

Cognitive safety and tolerability trials

Accurately assess the cognitive safety and tolerability of compounds throughout clinical development



Cognitive safety and tolerability

Optimize your clinical trials for better, more efficient outcomes with the Clinical Trial Information Systems (CTIS) on Cantab Connect.

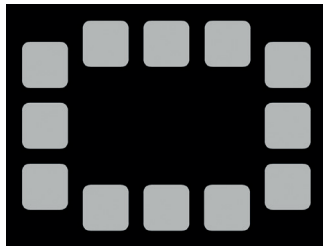
Cantab Connect products combine leading cognitive neuroscience with innovative cloud technology for more reliable and sensitive cognitive testing.

CTIS-Profile

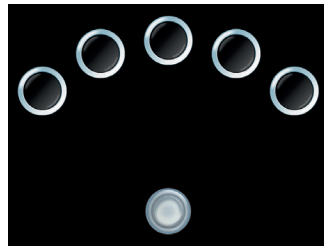
Assess cognitive safety in Phase I

Measures: <ul style="list-style-type: none"> • Visual episodic memory • Psychomotor speed • Processing speed • Executive function 	Application: Phase II-IV Clinical Trials CNS and non-CNS Healthy volunteer testing	Age range: 18 - 50 Length: < 15 minutes Administration: Standardized Scoring: Automatic Testing device: iPad Air
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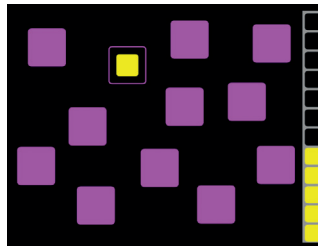
CTIS-Profile Test panel



Visual episodic memory task
 Sensitive to hippocampal and temporal-frontal functioning. Designed for healthy subjects, reducing ceiling effects.



Psychomotor and processing speed task Measured using a reaction time test, which is an assay for mental and movement reaction times.



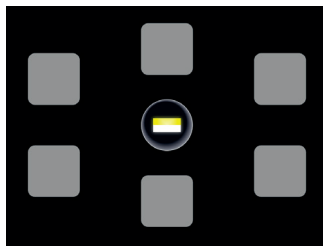
Working memory and executive function task Measures retention and manipulation of visuospatial information. Task difficulty is adapted for healthy subjects.

CTIS-Profile 2+

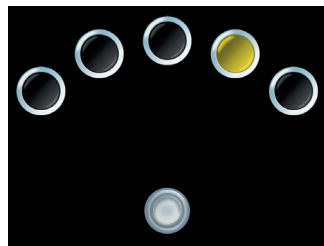
Evaluate and track cognitive safety in Phase II, III and IV

Measures: <ul style="list-style-type: none"> • Visual episodic memory • Processing speed • Psychomotor speed • Working memory • Executive function • Sustained attention 	Application: Phase II Phase III Phase IV CNS and non-CNS Patient testing Testing healthy volunteers over 40	Age range: All ages of patients 40+ healthy volunteers Length: 20 minutes Administration: Standardized Scoring: Automatic Testing device: iPad Air
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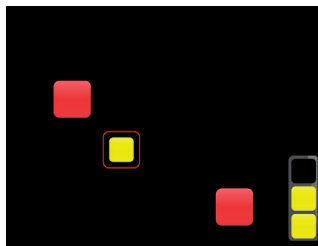
CTIS-Profile 2+ test panel



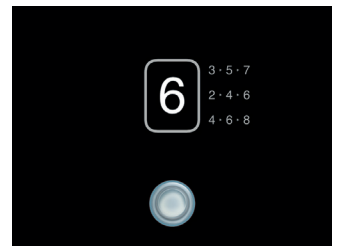
Visual episodic memory task
 Sensitive to hippocampal and temporal-frontal functioning. Suitable for testing impaired patients and older adults.



Psychomotor and processing speed task Measured using a reaction time test, which is an assay for mental and movement reaction times.



Working memory and executive function task Measures retention of visuospatial information and use of strategy.



Sustained attention task Provides measures of response bias, target sensitivity and reaction time.

CTIS-Abuse Liability

Measure the potential for human abuse liability in clinical studies

Measures: <ul style="list-style-type: none"> • Drug effects • Overall drug liking • Drug similarity • Subjective drug value • Potential for abuse 	Application: Phase I Phase II Phase III Phase IV CNS and non-CNS	Age range: 18 - 90 Length: 5 minutes Administration: Standardized Scoring: Automatic Testing device: iPad Air
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Evaluating cognitive safety

All drugs that cross the blood-brain barrier, and many which indirectly affect brain function, can cause cognitive impairment, such as memory loss, attention deficit and slowing of reaction time.

Determining the cognitive properties of compounds reduces patient and commercial risk, and complies with regulatory guidance.

Risk reduction – Detect and monitor cognitive signals in drug development.

Confidence in compounds – Clearer understanding enhances the ability to make informed decisions.

Drug differentiation – Identify a favourable cognitive safety profile to boost marketing claims.

Complete compliance – Fulfil regulatory requirements with data submissions that include cognitive safety in order to ensure your submissions are viewed more positively by regulators¹.

Efficient drug development on the cloud

Running on Cantab Connect, CTIS products deliver all the benefits of cloud technology, ensuring the best value, performance and speed in clinical trials.

Flexible – Easy to use, portable and accessible on multiple devices with tasks suitable for healthy participants and patients of different ages and levels of impairment.

Efficient – Workloads are reduced and productivity increased with minimal training requirements, automated test delivery, electronic data capture and instant scoring.

Fast – Rapid study initiation, instant data capture and scoring, and real-time access to connected data from anywhere in the world accelerate trials.

Secure – The continuity of studies is never in doubt with cloud-hosted data encryption and secure backups accessible from any device worldwide.

Quality – Clean and reliable data is guaranteed with CANTAB™ science and data management built into every product.



Optimized clinical trials

Simple, scalable touchscreen testing – Cantab Connect makes cognitive assessment easy. The intuitive control center and touchscreen tests enable the management of participants, data and trials in a simple to use application.

Better data, greater value – CTIS products guarantee better data, faster, and so optimize time and cost.

Fully supported – Customers are supported by expert neuropsychologists, project managers and data analysts, ensuring studies are run to the highest standards.

Expert neuroscience as standard – You benefit from the robust CANTAB™ scientific heritage, which is extensively validated with over 25 years of cognitive research.

Regulatory-approved product to support label claims – CTIS products are designed for GCP-compliant studies, compliant with the European Clinical Trials Directive 2001/20/EC and meet FDA regulations for computerized systems used in clinical trials and 21 CFR Part 11.



Contact us

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Cambridge Cognition is the leading global provider of computerized cognitive assessments – combining science, service and technology to optimize mental health through life.

Sensitively measure the safety profile of your compound

The CTIS Safety and Tolerability product test panels are sensitive to acute pharmacologically induced cognitive impairment in healthy subjects, as shown in Figure 1.

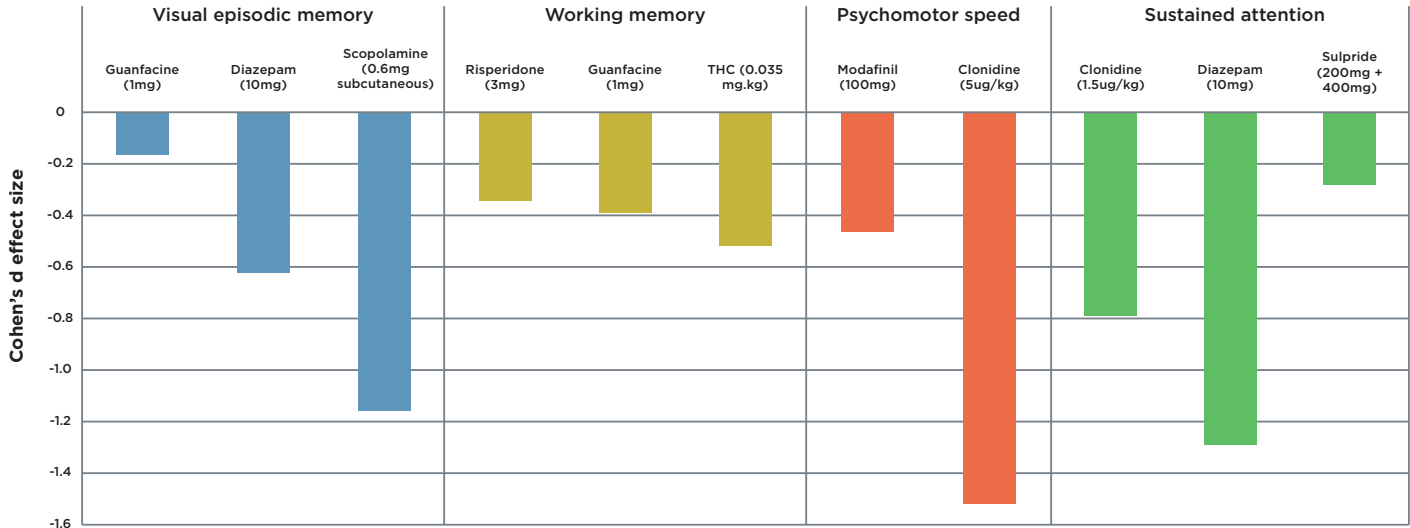


Figure 1.

Figure 1. Cohen's d effect size of cognitive impairment following acute administration of Guanfacine², Diazepam³, Scopolamine⁴, Risperidone⁵, THC⁶, Modafinil⁷, Clonidine⁸, Clonidine⁹, Diazepam¹⁰, Sulpride¹¹ in healthy volunteers, in four of the cognitive domains assessed in the CTIS Safety and Tolerability products: visual memory, working memory (a form of executive function), processing speed, and sustained attention.

Key references

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