**ASX Announcement** **16 March 2026**

# BlinkLab Completes Clinical Trial Network for Pivotal FDA Study with addition of Tenth Clinical Site

## Highlights

- **Final Clinical Site Onboarded:** University of Arkansas has joined BlinkLab's pivotal FDA 510(k) clinical trial for BlinkLab Dx 1, its smartphone-based diagnostic aid for detecting autism.
- **Onboarding of Clinical Sites Now Complete:** University of Arkansas is the tenth and final clinical site that will participate in BlinkLab's pivotal FDA 510(k) clinical trial.
- **U.S. Pilot Data Strengthens and De-Risks Pivotal Study:** The pivotal study follows BlinkLab's recent U.S. Pilot Study, where its flagship technology demonstrated 83.7% sensitivity and 84.7% specificity for autism in a sample of 485 children, far exceeding agreed FDA performance benchmarks (>65% / >65%).
- **FDA-endorsed Pivotal 510(k) Trial to Commence Imminently:** The pivotal study will validate the usability and diagnostic accuracy of BlinkLab Dx 1. The study will enrol a minimum of 528 children across the network of leading clinical autism centres and academic institutions and is set to commence in Q1 2026.
- **Strategic Network of Industry Leaders:** University of Arkansas joins as the last addition to BlinkLab's now completed network of leading autism clinical sites, including many of the most well-respected in their field in the U.S.
- **First Patient Testing expected to Commence Later This Month:** Pivotal 510(k) study is about to commence.

**BlinkLab Limited (ASX:BB1)** ("BlinkLab", or the "Company"), a developer of AI-powered digital diagnostics, is pleased to announce that the University of Arkansas, a globally recognised research university in Fayetteville, Arkansas, has been onboarded as the tenth and final clinical site for the Company's upcoming pivotal U.S. regulatory trial for BlinkLab Dx 1.

This final addition marks the completion of onboarding for BlinkLab's network of leading U.S. clinical sites where its imminent FDA 510(k) clinical trial will be conducted, allowing for a geographically and demographically diverse population of participant children and a rigorous clinical study protocol to evaluate BlinkLab's flagship technology. The network of ten leading clinical sites strengthens the study design of the trial and constitutes one of the most comprehensive and clinically rigorous diagnostic studies for autism conducted in the digital health field.

**Commenting on the finalisation of the clinical site network, Dr Henk-Jan Boele, Managing Director and CEO of BlinkLab, stated: "***We are proud to announce the finalisation of our clinical site network for the upcoming pivotal 510(k) study. These top-tier clinical and research centres will be instrumental not only in the timely completion of our regulatory study, but also in supporting post-FDA-clearance commercialisation. Together, these key opinion leaders in the autism field will help shape the future of autism assessment and define the role that AI-enabled technologies, such as BlinkLab, will play in clinical decision-making. At BlinkLab, we are excited to begin the next phase of this journey, with participant recruitment expected to commence later this month."*

## Next Steps in the Pivotal 510(k) Study

The pivotal study will validate both the usability and diagnostic accuracy of BlinkLab Dx 1. The first participants are expected to be enrolled and tested by the end of March 2026. During the upcoming site initiation visits, BlinkLab and the contract research organisation (CRO) conducting the study (MCRA/IQVIA) will confirm the readiness of each clinical site and verify that all locations are prepared to conduct the investigation in full compliance with the study protocol and regulatory requirements prior to enrolling participants. These activities include final training of the research teams, confirmation of ethical and protocol procedures, data collection and reporting processes, and any final operational verifications required to ensure the study is conducted safely, consistently, and in accordance with regulatory standards.

## About BlinkLab's Pivotal 510(k) Study

This latest onboarding of a tenth and final clinical site follows BlinkLab's U.S. Pilot Study of 485 children, completed in October of 2025, in which BlinkLab Dx 1 demonstrated 83.7% sensitivity and 84.7% specificity versus independent gold-standard clinical diagnoses[1]. Importantly, the performance observed in the Pilot Study significantly exceeded the >65% sensitivity and >65% specificity threshold that was agreed with the U.S. Food and Drug Administration (FDA) for the pivotal study ahead of its commencement. The results from the Pilot Study unblinded and announced in October of 2025 confirmed both the robustness of the technology in real-world clinical populations and the Company's readiness to progress its pivotal 510(k) program.

## Pivotal 510(k) Study & Strategic Importance

The pivotal study will enrol a minimum of 528 children, aged 2–11 years, across what is now a completed network of 10 leading U.S. clinical sites:

- Cincinnati Children's Hospital[2]
- Seattle Children's Hospital[3]
- University of Pennsylvania[4]

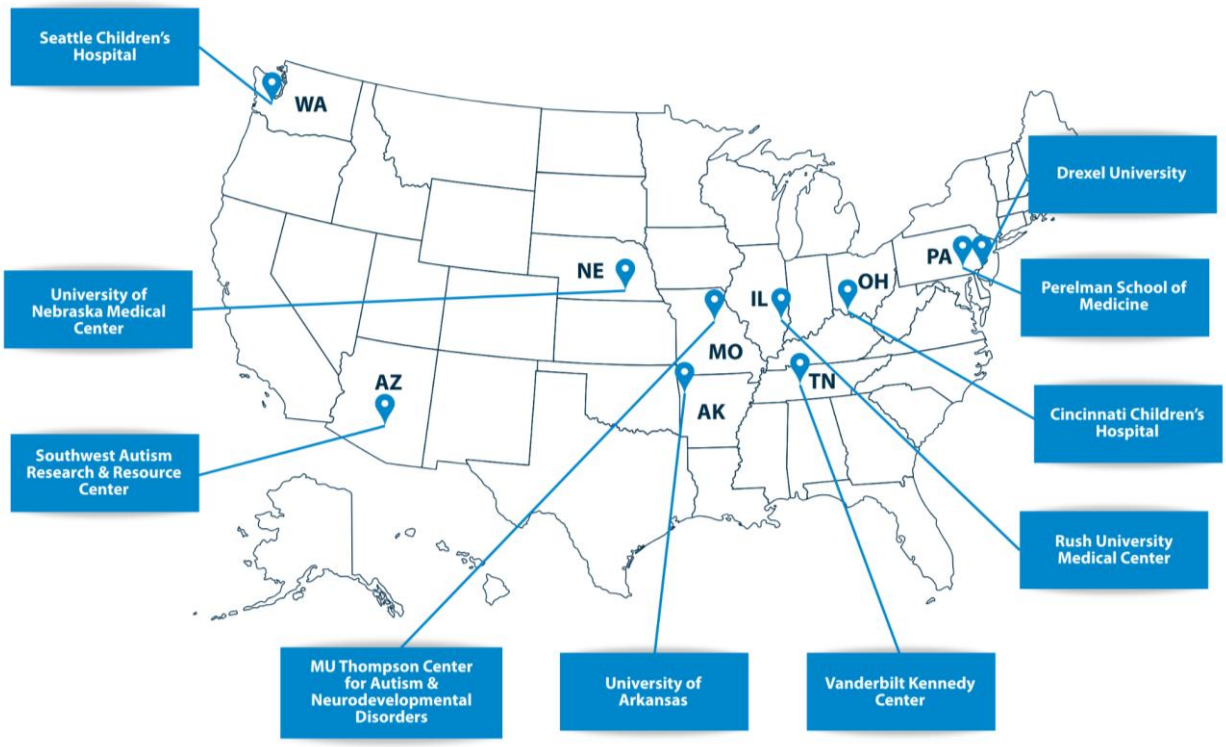
[1] ASX Announcement (22 October 2025) – *"Pilot Study Confirms High Diagnostic Accuracy and Readiness for FDA Trial"*

[2] ASX Announcement (26 August 2025) – *"Two additional strategic partnerships with top ranked U.S. institutions advance BlinkLab's FDA submission"*

[3] ASX Announcement (26 August 2025) – *"Two additional strategic partnerships with top ranked U.S. institutions advance BlinkLab's FDA submission"*

[4] ASX Announcement (21 August 2025) – "ASX Announcement (26 August 2025) – *"Two additional strategic partnerships with top ranked U.S. institutions advance BlinkLab's FDA submission"*

- MU Thompson Center for Autism & Neurodevelopmental Disorders[5]
- Southwest Autism Research & Resource Center[6]
- University of Nebraska Medical Center[7]
- Vanderbilt Kennedy Center[8]
- Rush University Medical Center[9]
- Drexel University[10]
- University of Arkansas




*Map of the USA showing the completed network of ten (10) onboarded clinical sites participating in the main study phase of BlinkLab's pivotal FDA 510(k) trial*

Together, these sites represent a geographically diverse and demographically representative sample of the U.S. population, each with a proven track record in autism research and clinical trial execution. By anchoring its pivotal trial in this elite network of clinical sites, BlinkLab is not only generating high-quality evidence for regulatory clearance but also building deep relationships with

[5] ASX Announcement (17 September 2025) – *"BlinkLab Engages The University of Missouri's Thompson Center for Autism & Neurodevelopment as its sixth Clinical Site for FDA 510(k) Diagnostic Trial"*

[6] ASX Announcement (22 May 2025) – *"BlinkLab Expands U.S. Clinical Trial Network: University of Nebraska Medical Center Engaged as Second Site in Main Phase of FDA 510(k) Study"*

[7] ASX Announcement (8 July 2025) – *"BlinkLab Expands U.S. Clinical Trial Network: University of Nebraska Medical Center Engaged as Second Site in Main Phase of FDA 510(k) Study"*

[8] ASX Announcement (18 September 2025) – *"BlinkLab Onboards 'The Vanderbilt Kennedy Center' as Seventh Clinical Site for FDA 510(k) Autism Trial"*

[9] ASX Announcement (13 November 2025) – *"Rush University Medical Center Joins BlinkLab's Pivotal U.S. Autism Diagnostic Trial"*

[10] ASX Announcement (12 February 2026) – *"BlinkLab Expands Pivotal FDA Trial Network to Nine Elite U.S. Sites Ahead of Imminent Study Commencement"*

key opinion leaders (KOLs) and future implementation partners within major U.S. centres of excellence. These collaborations are expected to play a critical role in informing real-world clinical workflows for the BlinkLab Dx 1 technology, supporting guideline and payer engagement, and accelerating adoption upon FDA clearance.

A successful pivotal study and subsequent FDA 510(k) clearance would position the BlinkLab Dx 1 technology as a first-of-its-kind AI-powered diagnostic aid that can be deployed at scale, ultimately bringing earlier and more objective autism assessments into clinics and communities to help address long waitlists, regional inequities, and delayed care and support.

## About the University of Arkansas and the University of Arkansas for Medical Sciences

The University of Arkansas (Fayetteville) is the state of Arkansas' flagship land-grant university, and is recognised as a leading research university in the U.S. for a broad portfolio of applied and interdisciplinary research (classified as a "R1: Very High Research Activity" by the Carnegie Foundation). In addition to its discipline-based research across core areas of science, engineering, and the social sciences, the University also has specialised initiatives for population-based and public-health-based research across areas that include digital technologies and mixed-methods approaches for the support of public health interventions. University of Arkansas is also the flagship campus of the broader University of Arkansas System, which includes the University of Arkansas for Medical Sciences (UAMS), a specialised centre that integrates the education of health professionals, clinical care, and biomedical research projects throughout its footprint of colleges and healthcare locations. UAMS's research emphasis is positioned around the translation of research into improved care and health outcomes, as well as an institutional emphasis on population health. UAMS also has a strong orientation toward clinical research and clinical trials as part of its focus, including the evaluation of new therapies, devices, and care models, as well as an Institute for Digital Health & Innovation, which aims to reduce disparities in access to health through digital health technology and technology-enabled care, education, and research.

**This announcement has been authorised for release by the Board of BlinkLab Limited.**

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**About BlinkLab Limited**

BlinkLab Limited was founded by neuroscientists at Princeton University and is developing a smartphone-based diagnostic platform for autism. Its most advanced product, BlinkLab Dx 1, is an autism diagnostic aid for clinicians that leverages smartphones, artificial intelligence, and machine learning to capture objective, reflex-based measures, supporting earlier and more accurate autism identification. This enables timely intervention during critical periods of brain development. BlinkLab is led by an experienced management team and Board with deep expertise in digital healthcare, computer vision, and AI, supported by a Scientific Advisory Board of leading experts in autism and brain development.