

## ASX Announcement

22 May 2025

# BlinkLab Engages First Clinical Site for Main Study Phase of FDA 510(k) Diagnostic Trial

### Highlights:

- **New Clinical Site:** BlinkLab has engaged The Southwest Autism Research & Resource Center (SARRC) as the first new clinical site for the main study phase of its pivotal FDA 510(k) diagnostic trial.
- **Main Study Phase:** Following the initial 100-participant pilot phase, this main phase will see an additional 750-900 participants undergo testing.
- **Initiation of Testing:** Site activation will be initiated in the coming weeks with the recruitment commencing after completion of the pilot phase.
- **FDA 510(k) Submission:** Final submission is expected in Q1 of CY2026 for the BlinkLab Dx 1 technology.

**BlinkLab Limited (ASX:BB1) (“BlinkLab”, or the “Company”)**, a leading digital healthcare company focused on AI-powered diagnostics, is pleased to announce that it has engaged **The Southwest Autism Research & Resource Center (SARRC)** as a new clinical site for the main study phase of BlinkLab Dx 1’s ongoing FDA 510(k) diagnostic trial.

SARRC has been selected as it is a nationally recognised leader in the autism space with nearly three decades of operation and a strong track record of clinical services, pioneering research, and providing inclusive community support. SARRC provides a robust platform for research and collaboration with its dedicated research facilities, multidisciplinary clinician teams, and community connections. This main phase of the registrational trial will see an additional 750 to 900 participants enrolled, now that the early 100-participant phase of the study is nearing completion.

### Dr Christopher J. Smith, Chief Science Officer at SARRC, commented:

*"At SARRC we are committed to improving early detection of autism and efficient access to diagnostic evaluations for all families. To that end, we support out-of-the-box thinking about the use of technology to help expedite and make objective results easily obtainable, so more children can get into treatment sooner."*



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**Commenting on the partnership with SARRC, Co-founder and CEO, Dr Henk-Jan Boele, stated:**

*"We are thrilled to collaborate with the SARRC—an esteemed institution in the US with extensive experience in conducting clinical trials and efficiently recruiting children at high volumes. We feel privileged to work alongside such a capable team! I'm pleased that my team made the strategic decision to implement a pilot phase ahead of the main study. This proactive step proved invaluable in optimizing recruitment workflows and refining standard operating procedures for clinicians, ultimately laying the groundwork for a more cost-effective and labor-efficient main study."*

**BlinkLab's Chairman, Mr Brian Leedman, also commented:**

*"Shortly we will commence data analysis on the first 100 patients in the initial pilot phase of this registrational study. The rate at which BlinkLab has reached this pivotal milestone has been quicker than anticipated, primarily due to a rapid rate of recruitment alongside a demonstrated enthusiasm from participating families."*

## About SARRC

The Southwest Autism Research & Resource Center (SARRC) is a non-profit organisation based in Phoenix, Arizona dedicated to advancing research into individuals living with autism, as well as providing ongoing support to them and their families. SARRC has a robust diagnostic services program. Their expertise in diagnostic assessments is recognized around the US, and because of their expertise, they pride themselves on an efficient and accurate diagnostic model that other sites have tried to emulate.

SARRC conducts cutting-edge research aimed at ways to improve outcomes for individuals living with autism and their families, as well as examining effective interventions and improvements to best practice in the neurodivergence space.

The center also offers services like diagnostic evaluations, early intervention strategies, hosting educational programs and providing resources, vocational training programs, and support programs for individuals living with autism across all stages of life.

## The BlinkLab Dx 1 FDA 510(k) Registrational Trial

BlinkLab's US-based FDA 510(k) registrational study is intended to support the regulatory clearance of its smartphone-based diagnostic tool for detecting autism, "BlinkLab Dx 1", primarily aimed at demonstrating its effectiveness and safety compared to existing diagnostic methods.

The registrational trial formally commenced with the activation of its first clinical site on 5 February 2025 and the first participant officially tested in March 2025.

## Study Methodology

The registrational trial for BlinkLab Dx 1 uses a double-blinded, within-subjects comparison study design.

During the test using the BlinkLab smartphone app, participants watch a series of child-friendly videos while the app presents visual and auditory stimuli. Throughout the session, BlinkLab's computer vision and machine learning technology monitors subtle behavioral responses—such as blinking, facial expressions, and head movements—to identify diagnostic biomarkers associated with autism.

## FDA Pre-Submission Phase

Prior to commencing recruitment of participants for the registrational trial, BlinkLab was required to engage with the US Food & Drug Administration (FDA) for Pre-Submission Meetings. BlinkLab received positive feedback and approvals for its intended diagnostic trial from the FDA.<sup>1</sup>

## Initial Pilot Phase

The initial pilot phase of the registrational trial has seen a small initial sample aim of 100 participants enrolling for testing. The focus of the initial pilot phase has been to familiarize researchers with procedures, train staff and refine recruitment strategies, and to pre-test trial methods, screenings, and other logistics.

The first US clinical site, PriMED Clinical Research in Ohio, was announced on 5 February 2025<sup>2</sup>, with the first child officially tested there in March 2025<sup>3</sup>. PriMED Clinical Research is a leading primary pediatric care provider to over 30,000 children in Southwest Ohio, and with a strong track record of conducting clinical study research.

The second US clinical site, North Shore Pediatric Therapy (NSPT) in Illinois, was announced on 10 February 2025<sup>4</sup>. NSPT is a leader in early autism intervention, and specializes in use of the ADOS-2 diagnostic tool, which is being used as a benchmark against BlinkLab Dx 1 in the registrational trial.

On 1 April 2025, BlinkLab surpassed the halfway-point of the initial phase of its registrational trial, announcing it had successfully recruited 54 participants<sup>5</sup>. To date BlinkLab has recruited 117 with the data analysis scheduled to start next month.

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<sup>1</sup> ASX Announcement (19 December 2024) – *“Positive Outcome from FDA Pre-Submission Meeting”*

<sup>2</sup> ASX Announcement (5 February 2025) – *“BlinkLab Initiates its First US-based Clinical Site for Autism Diagnostic Registrational Trial”*

<sup>3</sup> ASX Announcement (12 March 2025) – *“BlinkLab Commences US Autism Diagnostic Study with First Child Tested”*

<sup>4</sup> ASX Announcement (10 February 2025) – *“North Shore Pediatric Therapy in Chicago Joins BlinkLab’s US Registrational Study”*

<sup>5</sup> ASX Announcement (1 April 2025) – *“BlinkLab Surpasses Key Milestone in Pivotal US Autism Diagnostic Trial”*

## Main Study Phase

In the main phase of the study, remaining recruitment of participants will take place, up to the 1,000 children in total. Testing will take place at up to ten clinical research sites across the United States.

## Evaluation & Submission

Once all participants have been tested, and all components of the study design have been satisfied, testing will close and the final analyses of results will be conducted by the research team.

Finally, the formal FDA 510(k) submission will be made to the regulatory authorities for assessment.

## About BlinkLab Dx 1

BlinkLab Limited's initial diagnostic technology, BlinkLab Dx 1, is a diagnostic aid aimed at supporting clinicians in identifying autism. 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.

**This announcement has been approved by the Board of Directors.**

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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.