

# A New Composite Score: Optimizing Responsiveness to Disease Progression and Treatment Improvement in Early AD

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Many paths, *one priority*—to fight Alzheimer's disease.™

# Background

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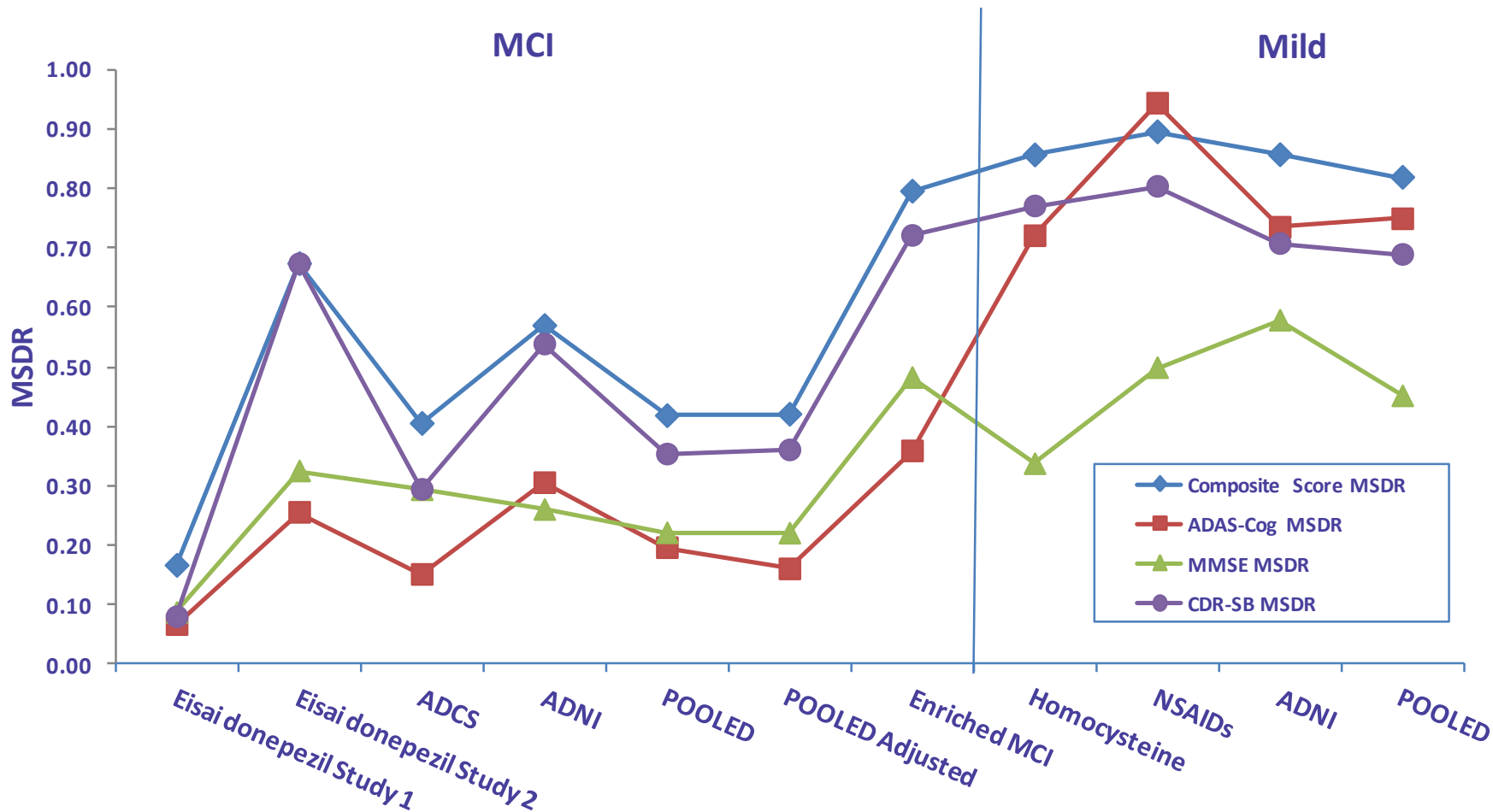
- No well established and sensitive endpoint exists for MCI
- ADAS-Cog, CDR-SB and other standard scales not sensitive for disease progression in MCI population
- MCI populations are highly heterogeneous
- Certain items in existing clinical scales are more relevant to an MCI population
- Possible to use existing clinical data to create a new clinical assessment
- Important to identify these items and to find the right combination that shows sensitivity to progression *and* treatment effect

# Composite Score: Selected Items

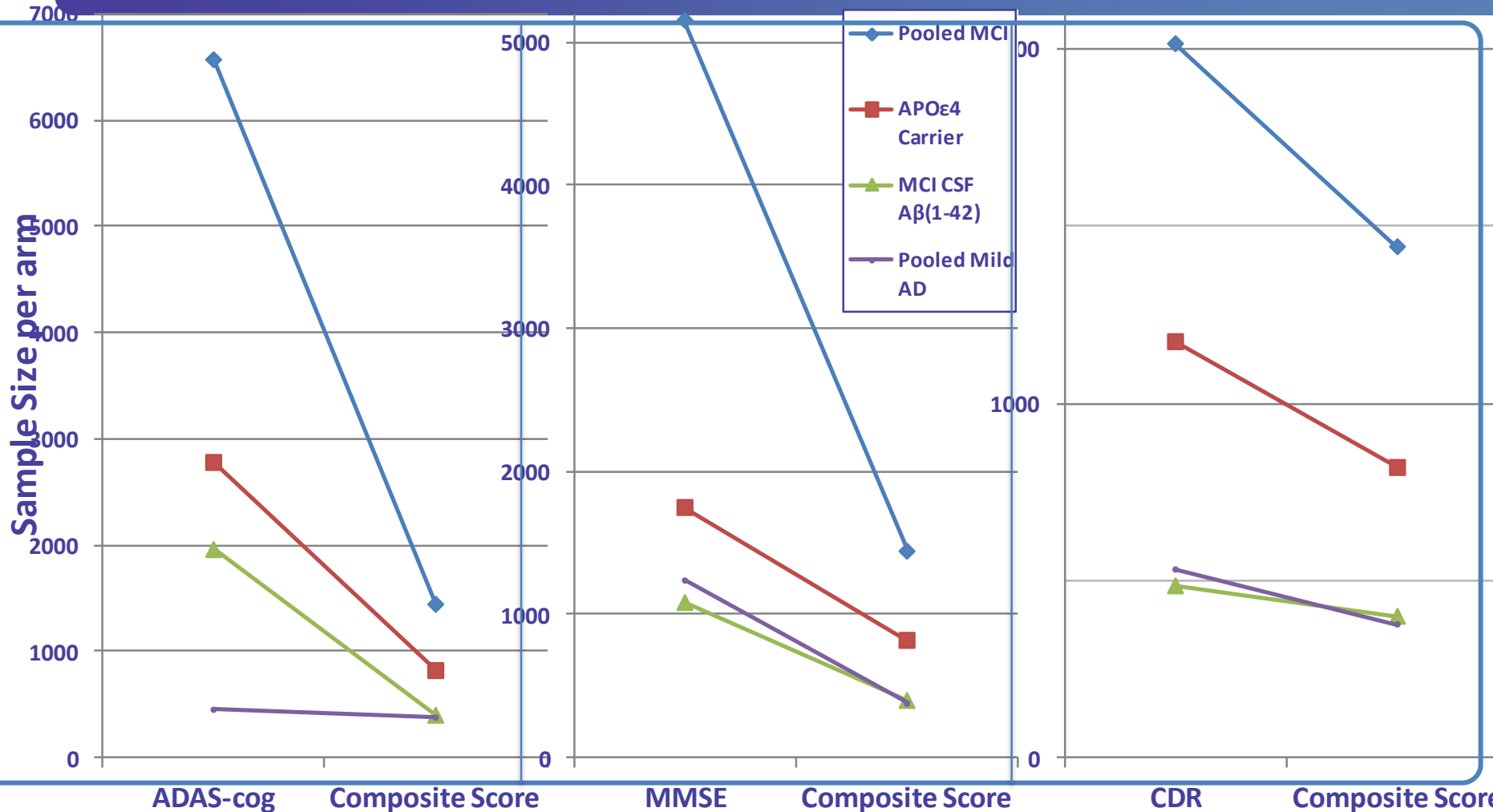
	Item
<b>ADAS</b>	<b>Delayed Word Recall</b>
	<b>Orientation</b>
	<b>Word Recognition</b>
	<b>Word Finding Difficulty</b>
<b>MMSE</b>	<b>Orientation Time</b>
	<b>Constructional Praxis</b>
<b>CDR</b>	<b>Personal Care</b>
	<b>Community Affairs</b>
	<b>Home and Hobbies</b>
	<b>Judgment and Problem Solving</b>
	<b>Memory</b>
	<b>Orientation</b>

**Composite score is a weighted sum of selected items**

# Composite Score Shows Higher Sensitivity in MCI



# Composite Score Decreases Sample Sizes



Further improvement possible for MCI using enriched populations, such as ApoE ε4 carriers and CSF Aβ levels (reduced heterogeneity and increased progression)

# Responsiveness to Treatment Effect: Difference of Donepezil Versus Placebo in Change from Baseline

Study	Population	Study duration	Treatment <sup>†</sup>	ADAS-Cog	CDR-SB	MMSE	Composite
Eisai donepezil Study 1	MCI	12 mo	10 mg	-	-	-	-
Eisai donepezil Study 3	Mild AD	6 mo	5 mg	+	-	+	+
			10 mg	+	-	-	+
ADCS	MCI	12 mo	10 mg	-	-	+	+
			2000 IU Vitamin E	-	-	-	-

+ indicates statistical significance at alpha=0.05; - indicated statistical significance was not reached

† Treatment was donepezil unless otherwise indicated

- Composite score captures treatment effects detected by established clinical tools
- Composite score can be used as a single outcome measure in MCI and mild AD

# Summary and Conclusions

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- The composite score is a novel tool (composite score), most suited to analyze clinical trial data (not a stand-alone battery)
- This tool could be proposed as a single clinical outcome in Early AD population
- The composite score is sensitive to disease progression and to treatment effects

# Thank you

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Q & A