

6 June 2024

BlinkLab starts a clinical study with Bates College in the US to validate the smartphone-based platform for the assessment of Functional Neurological Disorder

Highlights

- **BlinkLab to participate in clinical study with Bates College, Maine, to assess the performance of the BlinkLab smartphone test as an aid in the diagnosis of functional neurological disorder (FND).**
- **The tests will be used for remote testing of FND patient populations in Maine, New York, New Jersey, and other locations.**
- **This study will be led by Dr. Olivia Kim and will continue for up to three years and will recruit up to 500 patients.**
- **Collaboration agreement ensures that BlinkLab will have an option to acquire any intellectual property developed as a direct result of the partnership.**

BlinkLab Limited (ASX:BB1) (“BlinkLab”, “the Company”), an innovative digital healthcare company developing smartphone-based AI powered diagnostic tests for neurological disorders, advises it will be participating in a clinical study in Functional Neurological Disorder (FND) patients conducted by Bates College initially in the state of Maine in US. The purpose of the study will be validation of the BlinkLab Platform for the assessment of FND.

FND is commonly a misdiagnosed condition, characterised by loss of voluntary control over the movement of a body part. However, because FND symptoms are often taken as evidence for Factitious Disorder¹ and people with FND often exhibit other psychiatric and neurological comorbidities, including autism, ADHD, fibromyalgia, depression, and anxiety, patients must often visit multiple doctors and contend with multiple misdiagnoses before obtaining an FND diagnosis². Accordingly, there is a need to develop informative diagnostic screening tools and protocols that reduce the burden of and the time to reach an appropriate FND diagnosis.

¹ Edwards et al., Why functional neurological disorder is not feigning or malingering. J.Nat Rev Neurol. 2023 Apr;19(4):246-256.

² Ducroizet et al., Functional neurological disorder: Clinical manifestations and comorbidities; an online survey. Clin Neurosci. 2023 Apr;110:116-125.



The current study run by Dr Olivia Kim will aim to characterise the behavioural time course of Pavlovian eyeblink conditioning and acoustic startle habituation to validate the BlinkLab smartphone test for use as a remote neurobehavioral testing and diagnostic tool in FND. More specifically, these experiments will characterise the time course of different forms of associative learning and the degree of sensorimotor gating on blinking movements and other components of facial startle responses, with a focus on assessing whether these behavioural features differ between participants with FND, age and comorbidity-matched controls, and participants without neurological or psychiatric diseases. As FND is characterised by effects of attention, the study will also test whether patient performance varies as a function of their engagement with distractor stimuli.

The current study will help better understand the processes specifically disrupted by FND, which will allow the Company to isolate clinically useful information for remote assessment of this condition, through the BlinkLab smart-phone test.

Study design and experimental setup

The study will recruit up to 500 adults between the ages of 18-85 years old, including patients with a diagnosis of FND, as well as age- and comorbidity-matched controls.

The study will focus on equivalent, remote testing of patient populations recruited through networks in Maine, New York, New Jersey, and other locations accessed later. The BlinkLab test will also provide a direct means for disseminating any successful FND diagnostic tools to the medical community at large, increasing the potential impact of this study. The goal of the study will be to validate whether the BlinkLab smart-phone based test will be able to reduce the burden of testing on patients, expanding the clinical capacity to access a broad enough sample to draw reliable conclusions.

In initial experiments as part of this collaboration (those evaluating startle responses), participants will only engage with one or two sessions in the BlinkLab test, with sessions occurring at least five days apart. For other experiments involving the assessment of learning, participants will engage in three sessions per week for up to two weeks. The study will continue for up to three years.

About Bates College

Since 1855, Bates College has been well known for its studies in natural sciences, humanities, social sciences, and engineering. Bates College is often noted as one of the Little Ivies schools, along with other top universities in the US. Bates' Department of Neuroscience is well recognised for its research program that aims to identify and explore the neural and cognitive processes that give rise to this great diversity of human motor skill and experience with numerous publications in top tier journals. After obtaining a PhD at Baylor College of Medicine



and doing a postdoctoral fellowship at Princeton University, Dr Olivia Kim started her own research group at Bates College to study FND and related disorders.

Dr Olivia Kim, Assistant Professor at Bates College, commented:

“I am very excited to launch this study using the BlinkLab app. The app’s capacity to collect high-quality data in a location of the participants’ choosing will be key for reaching patients with Functional Neurological Disorder (FND). This will let us overcome logistical barriers that can make joining conventional, in-laboratory studies burdensome. Many people with FND are part of the workforce, and it is difficult to make time to travel to and participate in research. Thus, we will be able to work with a suitably large and representative sample of patients with FND and assess the extent to which our diagnostic approach can hold water. If we can add the BlinkLab app to physicians’ diagnostic toolboxes for FND, it could really accelerate patients’ paths to diagnosis and effective treatment. It is also always a pleasure working with Dr Boele and everyone else at BlinkLab, who are committed to conducting rigorous research and collecting high-quality, high-value data.”

Henk-Jan Boele, CEO of BlinkLab commented:

“It is a great pleasure to announce this collaboration with Dr Olivia Kim. Olivia and I share a longstanding passion for understanding the neural mechanisms underlying learning and memory formation. This collaboration will not only advance our understanding and diagnostic capabilities for Functional Neurological Disorder but will also enhance the overall performance of our platform for autism and/or ADHD. By testing patients with FND, we will even further refine our app and AI/ML models, improving their diagnostic accuracy for autism and ADHD. This exciting collaboration will boost the reliability and utility of our platform in clinical settings, benefiting a broad spectrum of patients.”

Brian Leedman, Chairman of BlinkLab commented:

“I am very pleased that BlinkLab has once again partnered with such a prestigious university to demonstrate how the BlinkLab smartphone-based platform can be used to diagnose neurological conditions beyond autism and ADHD.”

Terms of the Collaboration Agreement (“Agreement”)

- *Responsibilities:* BlinkLab will provide access to its technology, data and shall facilitate the use of its platform during the term of the Agreement.
- *Financial arrangements:* None at the date of signing (to be determined via mutual agreement in the future and in a separate agreement).
- *Intellectual property (“IP”):* BlinkLab will have an option for an exclusive licence to acquire any intellectual property developed as a direct result of the partnership.
- *Term:* Three years, unless terminated earlier in accordance with the provisions of the Agreement.
- *Termination:* Either party may terminate the Agreement with 30 days written notice to the other party, should either fail to meet their obligations.
- *Confidentiality:* Standard confidentiality terms for an agreement of this nature included.



This announcement has been approved by the Board of Directors.

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About BlinkLab Limited

BlinkLab, a company founded by neuroscientists at Princeton University, over the past several years has fully developed a smartphone based diagnostic platform for autism, ADHD, schizophrenia, and other neuropsychiatric conditions. BlinkLab's most advanced product is an autism diagnostic test that leverages the power of smartphones, AI and machine learning to deliver screening tests specifically designed for children as young as 18 months old. This marks a significant advancement, considering traditional diagnoses typically occur around five years of age, often missing the crucial early window for effective intervention. BlinkLab is led by an experienced management team and directors with a proven track record in building companies and vast knowledge in digital healthcare, computer vision, AI and machine learning. Our Scientific Advisory Board consists of leading experts in the field of autism and brain development allowing us to bridge the most advanced technological innovations with groundbreaking scientific research.