Use of predictive algorithms for the selection of patients in clinical trials: an enrichment strategies comparison

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Background

The majority of disease-modifying trials (DMT) for Alzheimer's disease (AD) drugs have failed since 2003 (Yiannopoulou KG et al., Biomedicines. 2019)

Suboptimal patient cohort selection is one of the main causes for high trial failure rates in AD

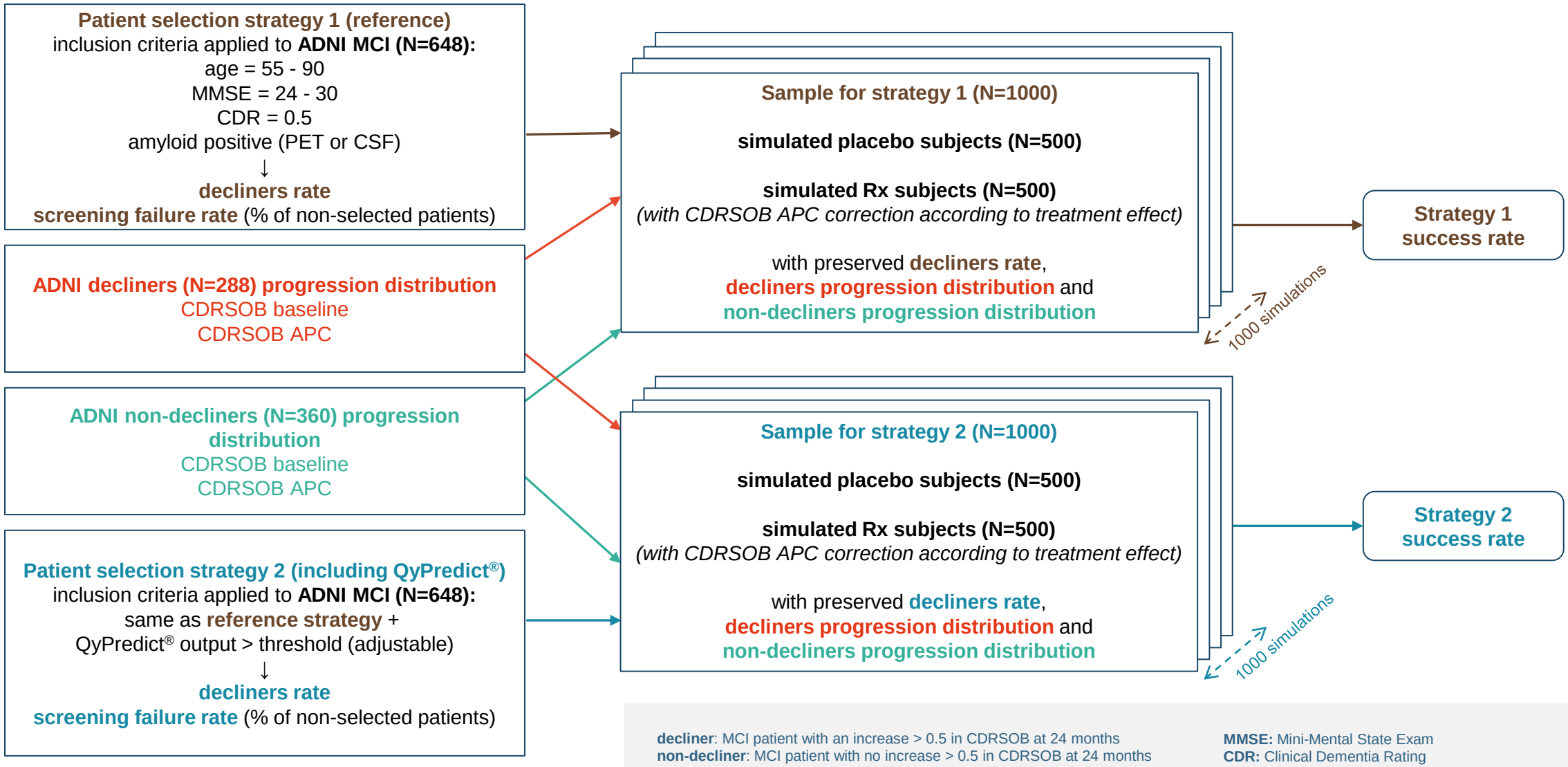
Recent advances in artificial intelligence (AI) could help select Mild Cognitive Impairment (MCI) patients who are more likely to decline cognitively

Objectives

To compare various recruitment strategies for patient enrichment in terms of trial success probability and screening failure rate

To evaluate the benefit of using a predictive tool such as QyPredict® to refine patient selection

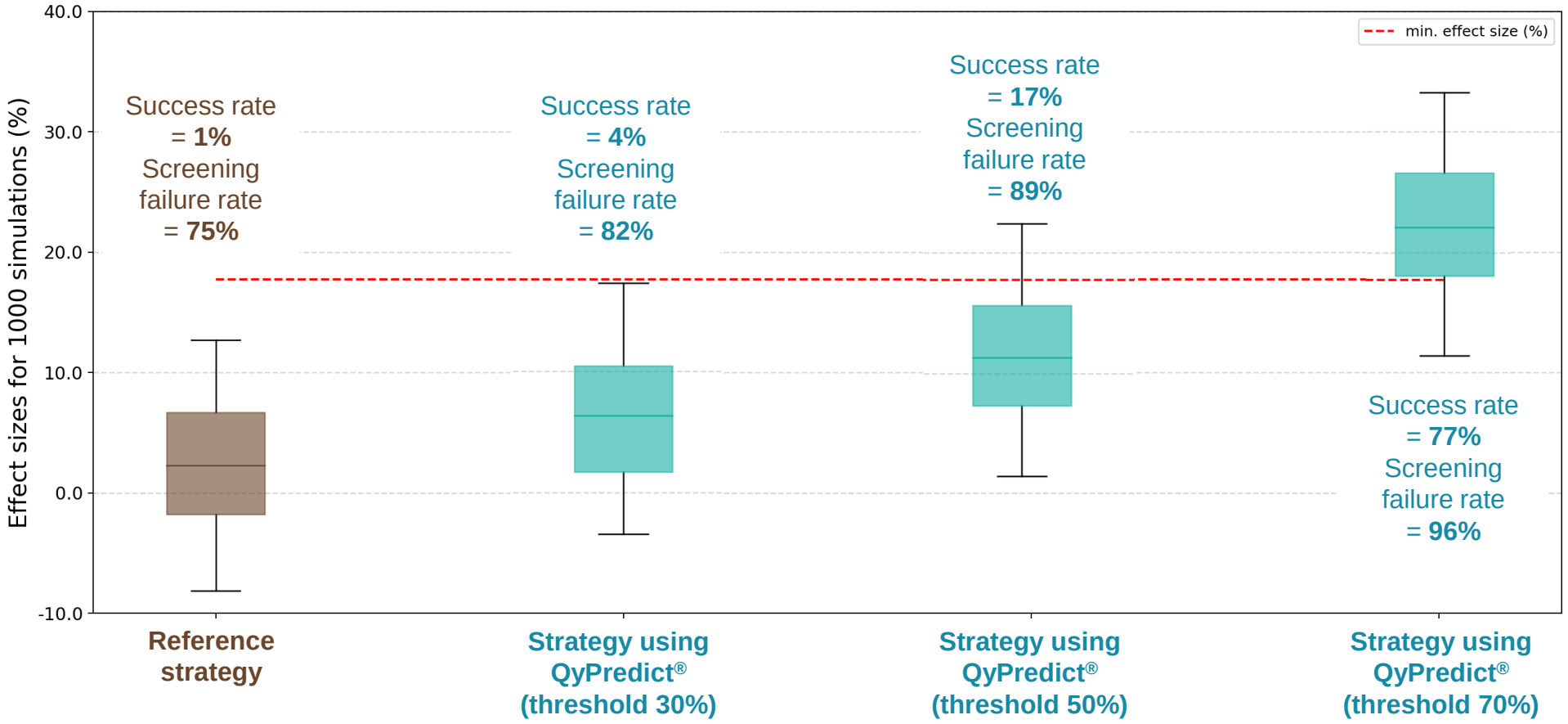
Methods



decliner: MCI patient with an increase > 0.5 in CDRSOB at 24 months
non-decliner: MCI patient with no increase > 0.5 in CDRSOB at 24 months
CDRSOB: Clinical Dementia Rating – Sum Of Boxes
CDRSOB APC: CDRSOB Annual Percent Change
MCI: Mild Cognitive Impairment

MMSE: Mini-Mental State Exam
CDR: Clinical Dementia Rating
QyPredict®: software that predicts whether an MCI subject is going to have a strictly positive increase in CDRSOB at 24 months

Results



Conclusion

We presented a framework to evaluate the success probability and screening failure rate of various patient selection strategies for a clinical trial.

Such a framework could also be used to derive the cost and the duration of a trial, depending on the patient selection strategy.

The use of a predictive solution such as QyPredict® to enrich the patient selection strategy increases the probability of success of the trial.

A trade-off is to be made, taking into account the trial's objectives in terms of success likelihood, cost and duration.