ASX Announcement

18 September 2025

BlinkLab Onboards 'The Vanderbilt Kennedy Center' as Seventh Clinical Site for FDA 510(k) Autism Trial

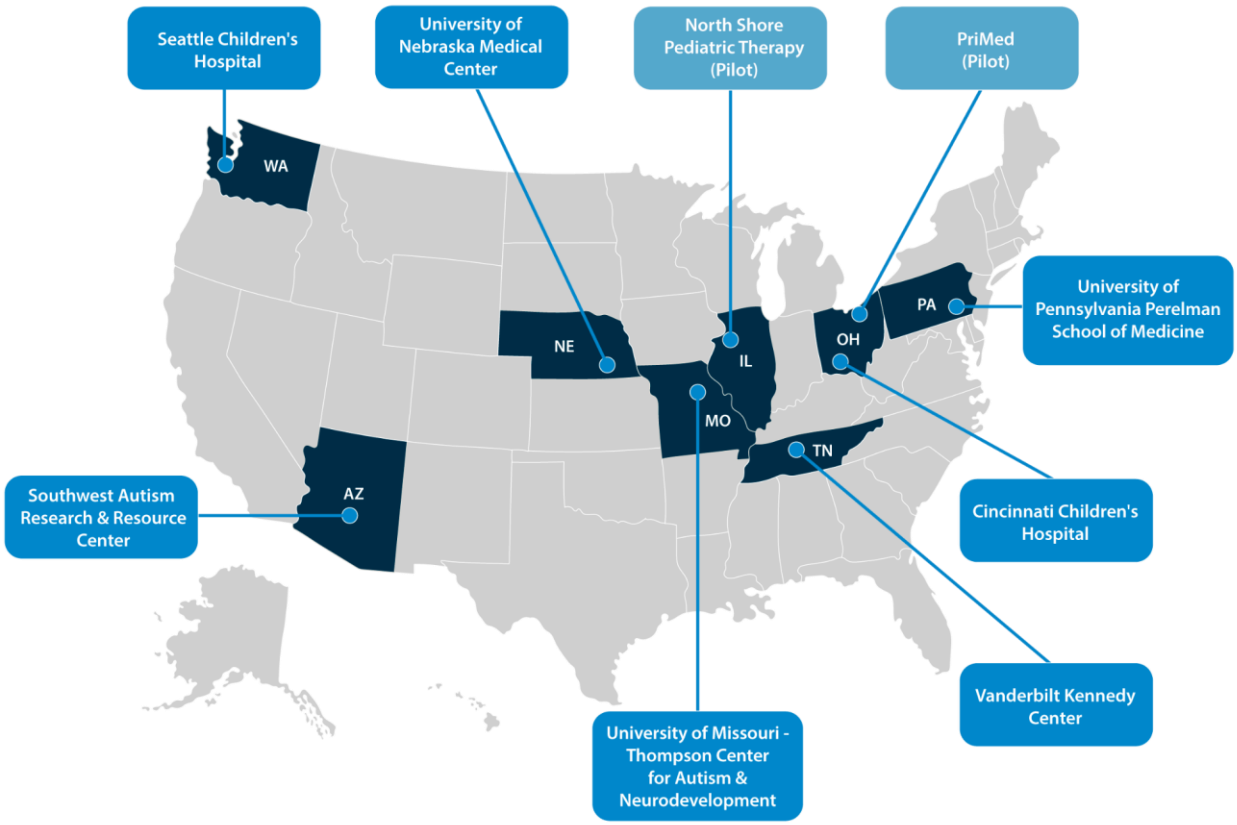
Multi-site study assists in fast-tracking testing and meeting FDA requirements for robust, valid, and generalisable data, reflecting the heterogeneity of autism.

Highlights:

- **New Clinical Site Engaged:** BlinkLab has partnered with The Vanderbilt Kennedy Center for the Main Study Phase of its FDA 510(k) Diagnostic Trial.
- **University Center of Excellence for Developmental Disabilities:** A leading research, training, and services provider in Nashville, Tennessee, with a research portfolio aimed at meaningful change for those with neurodevelopmental conditions.
- **Translational Research Expertise:** The Center emphasises the dissemination of new discoveries and evidence-based innovations leading to practical and meaningful change for its communities.
- **Main Study Phase:** The main phase of the FDA trial will proceed following the initial pilot phase, which is approaching completion.
- **FDA 510(k) Submission:** The FDA 510(k) trial for BlinkLab Dx 1 aimed at autism is expected to be completed Q2 of CY2026, with final submission to the FDA anticipated Q3 of CY2026.

BlinkLab Co-founder and CEO, Dr Henk-Jan Boele, stated: *"We are very pleased to welcome The Vanderbilt Kennedy Center as another Tier 1 partner in our FDA 510(k) trial. With seven onboarded sites up till now, we are moving at pace with onboarding clinical sites and finalising Clinical Trial Agreements (CTAs). At BlinkLab, we are encouraged by the high level of motivation from each center to begin enrolling participants. We maintain momentum as we will be transitioning soon from the pilot into the main FDA study phase. This keeps us firmly on schedule for our planned submission to the FDA in 2026."*

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 Vanderbilt Kennedy Center (VKC) in Nashville, Tennessee as the latest clinical research site for its ongoing FDA 510(k) diagnostic trial, assisting with the main study phase testing the BlinkLab Dx 1 technology for autism spectrum disorder (ASD).



Map showing the seven onboarded clinical sites participating in BlinkLab's pivotal FDA 510(k) trial across the United States, including both pilot and main study sites. North Shore (IL) and PriMed (OH) are part of the ongoing FDA pilot study.

About the FDA 510(k) Registrational Trial

BlinkLab is seeking FDA 510(k) clearance for its smartphone-based diagnostic tool, BlinkLab Dx 1. This registrational study aims to gain approval for the device, which is designed to assist in the detection of autism. The 510(k) study aims to prove the tool's safety and effectiveness against current diagnostic methods. BlinkLab is currently expanding clinical sites, prioritising quality and diverse participant recruitment. The double-blinded study involves participants watching child-friendly videos on the BlinkLab app, while its technology monitors subtle (often reflex-based) behaviors like blinking, facial expressions,

and head movements to identify autism biomarkers. BlinkLab Dx 1's results will be compared with traditional diagnoses for accuracy. The study will enroll a minimum of 260 children diagnosed with autism and 260 neurotypical children, with total enrollment potentially reaching 900. BlinkLab's 510(k) study is expected to be completed in Q2 with final submission to the US Food & Drug Administration expected in Q3 of CY2026 for BlinkLab Dx 1.

About The Vanderbilt Kennedy Center

Founded in 1965, the Vanderbilt Kennedy Center is one of the original Intellectual and Developmental Disabilities Research Centers that were established under legislation signed by President Kennedy by the United States National Institute of Child Health and Human Development. The Center was designated a Center for Excellence in Developmental Disabilities in 2005 as part of a national network of Centers aimed at addressing these conditions and houses specialised bodies like the Treatment and Research Institute for Autism Spectrum Disorders. Today, the Vanderbilt Kennedy Center is an interdisciplinary institute that leverages experts and research infrastructure from Vanderbilt University's Schools of Medicine and Nursing. The Center is a great partner for BlinkLab since it aims to conduct research that enable early interventions and support families.

Housed within Vanderbilt University Medical Center (VUMC), the Kennedy Center is a center for excellence in the field of developmental disabilities; combining research, community services, and innovative approaches to training for professionals and caregivers in an attempt to foster access to evidence-based best practices for autism and intellectual disabilities. The Kennedy Center places an emphasis on its research, advocating not only for innovative work for both diagnostic and interventional support, but also for informing policy and training as part of a translational research approach.

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 and

ADHD. Our most advanced product is an autism diagnostic test that leverages the power of smartphones, AI and machine learning. 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.