

BlinkLab Surpasses Key Milestone in Pivotal U.S. Autism Diagnostic Trial

- **BlinkLab has now recruited 54 children, passing the halfway point of the initial 100-patient phase of the pivotal US autism diagnostic clinical trial.**
- **Faster-than-anticipated enrolment in the study highlights the scalability and convenience of AI-powered digital diagnostics.**
- **Additional research and clinical centers are now joining the second phase of the FDA 510(k) trial and are expected to be announced in the coming weeks and months.**
- **Final FDA 510(k) submission is expected in Q1 of CY2026.**

BlinkLab Limited (**ASX:BB1**) (“**BlinkLab**” or the “**Company**”), a leading Australian digital healthcare innovator, is pleased to announce that it has successfully recruited 54 of the expected 100 children that are required for the initial phase of its pivotal regulatory U.S. autism diagnostic trial.

Recruitment for the trial is ahead of schedule, highlighting the scalability and convenience of the Blinklab’s Dx 1 diagnostic platform and its ability to address key unmet needs for physicians and affected families. This swift pace of recruitment reaffirms the potential of Blinklab Dx 1 for its ability to streamline autism assessment in clinical and real-world settings.

PriMED Clinical Research LCC¹ and North Shore Pediatric Therapy² are two of the clinical sites announced that have been selected for the initial 100-patient phase of the study, with the first child tested on 12 March 2025³.

Completion Now Expected Early Q3 2025

With patient recruitment progressing faster than anticipated, BlinkLab is now expected to complete enrolment of participants and data analysis of the initial 100-participant study by early Q3 of 2025. Following this initial phase, the clinical trial will proceed to the main study, scheduled to enrol an additional 750 to 900 children.

¹ ASX Announcement (5 February 2025) – “*BlinkLab Initiates its First US-based Clinical Site for Autism Diagnostic Registrational Trial*”

² ASX Announcement (10 February 2025) – “*North Shore Pediatric Therapy in Chicago Joins BlinkLab’s US Registrational Study*”

³ ASX Announcement (12 March 2025) – “*BlinkLab Commences U.S. Autism Diagnostic Study with First Child Tested*”

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The prospective, multicenter, double-blinded, within-subject comparison FDA 510(k) study is intended to validate BlinkLab Dx 1 as a diagnostic aid aimed at supporting clinicians in identifying developmental disorders. This smartphone-based neurological assessment is designed to provide rapid, accessible, and accurate autism screening, helping healthcare providers to intervene earlier and more efficiently, therefore, achieving better patient outcomes through earlier intervention.

Dr. Henk-Jan Boele, Co-founder and CEO of BlinkLab, commented:

"We are thrilled with the rapid pace of recruitment for this pivotal registrational study. Yet again, it demonstrates the scalability and accessibility of digital diagnostic tools, and especially those that utilise common household technologies, such as the smartphones we use every day. Our technology is proving its ability to deliver fast, reliable assessments for conditions like autism, bringing us closer to enhancing the formal autism diagnosis process, as well as making it more accessible. With this momentum, we remain well on-track for study completion and our subsequent FDA 510(k) submission early next year."

Brian Leedman, Chairman of BlinkLab, commented:

"Clinical research – and especially studies that require the participation of children – often face challenges with recruitment, due to the understandably sensitive nature of the research itself, parental considerations, and paediatric healthcare as a whole. In their most significant form, such challenges can lead to cost blow-outs, limitations on the data, and even discontinuation of the study. This is why we are pleased to see that recruitment for our ongoing registrational study is progressing at a pace that has quickly exceeded our initial trial milestones. This accomplishment is a culmination of the talented researchers at BlinkLab and our collaboration partners at PRiMED and North Shore. The enthusiasm of participating families underscores the unmet medical need for early autism diagnosis and intervention."

This announcement has been approved by the Board of Directors.

This announcement is intended to lift the trading halt of the Company's securities.

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About BlinkLab Limited (ASX:BB1)

BlinkLab Limited, 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 neurodevelopmental conditions. Our 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 most advanced technological innovations with groundbreaking scientific research.



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