ASX Announcement

12 February 2026

BlinkLab Expands Pivotal FDA Trial Network to Nine Elite U.S. Sites Ahead of Imminent Study Commencement

Highlights:

- **Ninth Clinical Site Onboarded:** Drexel University has now joined BlinkLab's pivotal FDA 510(k) clinical trial for BlinkLab Dx 1, its Software as Medical Device autism diagnostic aid.
- **U.S. Pilot Data Strengthens and De-Risks Study:** The onboarding of Drexel University follows BlinkLab's recently completed 485 children U.S. Pilot Study, where its flagship technology achieved 83.7% sensitivity and 84.7% specificity, far exceeding the FDA's agreed performance benchmark (>65% / >65%).
- **Ongoing Engagement with Global Research Community:** Preparations for the pivotal study follow BlinkLab's recent milestones in wider neuroscientific research, including a peer-reviewed publication in a leading journal and an invitation to speak at a prestigious event for the Simons Foundation Autism Research Initiative.
- **FDA-endorsed Pivotal 510(k) Trial to Commence Shortly:** The trial is set to enroll ~528 children across its growing network of leading clinical centres and academic institutions, and is expected to commence in Q1 2026.
- **Strategic Network of Top Centers:** Drexel University joins BlinkLab's growing network of leading autism clinical sites that are among some of the most well-respected in the U.S.

BlinkLab Limited (ASX:BB1) ("BlinkLab", or the "Company"), a leader in AI-powered digital diagnostics, is pleased to announce that Drexel University ("Drexel" or the "University"), a globally recognised research university and innovator in neurodevelopmental research, has joined as a clinical site for the Company's pivotal U.S. regulatory trial for BlinkLab Dx 1.

This makes Drexel University the ninth institution to participate in the FDA 510(k) registrational trial across the United States, helping to ensure a comprehensive and clinically rigorous study, along with a geographically and demographically diverse participant population of children as part of evaluating the diagnostic capabilities of BlinkLab's technology. The growing network of clinical sites continues to strengthen the study's design,

and what is emerging as one of the most comprehensive and clinically rigorous autism diagnostic studies conducted in the digital health field.

Commenting on the enrollment, Dr Henk-Jan Boele, Co-founder and CEO of BlinkLab, stated: *"I am very pleased to see an institution with such a longstanding track record of leadership in autism and neurodevelopmental research join BlinkLab for its FDA 510(k) diagnostic program. The University has enormous expertise across its research programs and specific autism initiatives will make it a valuable partner for this pivotal stage of our own clinical work.*

Institutions of this calibre are critical to giving our study the best chance at achieving the level of rigour required to demonstrate our technology at work, as well as maintaining the highest scientific and clinical standards for the sake of both our research output and our participants. I am grateful that Drexel University wants to work with BlinkLab. Having Drexel University as part of our pivotal trial will reinforce the momentum that we are now building with a strong start to 2026.

About BlinkLab's Pivotal 510(k) Study

This latest onboarding of a ninth 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 enroll ~528 children, aged 2–11 years, across what is now a network of nine leading U.S. sites:

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

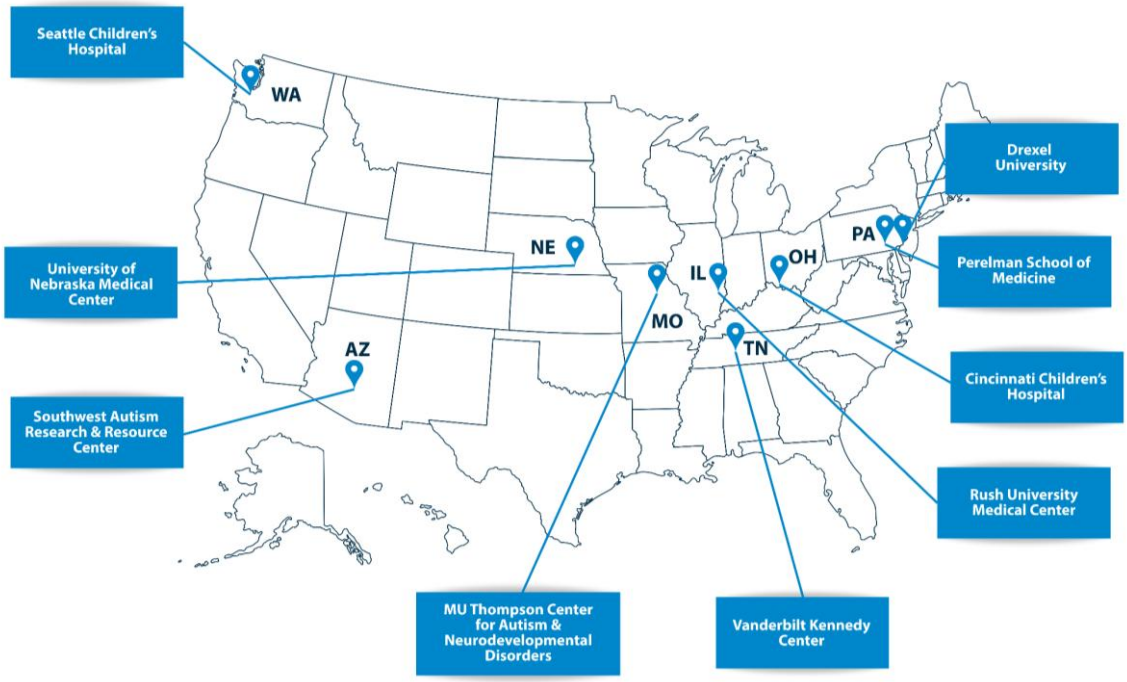
[1] ASX Announcement (22 October 2025) – "Pilot Study Confirms High Diagnostic Accuracy & Readiness"

[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



Map showing the onboarded clinical sites participating in main study phase of BlinkLab's pivotal FDA 510(k) trial across the United States

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, BlinkLab is not only generating high-quality evidence for regulatory clearance, but also building deep relationships with key opinion leaders (KOLs) and future implementation partners within major U.S. centers of excellence. These collaborations are expected to play a critical role in:

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[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"*

- Informing real-world clinical workflows for Dx 1
- Supporting guideline and payer engagement
- Accelerating adoption upon FDA clearance

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

About Drexel University and the A.J. Drexel Autism Institute

Drexel University is a private research-intensive institution located in Philadelphia, Pennsylvania, USA. As a university, Drexel is widely recognised for its academic excellence and the real-world impact of its research output and translational research efforts, especially across the health sciences, public health, and neurodevelopmental research including autism and ADHD. Drexel University, through its A.J Drexel Autism Institute, plays a unique and influential role within the U.S. autism ecosystem that extends beyond traditional academic research. The Institute is nationally recognised for its leadership in population-level autism surveillance, diagnostic access, and evidence-based policy development, working closely with government agencies, healthcare systems and community organisations across the United States.

Notably, the Institute is the publisher of the **National Autism Indicators Report (NAIR)** series, one of the most widely referenced datasets informing how autism is identified, diagnosed and supported across the U.S. healthcare and education systems. These reports are routinely used by policymakers, public health authorities and clinical leaders to shape national and state-level autism programs.

As a result, Drexel's involvement in BlinkLab's pivotal FDA study brings not only clinical and scientific credibility, but also strategic relevance to how new diagnostic tools may be evaluated, adopted and integrated into broader U.S. autism screening and care pathways over time.

This announcement has been approved by the Board of Directors.

For further information please contact:

Dr. Henk-Jan Boele
Managing Director/ CEO
henkjan@blinklab.org
M: +31 (0) 611 132 247

Brian Leedman
Non-Executive Chairman
brian@blinklab.org
M: +61 (0) 412 281 780

About BlinkLab Limited

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 aid for clinicians that leverages the power of smartphones, AI and machine learning, that enables early and accurate detection of autism enabling early intervention during crucial early windows of brain development. 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.