**ASX Announcement**

**30 June 2025**

# BlinkLab Receives US Ethics Approval for the Main Phase of FDA 510(k) Diagnostic Trial

**Highlights:**

- **US Ethics Approval:** BlinkLab has obtained Institutional Review Board (IRB) approval from WCG (WIRB-Copernicus Group), a leading provider of clinical research oversight, headquartered in Princeton, NJ.
- **FDA 510(k) Diagnostic Trial:** This IRB approval enables BlinkLab to proceed with the main phase of its ongoing FDA 510(k) diagnostic trial for the BlinkLab Dx 1 technology. The study will be conducted across multiple clinical sites in the United States and will include up to 1,000 participants.
- **Onboarding New Sites:** With IRB approval secured, at least eight autism centers are expected to be onboarded. IRB approval was a prerequisite for most of these participating sites for signing the Clinical Trial Agreement (CTA) and proceeding to site activation and participants recruitment.
- **Pilot Phase Close to Completion:** The results of the pilot study are expected to be released in the third quarter allowing time required for physician assessments using the reference standard method.

**BlinkLab Limited (ASX:BB1) ("BlinkLab" or the "Company"),** a leading digital healthcare company specializing in AI-powered diagnostics, is pleased to announce that it has received Institutional Review Board (IRB) approval for the main study phase of its FDA 510(k) diagnostic trial evaluating the BlinkLab Dx 1 technology. This technology is designed to serve as an aid in the detection and diagnosis of autism. Institutional Review Board (IRB) approval was granted by WCG, an established clinical research review organization based in Princeton, NJ, with extensive experience overseeing multi-site clinical trials. The BlinkLab study has been classified as minimally invasive and is therefore exempt from most requirements under the Investigational Device Exemption (IDE) regulations.

**Henk-Jan Boele, Cofounder CEO, commented:** *"The fact that our trial is classified as minimally invasive and exempt from most IDE regulatory requirements significantly streamlines our path forward. This IRB approval is a huge milestone that reflects our commitment to conducting rigorous, responsible research as we advance our mission to deliver accessible, AI-driven diagnostic tools for autism and beyond. I'd like to thank the entire team for their hard work and long hours in securing all necessary regulatory approvals to initiate the main phase of our US study."*

## About IRB Approval

IRB approval is a critical requirement for conducting human subject research in the U.S., including for non-invasive diagnostics like BlinkLab's smartphone-based autism assessment tool. Following positive pre-submission feedback from the FDA validating its study design and data strategy, BlinkLab received IRB approval earlier this year for the initial 100-participant phase of its FDA 510(k) clinical trial.

With the new approval in place for the main study, BlinkLab is now finalizing logistics and contracts with additional clinical sites to initiate the main trial phase. The IRB process ensures that all research complies with ethical and regulatory standards.

## About the FDA 510(k) Registrational Trial

BlinkLab's U.S.-based FDA 510(k) registrational study is designed to support the regulatory clearance of its smartphone-based diagnostic tool, *BlinkLab Dx 1*, which aims to assist in the detection of autism by demonstrating its safety and effectiveness compared to existing diagnostic methods. BlinkLab is rapidly onboarding additional clinical sites. This expansion is being carefully managed to maintain the high quality of participating autism evaluation centers and to ensure the recruitment of a diverse participant population that reflects the demographics of the U.S.

## Study Design

The registrational trial for BlinkLab Dx 1 uses a prospective, double-blinded, within-subjects comparison study design – meaning that participants nor clinicians will not be made aware of factors that may influence results, such as the methods employed for each subject. During testing 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. In the analysis of results, BlinkLab's output will be compared with that of traditional diagnosis methods for autism in order to evaluate the accuracy of BlinkLab Dx 1's assessments. The study will enroll a minimum of 260 children diagnosed with autism and 260 neurotypical children. Depending on autism prevalence at participating centers, total enrollment may reach up to 1,000 participants.

**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.