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Large-Scale Study Validates and Enhances BlinkLab's Accuracy in Detecting Autism in Children

Highlights

- **Analysis of a study conducted in 441 children diagnosed for autism using current standard-of-care protocols showed that 'BlinkLab Dx 1' detected autism with an improved sensitivity of 91% and specificity of 85%.**

- **These results bolster confidence that BlinkLab Dx 1 will surpass the accuracy parameters required for regulatory approval in the upcoming FDA registration trial, scheduled to commence by the end of this calendar year.**

- **The study is an expansion of the prior study conducted by BlinkLab, in partnership with the Turning Pointe Autism Foundation in Illinois, Princeton University, and the National Center for the Disabled in Morocco. The study was undertaken using the latest version of our digital diagnostic platform, BlinkLab Dx 1, that includes a novel set of digital biomarkers and refined machine learning models.**

- **This new data highlights BlinkLab Dx 1 potential as a rapid accurate test in the growing autism diagnostics market which is expected to reach $5.4[1] billion by 2036. A recent industry report shows families face a three-year average wait for autism assessments and 21% of U.S. clinics are unable to accept new referrals due to high demand.**

BlinkLab Limited (ASX:BB1) (**"BlinkLab"** or the **"Company"**), an innovative digital healthcare company developing smartphone-based AI powered diagnostic tests for autism and other neurological conditions, is excited to announce results from the latest study in autism confirming high-accuracy in detecting autism in children ahead of upcoming FDA registrational study.

About the study

A multi-center, within-subject comparison study was conducted on 441 children aged 4 to 12 years, including 285 diagnosed with autism and 156 without. This sample size far exceeded the minimum required to power the study for statistical significance.

[1] Research nester report, Report ID 5382, 20 November 2023

The study was conducted in accordance with all relevant guidelines and regulations and received approval from the institutional review boards of Princeton University (#13943) and the Faculté de Médecine et de Pharmacie de Marrakech in Morocco (#23/2022).

All neurobehavioral tests were administered using the BlinkLab smartphone-based platform. Assessments included general measures of spontaneous and stimulus-evoked postural, head, facial and vocal responses, as well as specific neurometric tests like prepulse inhibition and startle habituation. Each child completed two 15-minute sessions while watching an engaging video content, with auditory stimuli delivered via headphones. During each session, computer vision algorithms tracked and recorded the position of the children's facial landmarks over time. Analysing spontaneous and stimulus-evoked responses along with prepulse inhibition and startle habituation performance, our machine learning algorithms achieved a sensitivity of 91% and specificity of 85%. This is a substantial improvement compared to the 85% and 84%, respectively, we reported in our previous study (ASX Announcement, 2 April 2024 – BlinkLab Prospectus 2024, page 47). The BlinkLab Dx 1 model also demonstrated robust and consistent performance across gender and age groups.

The results indicate that BlinkLab's smartphone-based testing effectively identifies sensory sensitivities in children with autism, highlighting the potential of non-invasive digital biomarkers as a diagnostic aid for autism. Additionally, they reflect the benefits of BlinkLab's institutional collaborations over the past year, which have contributed to the ongoing training and refinement of our diagnostic models.

Significance of the project

Deficits in sensory processing represent a core feature of autism, which is typically assessed through subjective observations such as questionnaires or parent-child interviews and are susceptible to geographic and socio-economic biases. An objective approach to quantify sensory sensitivity is now possible through digital neurometric evaluations. The clinical application of these sensory assessments has been confined largely to laboratory settings that use fixed equipment to provide a stable test environment making it impossible to use at scale for clinical diagnosis. This study demonstrates that fast, scientifically validated smartphone-based tests can be widely deployed in clinical settings remotely and at scale. Unlike current time-intensive and costly multidisciplinary assessments which rely on specialist expertise and are often difficult to access, BlinkLab Dx1 test offers a more efficient and accessible alternative. Current wait times for a formal autism diagnosis using standard-of-care methods often extend up to three years, with individual assessments taking as long as eight hours to complete. Studies show that these delays impose a significant economic and healthcare burden on affected families and communities.

Brian Leedman, Chairman BlinkLab, commented: "These results confirm the accuracy of our disruptive digital diagnostic test for autism and provide confidence in replicating these results in our forthcoming FDA registration study."

Henk-Jan Boele, CEO BlinkLab, commented: "The team has delivered exceptional work. Thanks to our great developers and data scientists, we've made significant advancements in the platform's overall sensitivity and specificity. This progress is due to improvements in our experimental protocols, the extraction of new biomarkers, and the integration of combined feature sets. Again, we are a step closer to our goal: FDA regulatory approval for BlinkLab Dx 1. If approved, our platform will assist clinicians by providing an objective diagnostic tool that uses accessible technology, fundamental neuroscience and AI. I also want to extend my gratitude to all the children and families who participated in this important study. Together with these families, clinicians and our data scientists, we have created a product unlike anything currently available to clinicians."

Dr. Bas Koekkoek, CSO BlinkLab, commented: "My team has further pushed the scientific and methodological boundaries of smartphone-based neurobehavioral evaluations. We have improved the experimental parameters, recognizing that even a difference of a few milliseconds can have a substantial impact in this type of testing. Additionally, we have introduced new biomarkers that, when combined with previously established ones, serve as strong predictors for autism."

Peer-reviewed publication and FDA regulatory study

The study data is being prepared for submission to a peer-reviewed scientific journal. With the completion of this study, BlinkLab is now gearing up to begin the regulatory study for FDA clearance to enable widespread clinical use. If approved, the platform will serve as a valuable aid in autism diagnostic evaluations, marking a significant milestone in BlinkLab's mission to use mobile technology to advance mental health care.

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 (0) 611 132 247

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.