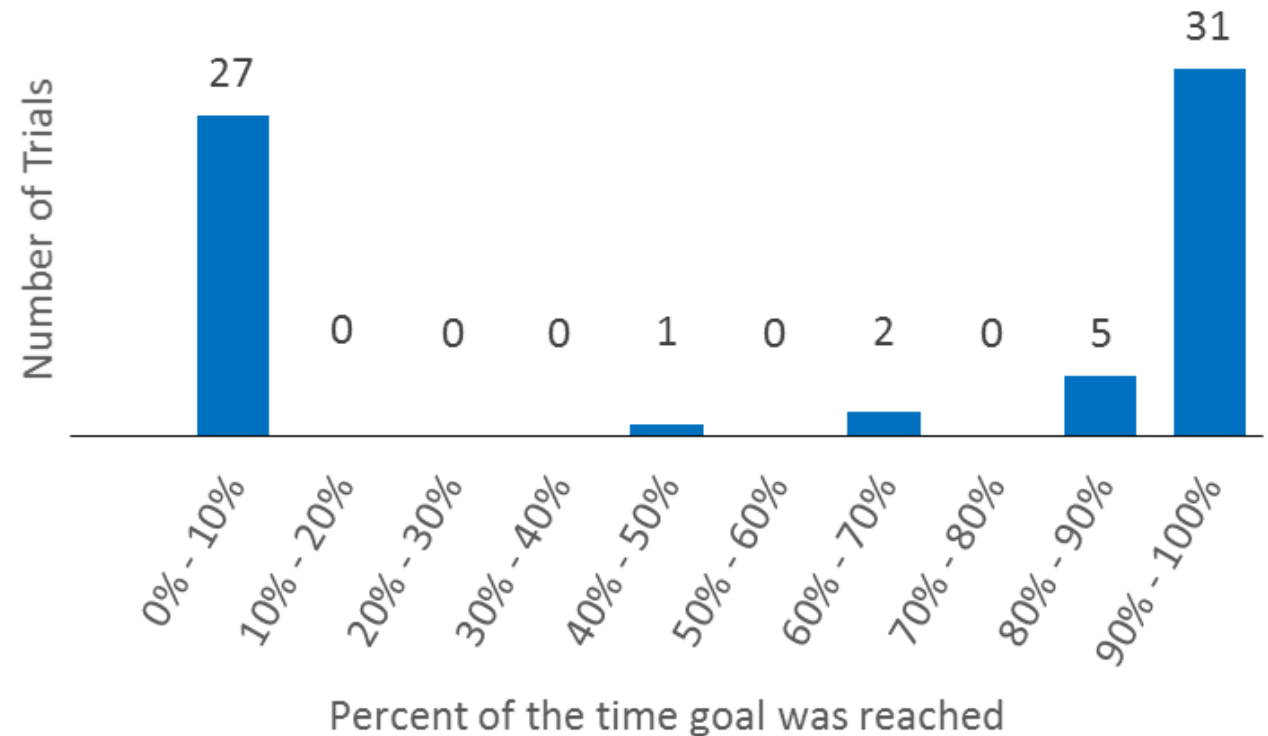
Modeling the Intermediate Paradigm

Partially coordinated recruitment: Simulation

Methods

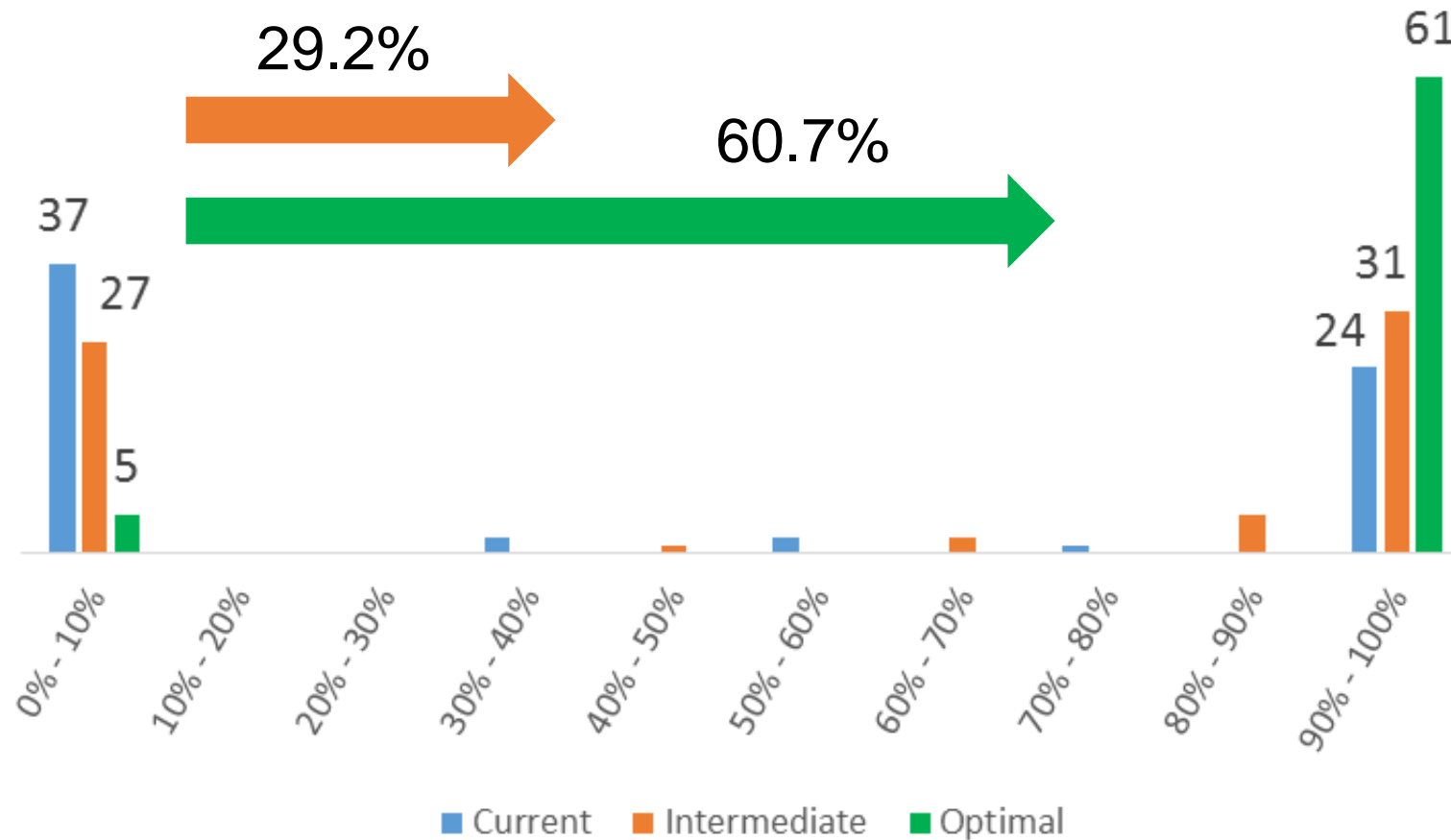
- For all patients, randomly select from the three rarest eligible trials
- Evaluate whether each trial has reached its goal
- Simulate with 500 iterations

Results



In Summary

Coordinated recruitment may improve success



In Summary

Limitations and future work

Limitations

- Validation
- Incomplete data sets
 - Patients
 - Trials
 - Eligibility Criteria
- Patient willingness to participate in trials
- Variations in recruitment paradigms

Future Work

- Understand key criteria that makes a patient eligible for many trials
- Understand which types of trials would benefit most from collaboration
- Expand models, patient population, and eligibility criteria in collaboration with a single department

In Summary

Acknowledgements

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