

Domains Tested

TASK	COGNITIVE DOMAIN
Maze Learning Task	Executive Function/Spatial Problem Solving
Detection Task	Psychomotor Function/Speed of Processing
Identification Task	Visual Attention/Vigilance
One Card Learning Task	Visual Learning

12 minute Early Phase cognitive test battery



Scientific Literature

Fredrickson A, Snyder PJ, Cromer C, Thomas E, Lewis M, Maruff P. (in press) The use of effect sizes to characterise the nature of cognitive change in psychopharmacological studies: An example with scopolamine. Human Psychopharmacol.

Collie A, Darekar A, Weissgerber G, Toh MK, Snyder PJ, Maruff P, Huggins JP. (2006) Cognitive testing in early-phase clinical trials: Development of a rapid computerized test battery and application in a simulated Phase I study. Contemp Clin Trials [Epub ahead of print].

Falletti MG, Maruff P, Collie A, Darby DG. (2006). Practice effects associated with the repeated assessment of cognitive function using the CogState battery at 10-minute, one week and one month test-retest intervals. J Clin Exp Neuropsychol., 28, 1095-1112.

Collie A, Maruff P, Snyder PJ, Darekar MA, Huggins JP. (2006). Cognitive testing in early phase clinical trials: outcome according to adverse event profile in a Phase I study. Hum Psychopharmacol., 21, 481-488.

About CogState

CogState is a provider of cognitive testing products and services that predominantly caters to the global pharmaceutical industry. CogState tests use simple but effective technology to detect cognitive change in subjects. Widely acknowledged as being the fastest tests in the world with outstanding levels of sensitivity, their validity has been confirmed in over 100 peer-reviewed publications. CogState tests have been used in over 60 clinical trials ranging from Phase I to Phase IV, with both healthy volunteers and patient groups.

CogState is a publicly listed company, trading on the Australian Stock Exchange (ASX:CGS), with offices in Melbourne, Australia, New Haven, CT, USA and the UK. CogState ClinicalTrials is used extensively by leading FDA-regulated pharmaceutical companies throughout the world to assess the effect of their drugs on human cognition. Our customers include 5 of the leading top 10 pharmaceutical companies, over 25 leading universities worldwide and numerous smaller pharmaceutical and biotech companies. FDA 21 CFR Part 11 compliant, the company's quality and data systems have been audited successfully by independent consultants and multinational pharmaceutical companies.

Now you can assess cognition in 12 minutes - your phase I protocol does not have to be designed around cognitive testing



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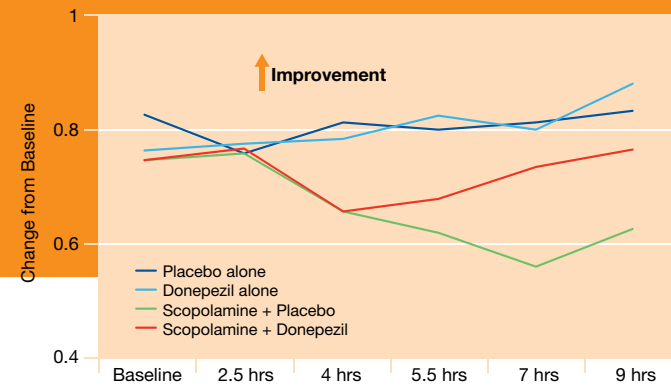
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THE MAZE LEARNING TESTS DESCRIBED HERE WERE DEVELOPED BY PFIZER AND ARE SOLD UNDER EXCLUSIVE LICENCE FROM PFIZER



Screenshot of Maze Learning Task

CogState testing shows stable performance on the maze learning task for subjects given placebo alone, but decline for subjects given 0.3 mg s/c scopolamine 3 hours after baseline testing. This can be partially reversed by donepezil. However donepezil alone has no significant effect.

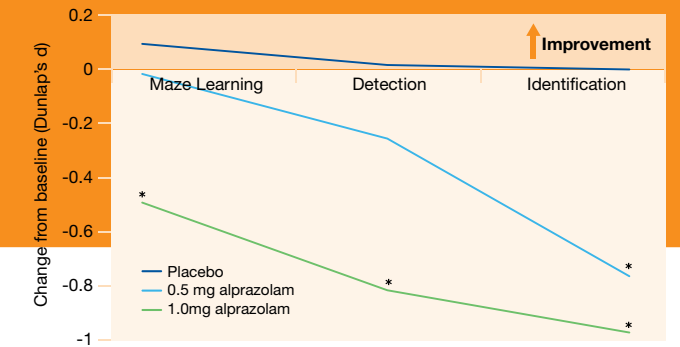


A scopolamine challenge



Screenshot of Detection Task

Graph shows change in performance on three tasks after alprazolam or placebo administration. A low dose (0.5 mg) of alprazolam causes a significant reduction in performance in the identification task, but no significant change in detection or maze learning. A higher dose (1.0 mg) causes a significant decline in all three of these tasks.



Dose-dependent effects

The CogState 12-minute test battery

The CogState 12-minute test battery is a rapid & accurate computerized test of cognitive function. Using playing cards and a hidden maze task as stimuli, the CogState 12-minute test battery measures the following cognitive domains: executive function, psychomotor function, visual attention and visual learning. The use of non-verbal playing cards and a maze game framework allows use in multilingual/multicultural settings. Completing the battery typically takes 10 minutes, and is limited to 12 minutes.

Because there are minimal practice effects, the CogState battery can be used across administrations to evaluate cognitive change over time. A single easy-to-understand composite score (derived from the scores on each of the tasks) is recommended as the endpoint for assessing cognitive change in trial subjects.

1 Maze Learning Task

This test was developed by Pfizer and is sold under exclusive license from Pfizer.

The subject is shown a 10 x 10 grid of tiles on a computer touch screen. A 28-step pathway is hidden among these 100 possible locations. The start is indicated by the blue tile at the top left and the finish location is the tile with the red circles at the bottom right of the grid. The subject is instructed to move one step from the start location and then to continue, one tile at a time, toward the end (bottom right).

The subject moves by touching a tile next to their current location with the stylus. After each move is made, the computer indicates whether this is correct by revealing a green checkmark (i.e. this is the next step in the pathway), or incorrect by revealing a red cross (i.e. this is not the next step in the pathway, or the subject has broken a rule, see below). If a choice is incorrect (i.e. a red cross is revealed), the subject must touch the last correct location (i.e. the last green checkmark revealed) and then make a different tile choice to advance toward the end.

The subject is required to adhere to two rules. Firstly, the subject cannot move diagonally or touch the same tile twice in succession. Secondly, the subject cannot move backwards along the pathway (e.g. move back to a location that displayed a green tick, but from which they have since moved on from).

The subject learns the 28-step pathway through the maze on the basis of this trial and error feedback. Once completed, they are returned to the start location and repeat the task, usually 5 times, trying to remember the pathway they have just completed.

There are 20 well-matched alternate forms for this task, and these are selected in pseudo-random in order to ensure that no subject will complete the same hidden path on any two different testing sessions throughout a study.

Cognitive Domain Tested:
Executive function/Spatial Problem Solving

Primary Outcome Measure:
Accuracy of performance (total errors across all 5 learning trials)

2 Detection Task

The pre-task on-screen instructions ask: "Has the card turned?"

A playing card is presented in the center of the screen. The card will flip over so it is face up. As soon as it does, the subject must press the "Yes" key. The card will go to the back of the pack and the subject must press the "Yes" key as soon as the next card flips over and so on.

Cognitive Domain Tested:
Psychomotor Function/Speed of Processing

Primary Outcome Measure:
Speed of performance

3 Identification Task

The pre-task on-screen instructions ask: "Is the card red?"

A playing card is presented in the center of the screen. The card will flip over so it is face up. As soon as it does this the subject must decide whether the card is red or not. If it is red they should press "Yes", if it is not red they should press "No".

Cognitive Domain Tested:
Visual Attention/Vigilance

Primary Outcome Measure:
Speed of performance

4 One Card Learning Task

The pre-task on-screen instructions ask: "Have you seen this card before in this task?"

A playing card is presented in the center of the screen. As soon as it flips over, the subject must decide whether or not the same card has been seen before in this task.

Subjects must try to remember all the cards that have been shown previously in order to decide whether or not they have seen each card before.

Cognitive Domain Tested:
Visual Learning

Primary Outcome Measure:
Accuracy of performance