ASX Announcement

26 August 2025

Two additional strategic partnerships with top ranked U.S. institutions advance BlinkLab's FDA submission

Highlights:

- **Two key institutes join BlinkLab's clinical trial sites:** Cincinnati Children's Medical Center and Seattle Children's Research Institute have joined BlinkLab's network of clinical trial sites in the U.S. for its pivotal FDA 510(k) Autism Diagnostic Trial.
- **World-Leading Pediatric Institutions:** Both institutions are ranked among the top 10 children's hospitals in the U.S. and are internationally recognised for their excellence in autism research, patient care, and innovation.
- **Expanded Clinical Network:** The new partnerships bring the total number of U.S.-based clinical sites participating in FDA Autism Diagnostic trial to five. These sites were chosen to enhance recruitment capacity and to ensure geographic and patient diversity.
- **FDA 510(k) Study Completion and Submission:** Expected completion date Q2 of CY2026, with final submission to the U.S. Food & Drug Administration ("FDA") expected in Q3 of CY2026 for BlinkLab Dx 1.

BlinkLab Limited (ASX:BB1) ("BlinkLab" or the "Company"), a digital healthcare company developing AI-powered diagnostic tools, today announced that **Cincinnati Children's Medical Center** and **Seattle Children's Research Institute** have been engaged as additional clinical sites for the main study phase of its pivotal FDA 510(k) trial of BlinkLab Dx 1, a smartphone-based diagnostic platform for autism.

The inclusion of the two leading clinical sites not only strengthens BlinkLab's clinical and scientific foundation but also ensures access to diverse patient populations across varied U.S. regions, which will help to accelerate recruitment towards the target of up to 900 participants once the main phase of the study is initiated.

About Cincinnati Children's Medical Center

Cincinnati Children's Medical Center is consistently ranked among the top three pediatric hospitals in the U.S. The Center is home to one of the nation's most advanced autism research and treatment programs, integrating cutting-edge science with comprehensive clinical care. The Center was recently listed among best children's hospitals for Behavioral Health in the U.S.

About Seattle Children's Research Institute

Seattle Children's Research Institute is recognised globally for its leadership in pediatric research and commitment to innovation in children's health. Its Center for Child Health, Behavior and Development is a pioneer in autism research, providing critical insights into early diagnosis and intervention strategies. The Center was recently listed among top 10 children's hospitals in the US and among the best children's hospitals for Behavioral Health.

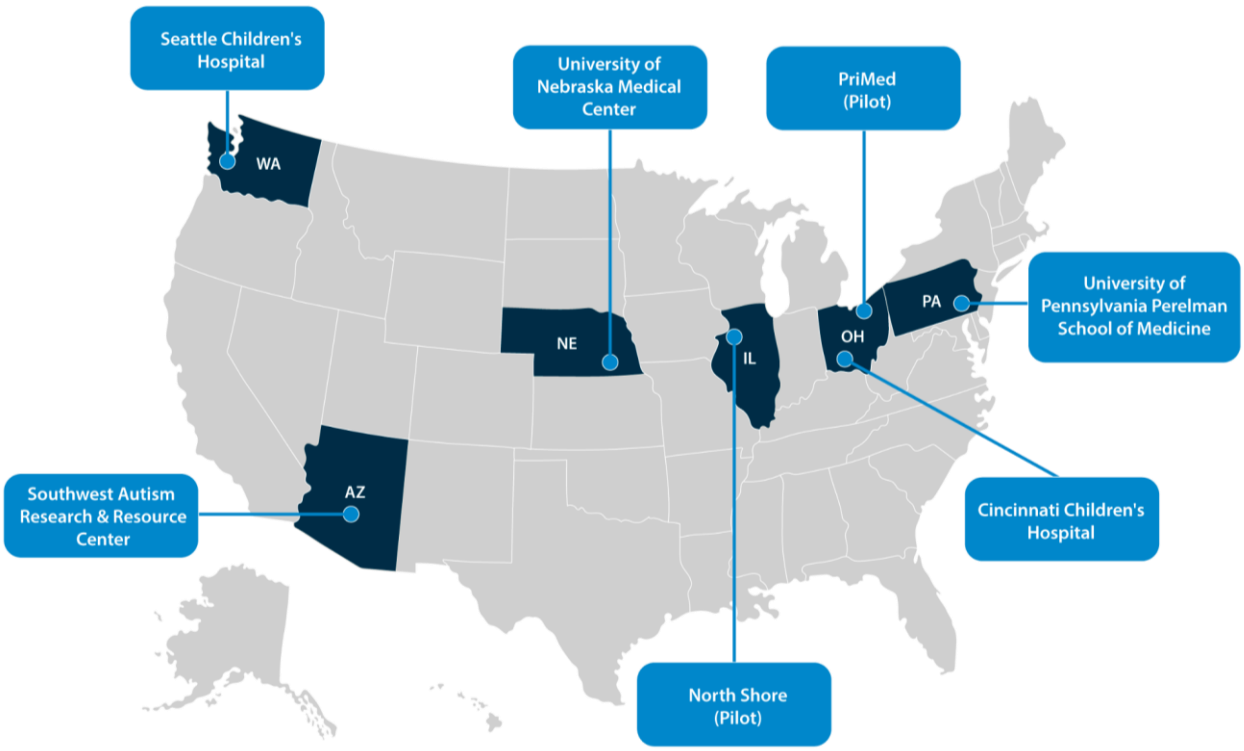

Figure | Map of clinical and research centers currently onboarded for BlinkLab's FDA 510(k) regulatory trial, including major hospitals, medical schools, and pilot sites across the United States.

Strategic Importance of Partnerships with Leading Institutions

To date, Blinklab has now partnered with five prestigious clinical centers for the main study Phase of its FDA 510(k) study. These institutions are home to some of the world's most influential key opinion leaders in autism research and pediatric medicine. An endorsement and early involvement from sites such as those engaged provides the Company with powerful validation for its BlinkLab Dx 1 technology and will be critical in driving future adoption across health systems.

Market and Regulatory Opportunity

Autism is one of the fastest-growing areas of unmet medical needs, with prevalence in the U.S. increasing steadily over the past decade. Traditional diagnostic methods require lengthy periods of observation by clinicians, making it time-intensive and resource-limited, creating substantial bottlenecks in access to care. Digital solutions, such as BlinkLab Dx 1, are positioned to transform this landscape by offering accessible, scalable, objective, and early diagnostic capabilities that are not achievable by traditional methods for diagnosis.

The FDA 510(k) trial is designed as a double-blind study, enrolling at least 260 children diagnosed with autism and 260 neurotypical children (controls), with the potential to reach up to 900 participants in total. Study completion is expected in Q2 CY2026, with regulatory filing to the FDA targeted for Q3 CY2026.

Commenting on the engagement with the two new sites, BlinkLab Co-founder and CEO, Dr. Henk-Jan Boele, stated:

"Adding Cincinnati Children's Medical Center and Seattle Children's Research Institute to our trial network is a significant milestone. These are two of the most respected pediatric institutions in the world, and their involvement will strengthen the credibility of our data and ensure efficient recruitment, as both sites have extensive experience in running clinical trials. With this expanded clinical base, BlinkLab is well-positioned to deliver a robust data package for our FDA 510(k) submission and capture a major opportunity in the fast-growing autism diagnostics market."

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 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.