



Want to make precision medicine a reality? A global collaboration is needed!

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Once upon a time, on a mission to find a new bike...



One-size-fits-all? Not for bikes. Not for medicines either.

The 5Rs of **precision medicine**:

The Right patient

The Right medicine

The Right time

The Right dose

The Right route



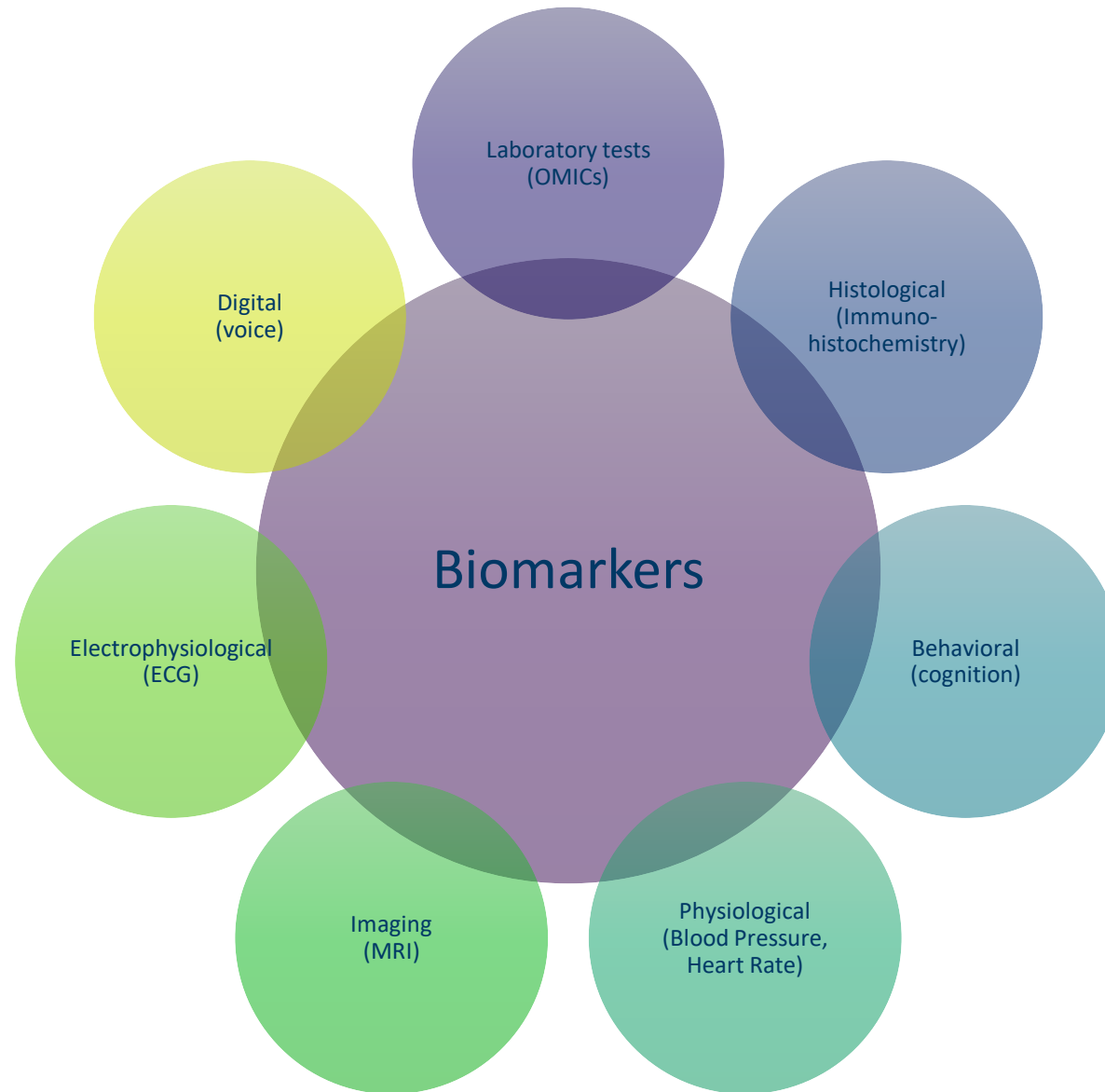
Biomarkers: an umbrella definition

“A defined characteristic that is measured as an indicator of normal biological processes, pathogenic processes, or biological responses to an exposure or intervention, including therapeutic interventions.”

BEST (Biomarkers, EndpointS, and other Tools), FDA – NIH, 2016



Biomarkers: very diverse kinds of data



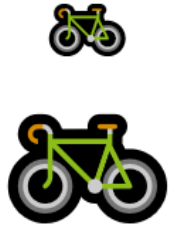
A biomarker can be prognostic

Treatment A

Treatment B



Biomarker:
Bike size



Treatment:
Training

Do not train

Train 1 hour a month

Train 4 hours a day

Endpoint:
Climb Mont
Ventoux
under 1.5 hour

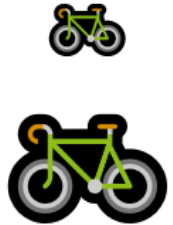




Size of your bike?

A prognostic biomarker of climbing Mont Ventoux under 1.5 hour

Biomarker:
Bike size



Treatment:
Training

Do not train

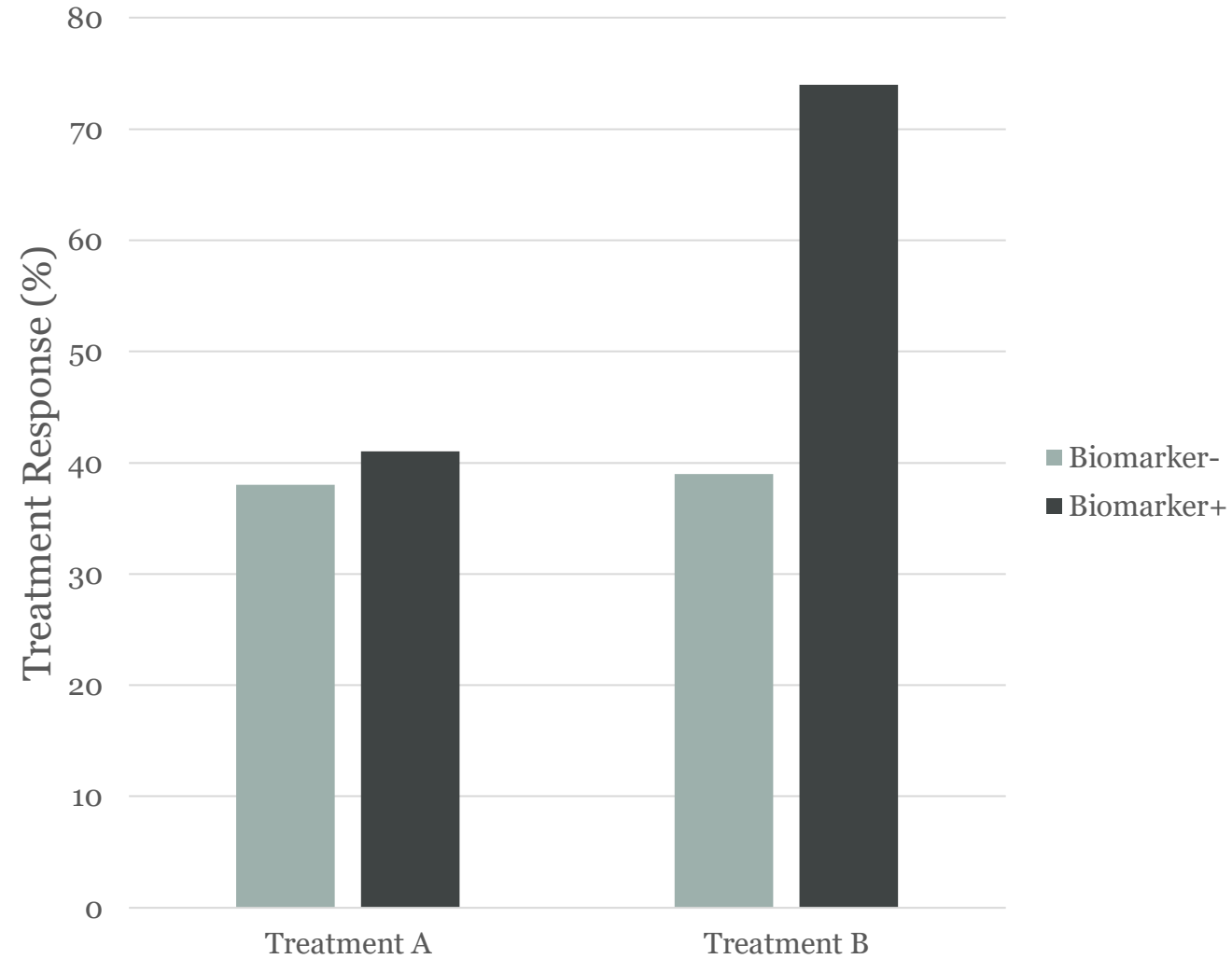
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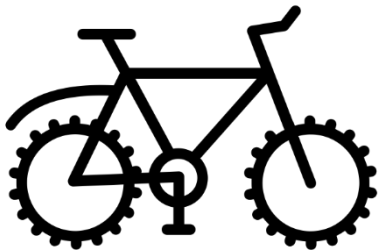
A biomarker can be predictive



The bike model?

A biomarker predictive of your treatment response!

Biomarker:
Bike model



Treatment:
Training

Do not train

Train 1 hour a month

Train 4 hours a day

Endpoint:
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Ventoux
under 1.5 hour



So, what is a biomarker already? 🤯

A biomarker can be many things and can play many roles.





Pool of patients that can be recruited in a trial? A very big pie!





When starting a trial, we never have access to that big pie. 🥹

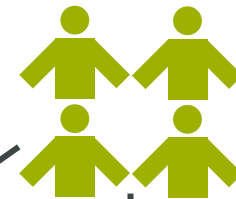
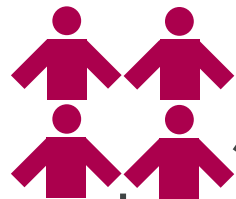


Once upon a time, a world with 2 randomized clinical trials,
in a specific indication...

STUDY A (Precision-Medicine)

STUDY B (All-Comer)

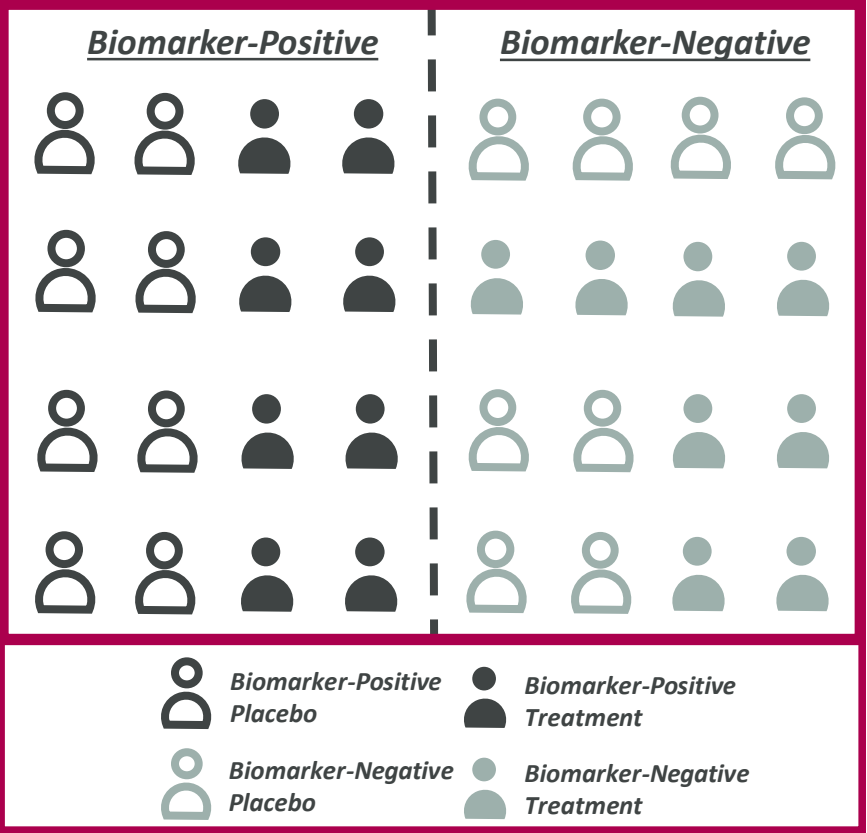
**STUDY A
PARTICIPANTS**



**STUDY B
PARTICIPANTS**



STUDY A (Precision-Medicine)

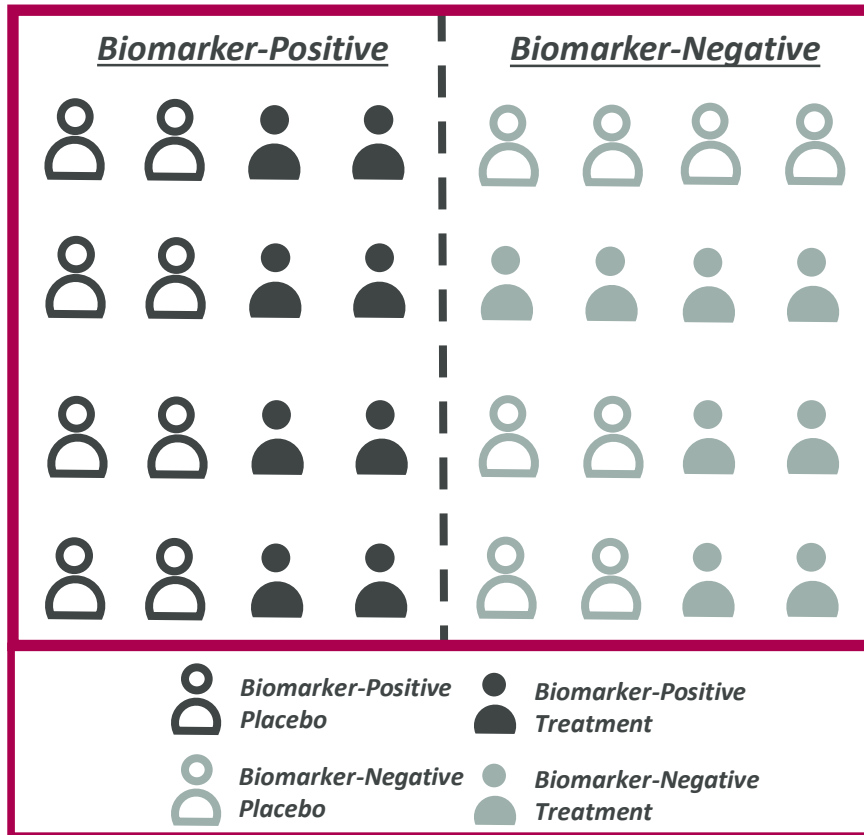


STUDY B (All-Comer)

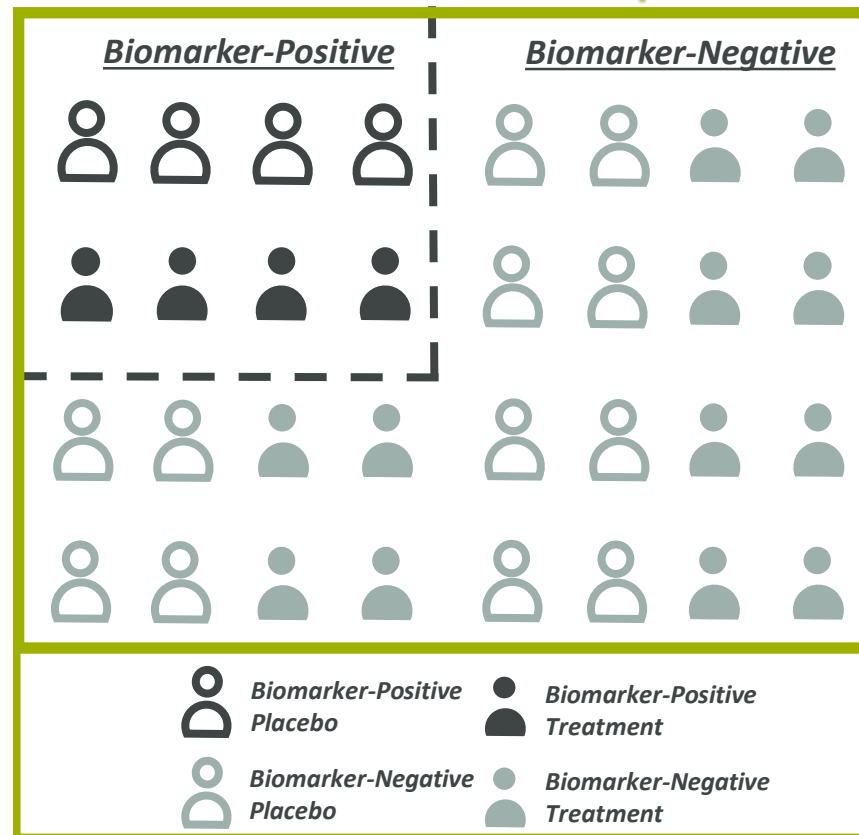


Even if not all studies are precision-medicine-based,
biomarkers are never far

STUDY A (Precision-Medicine)

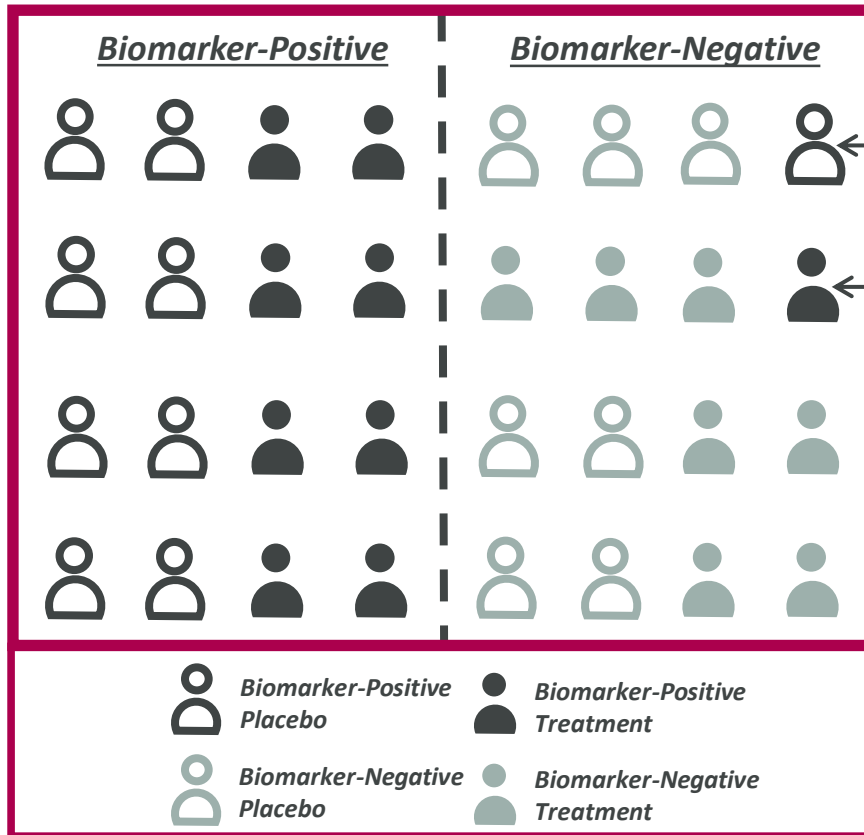


STUDY B (All-Comer)

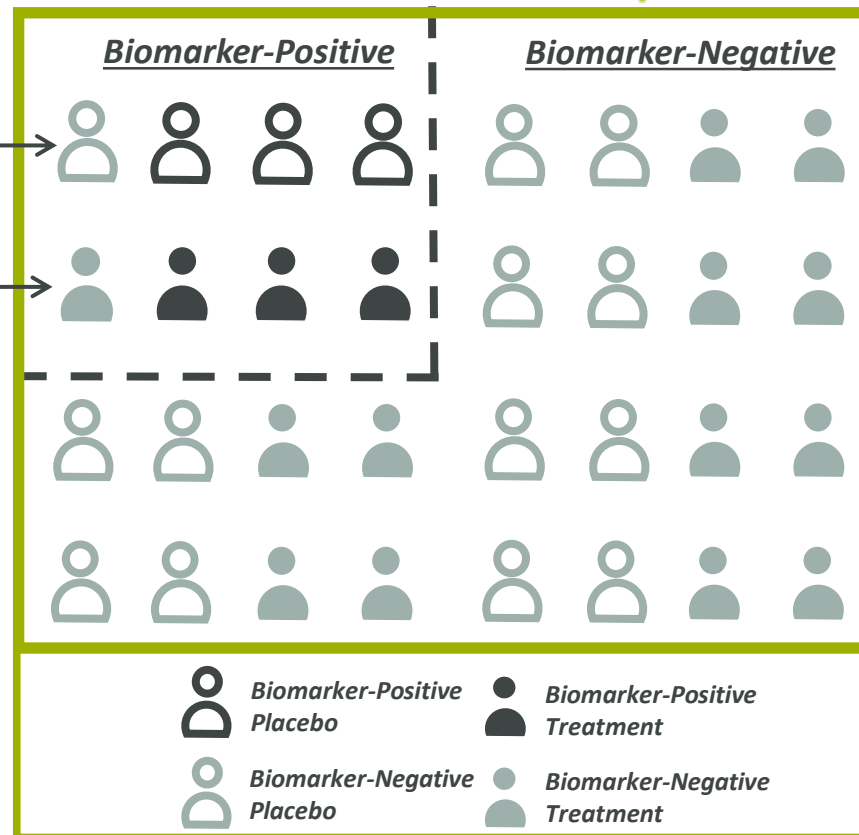


What if we were to reallocate some patients to the precision-medicine study?

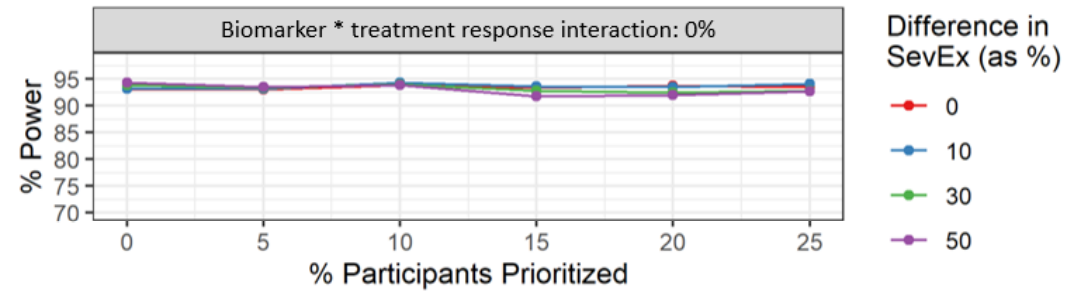
STUDY A (Precision-Medicine)



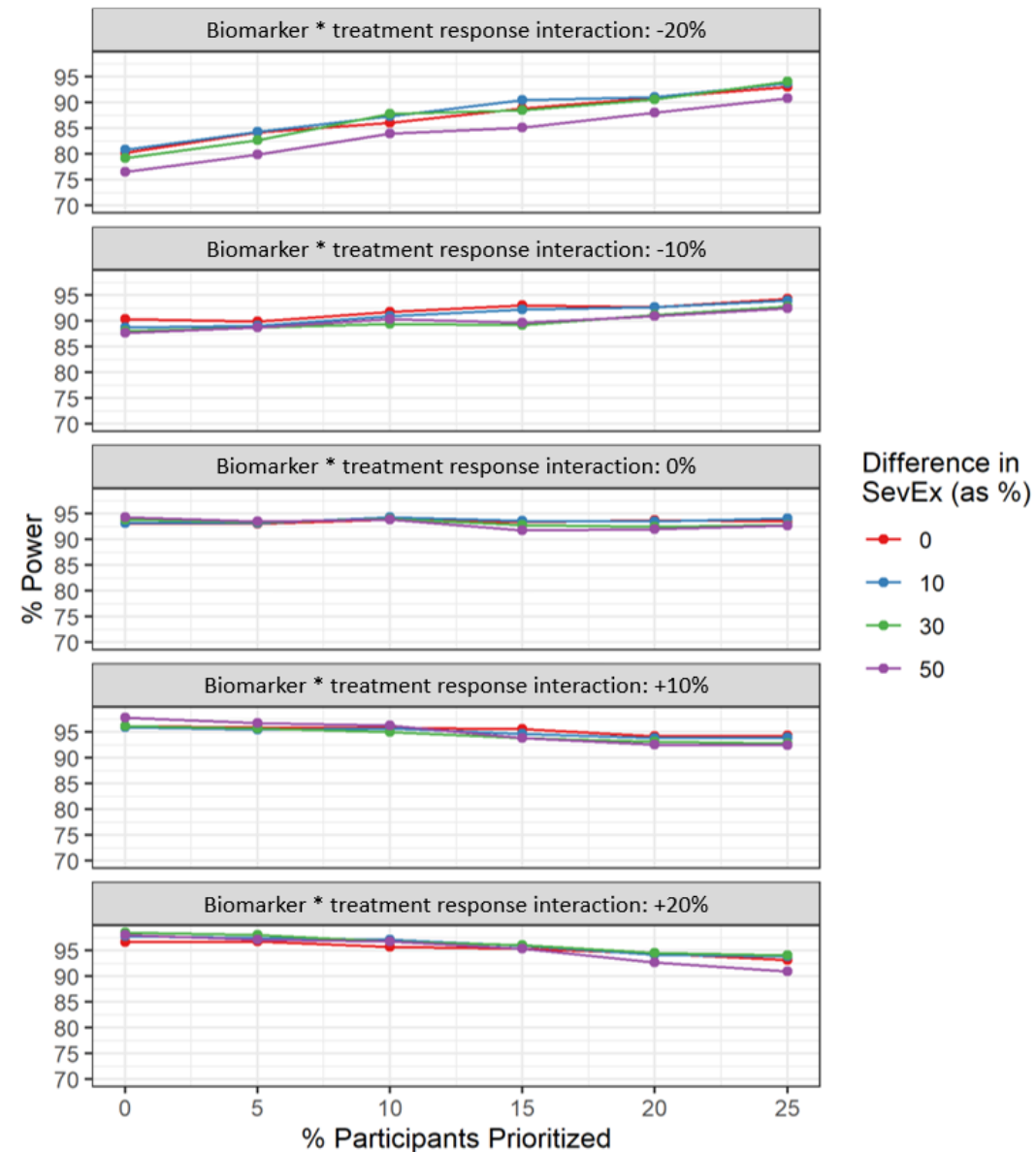
STUDY B (All-Comer)



Based on simulations, limited impact on the power of a Phase 3



Based on simulations, limited impact on the power of a Phase 3



It's time we stop fooling ourselves: there is one single pie.



What about an industry-wide consortium
to see a true implementation of precision medicine?



Let's develop medicines the way we develop bikes!



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