

21 November 2024

BlinkLab to Participate in the Landmark Monash University Autism/ADHD MAGNET Project

Highlights

- **The MAGNET project is an ongoing large cohort study aiming to enrol 1,000 families with children diagnosed with only autism, only ADHD, or with both autism and ADHD.**
- **MAGNET is utilising a novel family-based trial design where the parents, affected child and siblings (either affected or unaffected) are all enrolled in the same study.**
- **The aim of the study is to identify novel data-driven autism and ADHD subtypes using deep phenotyping data, including the BlinkLab Dx 1 biomarkers, that may outperform current categorical diagnoses with potential future implications for better and more personalised autism and ADHD diagnosis and treatment.**

BlinkLab Limited (ASX:BB1) (“BlinkLab”, “the Company”), an innovative digital healthcare company developing smartphone-based AI powered diagnostic tests for neurological conditions, is pleased to announce their participation in the landmark MAGNET (Monash Autism & ADHD Genetics and Neurodevelopment) study conducted by Monash University’s School of Psychological Sciences.

Link: <https://molecularautism.biomedcentral.com/articles/10.1186/s13229-021-00457-3>.

The project will help to unravel the complex symptoms of autism and Attention Deficit Hyperactivity Disorder (ADHD), and why they overlap in some children. The data generated by the study will address several limitations of categorical conceptualisations of these conditions. It is an important step towards a more dimensional understanding of their psychopathology, leading to better diagnostic models and more personalised support for children diagnosed with autism and/or ADHD. Using BlinkLab Dx 1, we aim to complete comprehensive deep sensory phenotyping of subjects with only autism, only ADHD, or with both autism and ADHD from the large MAGNET cohort.

Significance of the Study

Autism and ADHD are neurodevelopmental conditions affecting 1-4% and 5-7% of the population, respectively. Autism is characterised by deficits in social communication, restricted and repetitive patterns of behaviour and interests and altered sensory processing, whereas ADHD is defined by hyperactivity, impulsivity and inattention. In autism, 30-80% of cases exhibit ADHD symptomatology. In ADHD, 20-50% of cases exhibit autism symptoms.

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The introduction of the DSM-5 has allowed, for the first time, the concurrent diagnosis of autism and ADHD and the two conditions are now recognized to co-occur in up to 50% of cases. This co-occurrence can be associated with a more severe ADHD phenotype and higher treatment needs overall. DSM-5 is a comprehensive classification system published by the American Psychiatric Association (APA). It serves as the authoritative guide used by healthcare professionals to diagnose mental disorders.

Prepulse inhibition (PPI) is a key measure used in BlinkLab Dx 1 and is considered an effective proxy for sensorimotor gating - the brain's ability to filter out irrelevant information and prioritise what is relevant. Deficits in PPI have been observed in individuals with autism but not in those with ADHD, suggesting its potential as a tool to differentiate between these two conditions. Clinically, this distinction is crucial, as treatment, support, and care strategies differ significantly for individuals with only autism, only ADHD, or with both autism and ADHD. There is also little known about the extent to which any deficits in PPI extend to the undiagnosed family members of children with autism, ADHD, or with both autism and ADHD. The diagnostic process for these neurological conditions is time-consuming and expensive and they are both characterised by significant heterogeneity in presentation. Objective behavioural markers, like PPI, potentially will play an important role in the next generation of diagnostic pathways and personalised interventions.

Dr. Henk-Jan Boele, CEO BlinkLab, commented: *“Participation in the MAGNET study will enable BlinkLab to assess how its digital biomarkers, including the PPI measure, correlate with other validated behavioural, neurocognitive, neuroimaging and, potentially, genetic markers. Using these deep phenotyping and machine learning techniques, we expect to uncover novel, homogeneous data-driven clusters and subtypes of these diseases with significant future implications for better and more personalised autism and ADHD diagnosis and treatment.”*

Study Design

The MAGNET study will enrol approximately 1,000 families with children aged between 4 and 18 years of age. The study will incorporate the BlinkLab PPI measure to determine how prepulse inhibition measures vary within the different diagnostic categories (*i.e.* ADHD vs autism vs ADHD+autism). The results will show whether BlinkLab's Dx1 platform can distinguish between these groups. BlinkLab Dx 1 platform will be assessed alongside other validated questionnaires and biomarkers used in the MAGNET project. A unique feature of the study design is that tests will be carried out with the diagnosed child and their family members. The data from both parents (wherever possible) will determine the degree to which BlinkLab can detect performance variation within families, and thus can serve as a proxy for familial risk for these conditions.

“From the very foundation of our technology, the BlinkLab mission was always to disrupt the traditional methods of diagnosis and categorisation of psychiatric and neurodevelopmental conditions. Using more objective methods will lead to more personalised treatments and interventions. Participation in this landmark study with world-leading researchers and authorities in the field of autism and ADHD, is a testament to our mission and hard work by our team,” commented CEO of BlinkLab, Dr Henk-Jan Boele.

Lead researcher Professor Mark Bellgrove of Monash University's School of Psychological Sciences said that he is delighted to collaborate with BlinkLab on the MAGNET study. "BlinkLab's innovative digital technologies make it easy for the children and families enrolled in the study to provide critical data. This will hopefully lead to better outcomes for future families and children affected by these two complex and challenging conditions."

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.
- **Term:** 24 months from signature by the last party to sign (the 'Commencement Date'), 12th of November 2024.
- **Financial arrangements:** BlinkLab will pay (A\$389,398) in fees over the term with Monash providing in-kind contributions.
- **Intellectual Property:** Monash University grants BlinkLab an Option to acquire a Commercial Licence for the new technology developed as a result of the project.
 - As a condition of the grant of the Option, BlinkLab must pay all registration and maintenance costs, of any registrable developed IP. If at any time BlinkLab elects not to continue to pay the registration costs, then BlinkLab will immediately cease to have the right to exercise the Option.
 - BlinkLab may exercise the Option by providing Monash with written notice it wishes to exercise the Option.
 - If BlinkLab exercises the Option, BlinkLab and Monash will, in good faith and using best endeavours, negotiate the terms of a Commercial Licence. If BlinkLab and Monash are unable to agree on the terms of the Commercial Licence by the end of the negotiation period or any agreed extension of the negotiation period, then senior representatives from each Party will meet as soon as reasonably practicable for the purpose of determining whether the parties can resolve the Commercial Licence terms. If within 20 Business Days of submitting the matter to senior representatives the parties remain unable to agree the terms of the Commercial Licence, negotiations will immediately cease.
- **Termination:** Either party may terminate the Agreement with 20 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.

For further information please contact:

Henk-Jan Boele
Chief Executive Officer
henkjan@blinklab.org
M: +31 71 799 6194

Brian Leedman
Non-Executive Chairman
brian@blinklab.org
M +61 (0) 412 281 780



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.

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