blinklab *(ASX:BB1)*

Early and Accurate Diagnosis of Autism and ADHD

Introducing an AI-powered smartphone platform for neurological testing

December 2025, BlinkLab Ltd

Disclaimer

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Corporate Snapshot

Next-Generation Digital Solutions for Neurodevelopmental Health

CAPITAL STRUCTURE - ASX:BB1	
Shares on Issue	**125.7M**
Options on Issue	**44.5M**
Performance Rights	**3.0M**
Founders'/ Directors' percentage	**±24%**
Market Cap (28 November 2025)	**$114M**
Cash (30 September - Quarterly)	**$7.2M**

Henk-Jan Boele, Cofounder and CEO

MD, PhD, Entrepreneur and Neuroscientist at Erasmus MC and Princeton University

Anton Uvarov, Co-founder, COO & Executive Director

MBA, PhD, Biotech Analyst with Citibank

Bas Koekkoek Cofounder and CSO

PhD, Assistant Prof. of Neuroscience, Erasmus MC

Peter Boele Cofounder and CTO

MA, Startup Entrepreneur, PhD Candidate at Erasmus MC

Brian Leedman Chairman

Experienced Chairman and Co-Founder of Five ASX-listed Healthcare Companies

Jane Morgan Director

18+ Years Experience in Strategic Investor & Media Relations

Richard Hopkins Director

20+ Years in Corporate Leadership Roles with Public Biotechnology Companies

What is Autism?

“Neurodevelopmental condition that affects how the brain processes sensory information.”

Autism can impact:

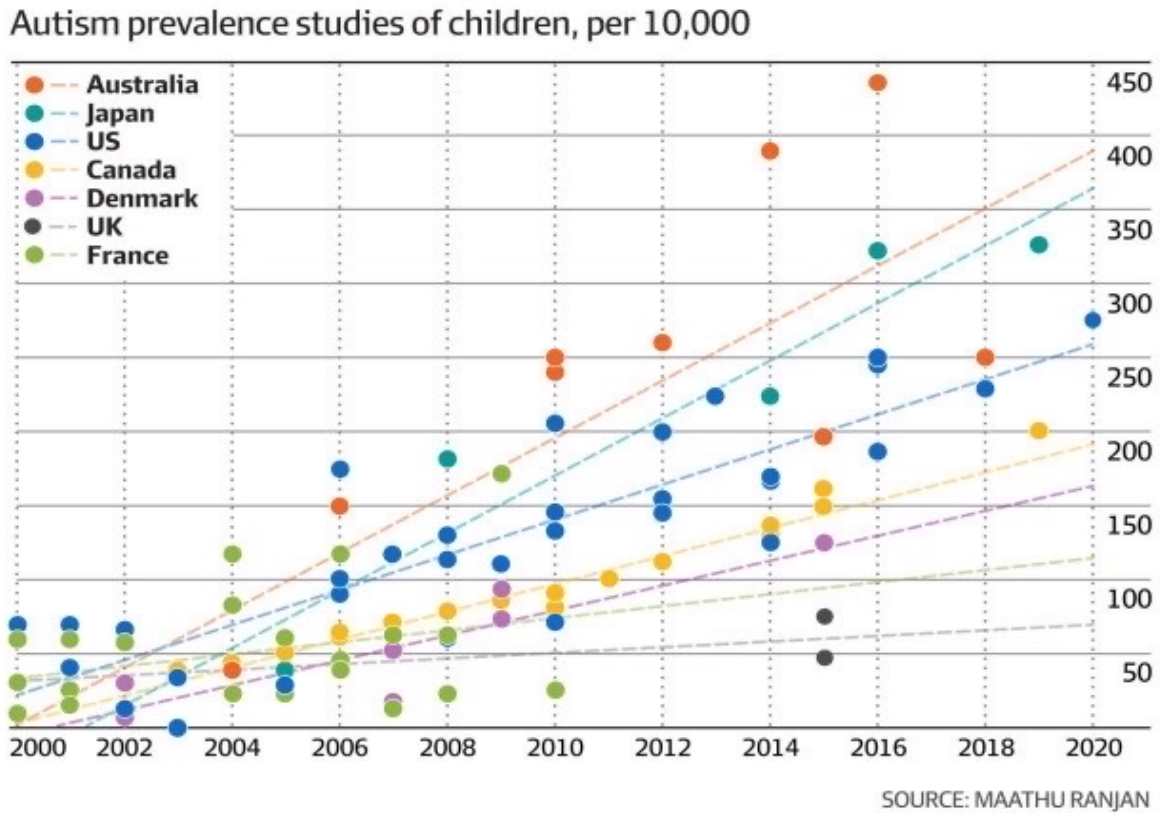
- Social development
- Language and communication
- Sensorimotor development
- Behavior and interests

USA: Economic burden of autism was $700B in 2024

"The economic burden is significant and alarming" [1]

- **Prevalence has grown up to 2-4% among children[2]**

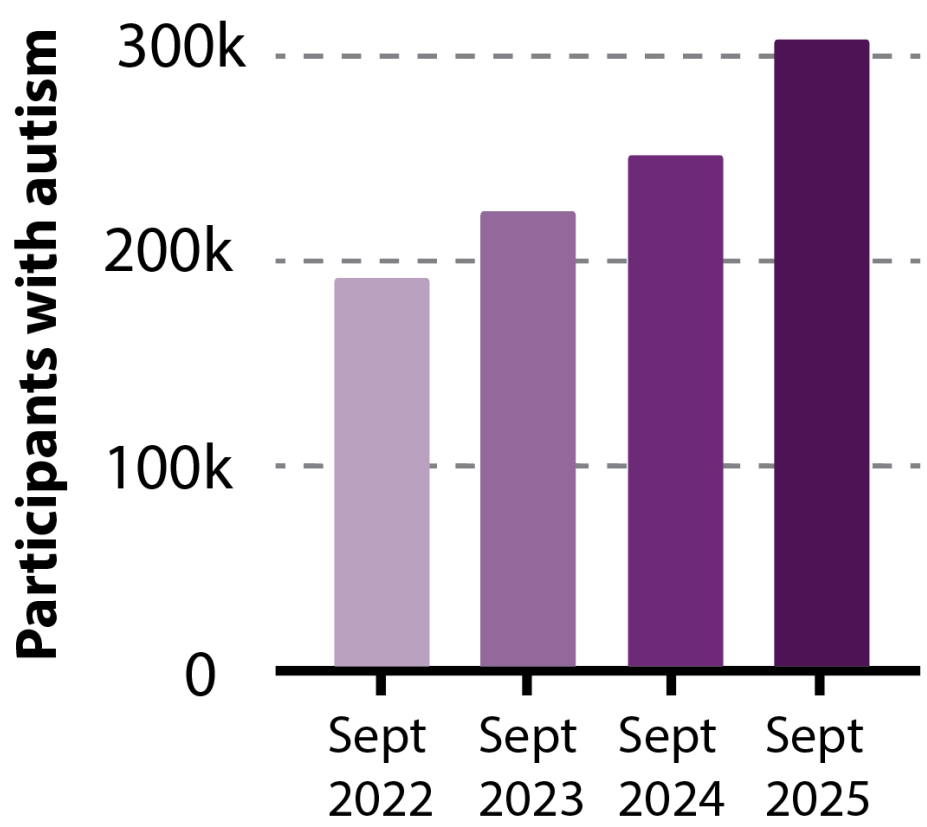
- **Autism healthcare expenses are soaring[3]**
  - *Costs for an autism diagnostic evaluation:* ***$1,000 to $7,000***
  - *Lifetime cost for individual with ASD:* ***$3.6M[3]***

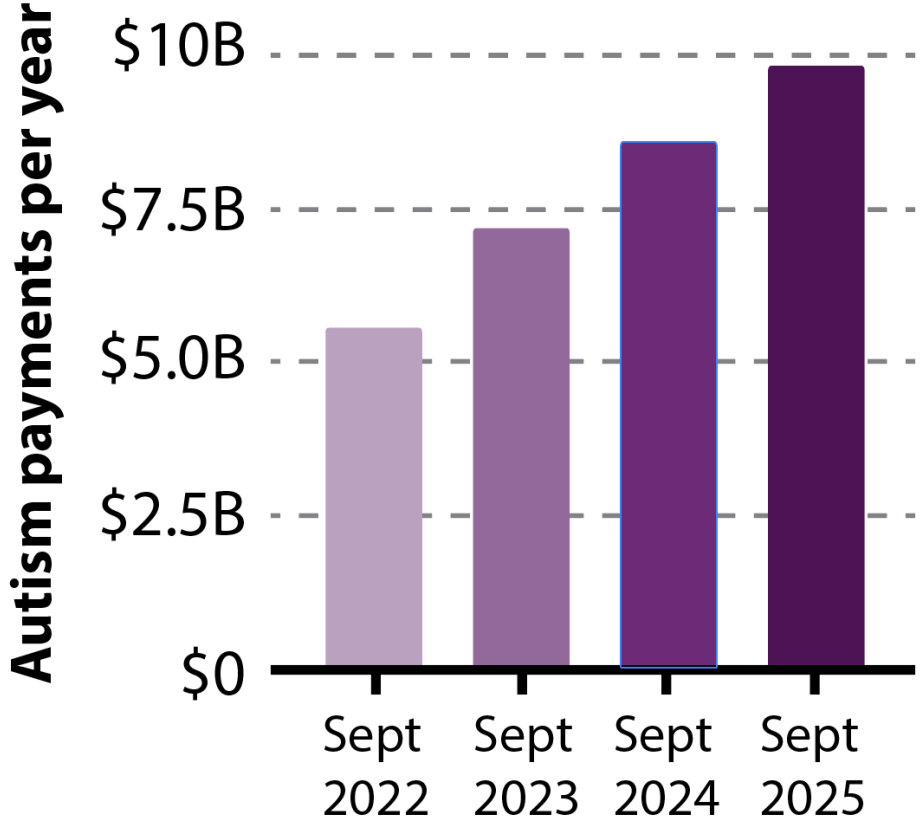


[1] *Leigh and Du (2015), Forecasting the economic burden of autism in 2015 and 2025 in the US, Journal of Autism and Developmental Disorder*
[2] *Center for Disease and Control, World Health Organization*
[3] *Cakir et al. (2020) The lifetime social cost of autism: 1990-2029, Research in Autism Spectrum Disorder*
[4] *National Disability Insurance Scheme (NDIS)*

Australia: NDIS payments for autism is over A$9.9B in 2025

Autism accounts for 41% of all NDIS participants, making it the most common disability.





Data extracted and visualized by BlinkLab, based on information from the National Disability Insurance Scheme (NDIS) - https://dataresearch.ndis.gov.au/reports-and-analyses/participant-dashboards/autism

Consensus: Early diagnosis and intervention helps children to develop crucial skills and reduces long-term support needs and costs

Early detection and diagnosis is crucial [1-5]

The American Academy of Pediatrics recommends that all children must be screened for autism at ages 18 and 24 months.

Children born annually: US – 3.6M, EU – 3.7M, AU – 296K

Early intervention is cost-effective [6-12]

Every dollar spent on early treatment saves more than three dollars in future support costs by the time a child turns 13 (Segal, using NDIS data)[13].

Image from Southwest Autism Research & Resource Center's (SARRC), one of the sites participating in BlinkLab's 510(k) pivotal study

1.National Research Council, Committee on Educational Interventions for Children with Autism. *Educating Children With Autism*. Lord, C., McGee, J. P., eds. Washington, DC: National Academies Press; 2001.
2.Olley, J. G. (2005). Curriculum and classroom structure. In: Volkmar, F. R., Paul, R., Klin, A., Cohen, D. (Eds.), *Handbook of Autism and Pervasive Developmental Disorders*. 3rd ed. Vol II (863–881). Hoboken, NJ: John Wiley & Sons.
3.Helt, M., Kelley, E., Kinsbourne, M., Pandey, J., Boorstein, H., Herbert, M., et al. (2008). Can children with autism recover? If so, how? *Neuropsychology Review, 18*(4), 339–366.
4.Rogers, S. J., & Lewis, H. (1989). An effective day treatment model for young children with pervasive developmental disorders. *Journal of the American Academy of Child and Adolescent Psychiatry, 28*(2), 207–214.
5.Reichow, B., & Wolery, M. (2009). Comprehensive synthesis of early intensive behavioral interventions for young children with autism based on the UCLA young autism project model. *Journal of Autism and Developmental Disorders, 39*(1), 23–41.
6.Pye K, Jackson H, Iacono T, Shiell A. Economic Evaluation of Early Interventions for Autistic Children: A Scoping Review. J Autism Dev Disord. 2024 May;54(5):1691-1711.
7.Tinelli M, Roddy A, Knapp M, et al. Economic analysis of early intervention for autistic children: findings from four case studies in England, Ireland, Italy, and Spain. *European Psychiatry*. 2023;66(1):e76.
8.Hope For Three. (2025). Understanding the High Costs of Autism Care.
9.University of California. (2015). Autism's costs estimated to be $500 billion, potentially $1 trillion, by 2025. ScienceDirect. (2020).
10. The lifetime social cost of autism: 1990- 2029.
11. Above and Beyond Therapy. (2025). How Much ABA Therapy Really Costs with Insurance.
12. Cross River Therapy. (2025). ABA Therapy Insurance Coverage for Autism (By State).
13.Preemptive therapy prior to autism diagnosis may be highly cost-effective, article originally appeared in Autism Research Review International, Vol. *37, No. 2, 2023, by* Leonie Segal

AUTISM RESEARCH INSTITUTE

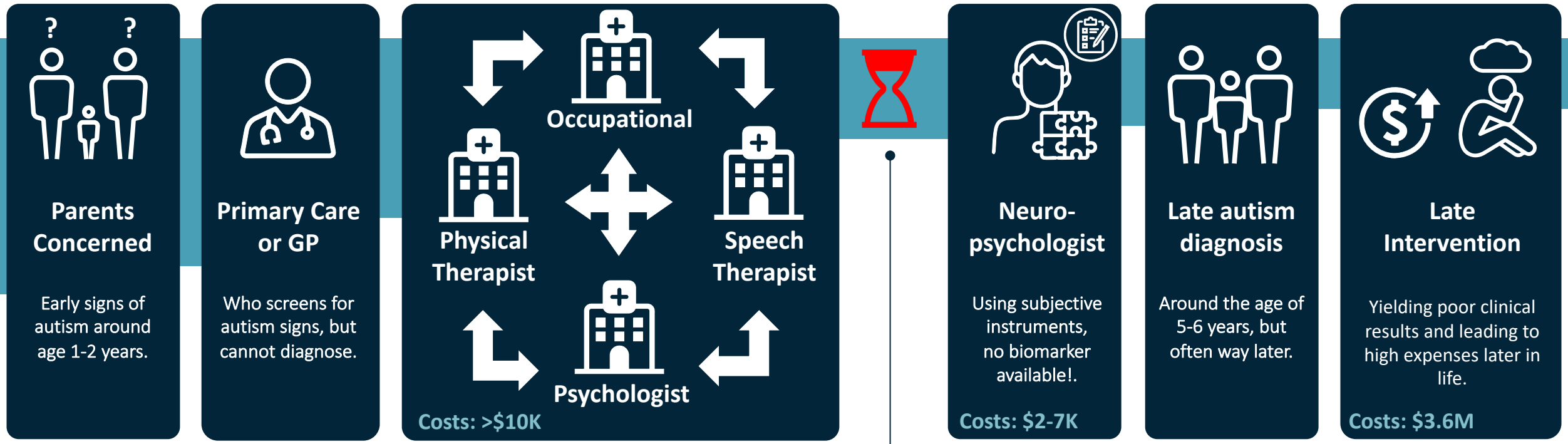
American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®

Autism diagnosis is expensive, inefficient, and often late

The costly labor and time-intensive diagnostic evaluations are unnecessary for many children.

1-3 years of uncertainty for family and child



Currently, a clinical autism diagnosis requires input from multiple disciplines.

Long waitlists because of extreme shortage of specialists that can diagnose autism. Total time for evaluation is between 3-8 hours.

BlinkLab's digital solution accelerates path to diagnosis

The costly labor and time-intensive diagnostic evaluations are unnecessary for many children.

Diagnosis in weeks to months

Parents Concerned

Early signs of autism around age 1-2 years.

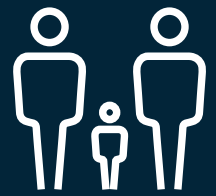
Primary Care or GP

Using BlinkLab's digital biomarkers as a highly accurate diagnostic aid for autism.

Pricing: ± $250

Neuro-psychologist

Using clinical judgement and subjective rating instruments.



Early autism diagnosis

Diagnostic certainty at the age of 2-3 years.

Early and personalized intervention and accurate treatment monitoring

Early therapy improve outcomes, helping children develop crucial skills and reducing long-term support needs. This will significantly reduce in costs later in life.

BlinkLab diagnosis is instantaneous after completing the two 15-minute video session. Only necessary specialists will need to be consulted. BlinkLab is currently conducting their FDA 510(k) regulatory study.


BlinkLab’s AI-enabled
Smartphone-based Assessment
blinklab

Our patented solution: Neuroscience on a smartphone

Minuscule facial reflexes, evoked by our app, generate a digital biomarker for autism.

Evokes Facial Reflexes

By presenting visual and auditory stimuli during smartphone use.

Computer Vision

Facial features are tracked on the smartphone and transferred to the **BlinkLab platform**.

Biomarker Detection

Biomarkers are detected in **real-time** and made available to the clinician.

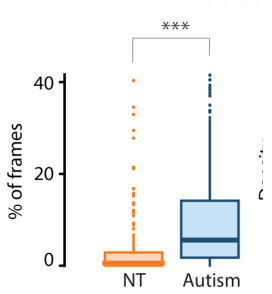
Evaluates brain function

State-of-the art analysis methods and AI modelling to **map the functioning of brain regions involved in autism**.

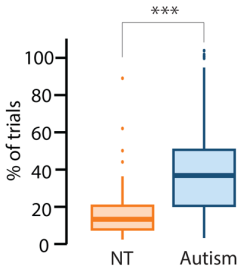
Patents: PCT/US2021/058698; US 18/036,009; Europe 21892692; Japan 2023-528017; Canada 3,195,596; Korea 10-2023-7018839; Australia 2021378273; US Provisional 63/218,607; 63/460,451; 63/548,542

Beyond blinks: Tracking of vocal responses and hand/head movements as objective markers for autism

Screen avoidance



Head rotations



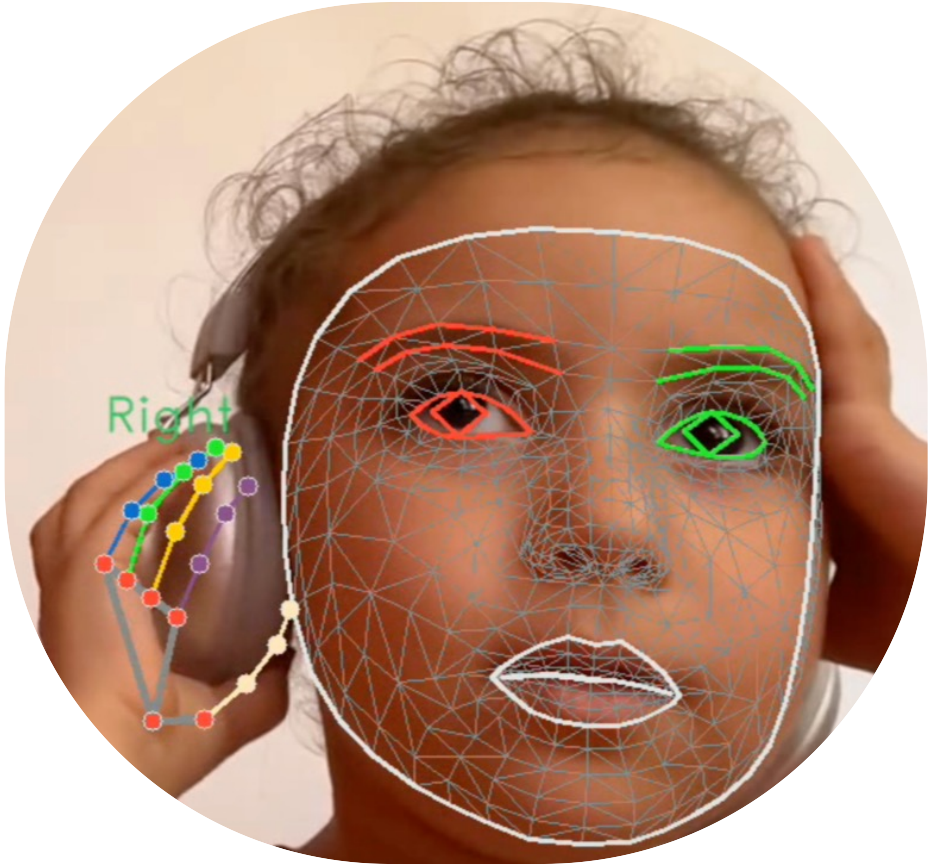
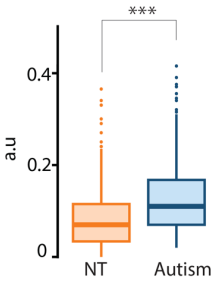
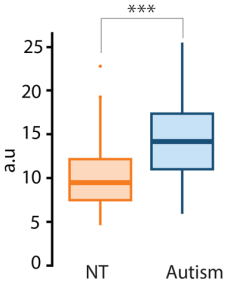


Image used with permission

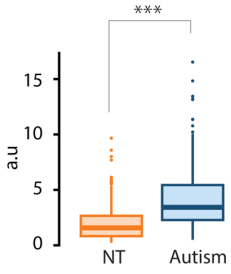
Side eye



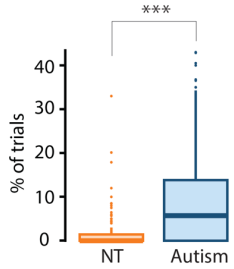
Pupil range



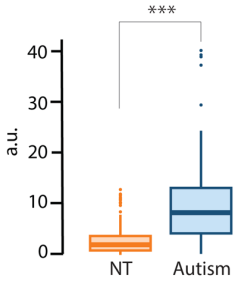
Postural stability



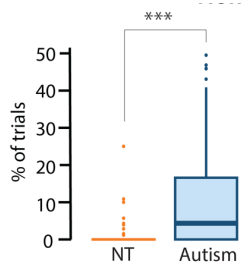
Headphone touches



Mouth openings



Vocalizations



Gultig et al., 2025; https://www.medrxiv.org/content/10.1101/2025.07.25.25331276v1; ASX Announcement, 19th Aug 2025, Presentation - TechKnow Invest Roadshow Conference

Pilot Study Confirms High Diagnostic Accuracy and Readiness for FDA Trial

ASX Announcement 22 October 2025

Highlights:

- **Pilot Study Completion:** BlinkLab has successfully completed its U.S. Pilot Study of the Dx 1 diagnostic device, involving **485 children**.

- **Strong Diagnostic Performance:** Across a clinically diverse population representing the full spectrum of developmental concerns, BlinkLab Dx 1 achieved **83.7%** sensitivity and **84.7%** specificity relative to clinical reference diagnosis.

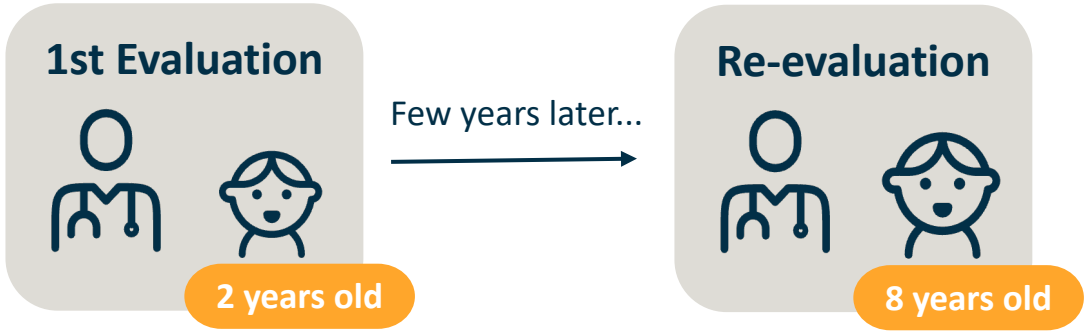
- **Performance Exceeds FDA Benchmark for Registrational Study:** In a formal meeting with the U.S. FDA on 16 October 2025, the agency agreed with BlinkLab's pivotal 510(k) study design and confirmed a minimum performance **threshold of >65%** sensitivity and **>65%** specificity for regulatory clearance. Based on FDA feedback, the main study has been refined to enroll approximately **528 participants** across leading U.S. autism research centres, streamlining timelines and reducing cost.

Why not 100% sensitivity and 100% specificity?

*The 'ceiling' for BlinkLab Dx 1 is **85-90%** for both sensitivity and specificity, because...*

➢ Diagnostic Stability

Autism clinical diagnostic stability is estimated around 80-90% stability. [1–5]



➢ Expert Consensus

Autism expert consensus is estimated around 70-80% accuracy. [6– 8]

"BlinkLab's sensitivity and specificity reflect the limits of the diagnostic process itself. If two expert clinicians or two follow-up years apart don't always agree, a digital biomarker trained on that label can't be perfect either."

[1] Elias et al. (2022). *Diagnostic stability in individuals with autism spectrum disorder: Insights from a longitudinal follow-up study.*

[2] May et al. (2021). *Parent-reported autism diagnostic stability and trajectories in the Longitudinal Study of Australian Children.*

[3] Pierce et al. (2019). *Evaluation of the diagnostic stability of the early autism spectrum disorder phenotype in the generalpopulation starting at 12 months.*

[4] Chawarska et al. (2009). *A prospective study of toddlers with ASD: Short-term diagnostic and cognitive outcomes.*

[5] Lord et al. (2006). *Autism from 2 to 9 years of age.*

[6] Esler et al. (2015). *The Autism Diagnostic Observation Schedule, Toddler Module: Standardized severity scores.*

[7] Mazefsky et al. (2013). *Comparability of DSM-IV and DSM-5 ASD research samples.*

[8] de Bildt et al. (2013). *How to use the ADI-R for classifying autism spectrum disorders?*

BlinkLab Outperforms FDA-approved Digital Peers

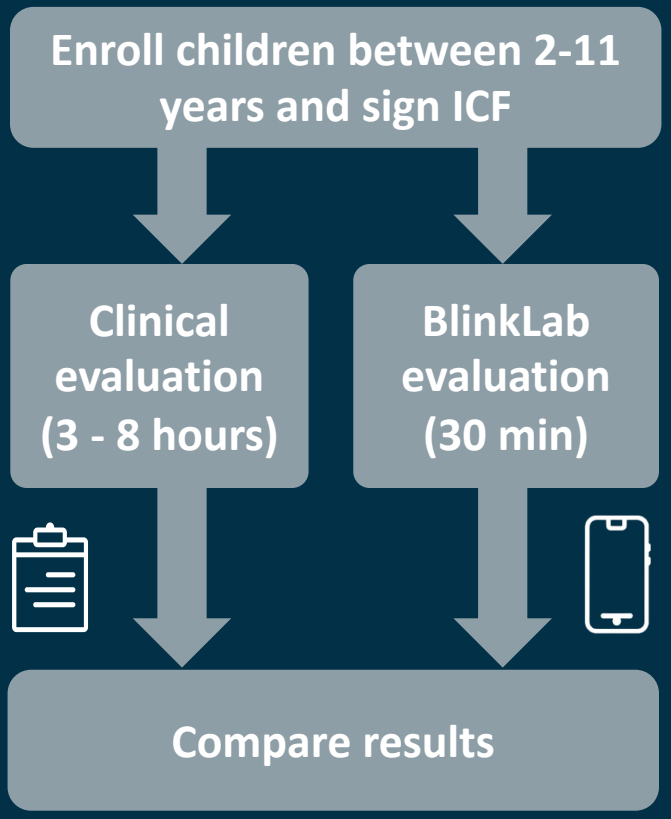
We are leaders in the digital autism diagnostics space

	blinklab	cognoa	EarliTec Diagnostics Inc.
Sensitivity	84%	52%*	71%
Specificity	85%	19%*	81%
Smartphone-based	Yes	Yes	No
FDA approval	No - *510(k)*	Yes - *De Novo*	Yes - *510(k)*

* Calculated over all study completers (Cognoa's device yielded indeterminate results in 68% of cases)

Study Design and Timeline for 510(k) Regulatory Trial for Dx 1

Prospective, multicenter in US, double-blinded, within-subject comparison study.

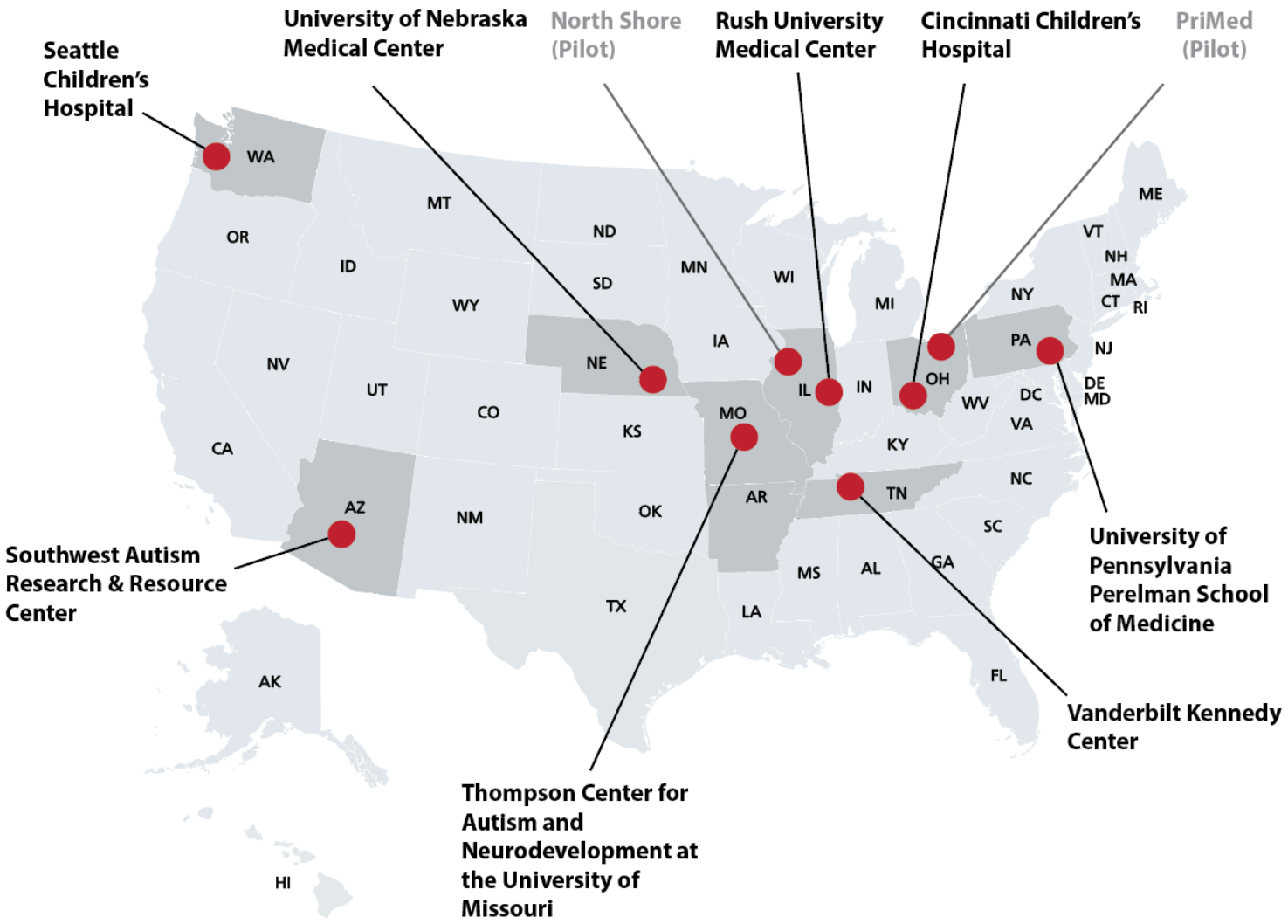


Main study: N = 264 children with autism and N = 264 children without autism.

Q4 2024	- CRO assigned
	- IRB approval for Pilot Study
	- First pre-submission meeting with FDA
Q1 2025	- Onboarded two US clinical sites for initial study: PriMED and NorthShore Pediatrics
	- Compliant with HIPAA and 21 CRF parts 11, 820
	- Started data collection for Pilot Study
Q2 2025	- IRB approval for main 528-patient Pivotal Study
Q3 2025	- Onboarding clinical and research sites for Pivotal Study
Q4 2025	- Second pre-submission meeting with FDA
	- Release of results from 485 patient Pilot Study
Q1 2026	- Start Pivotal 510(k) Study
2H 2026	- Completion Pivotal Study and submission to FDA
Q1 2027	- Outcome from FDA 510(k)

* completed

BlinkLab is onboarding Top-Tier hospitals in the US to participate in the 510(k) autism study



Perelman School of Medicine, University of Pennsylvania

Cincinnati Children's

SARRC — Southwest Autism Research & Resource Center

Thompson Center for Autism & Neurodevelopment, University of Missouri

University of Nebraska Medical Center, Nebraska Medicine

Vanderbilt Kennedy Center for Excellence in Developmental Disabilities

Seattle Children's Hospital • Research • Foundation

Rush University Medical Center

We are experts in science, tech and commercialization

Henk-Jan Boele, CEO

MD, PhD, Entrepreneur and neuroscientist at Erasmus MC and Princeton University

Fifteen years of experience in neurobehavioral testing with over 35 publications. Recipient of many prestigious awards. Team leader and inventor of BlinkLab.

Anton Uvarov, COO
Executive director

MBA, PhD, Biotechnology Analyst with Citibank

Cofounder of two biotechnology companies, developed therapeutics for neurodegenerative disorders. Both successfully IPO and publicly traded.

Bas Koekkoek, CSO

PhD, Assistant Professor of Neuroscience. Erasmus MC

Twenty-six years of experience in neurobehavioral testing with over 55 publications in IEEE and the field of neuroscience. An innovator in heart and soul. Cofounder of Neurasmus BV.

Peter Boele, CTO

MA, PhD candidate, Erasmus MC

Born to code, with over 20 years of experience in software development, both as developer as well as executive.

Our mission is to use neuroscience to improve the daily life of families with autism.

We are backed up by an expert advisory board

Company Chairman

Brian Leedman

Experienced Chairman and co-founder of five ASX listed healthcare companies including digital healthcare company ResApp Health, acquired by Pfizer for $180M in 2022.

ResApp HEALTH Neurotech International

Company Director

Jane Morgan

Providing strategic investor and media relations services for over 16 years. Founder of JMM.

JMM JANE MORGAN MANAGEMENT

Company Director

Richard Hopkins

Experienced bio-pharmaceutical executive with over 20 years in corporate leadership roles with public biotechnology companies.

zelira THERAPEUTICS PharmAust LIMITED PYC THERAPEUTICS

Scientific advisor

Prof. Samuel Wang

Professor of Neuroscience at Princeton University and author of 2 bestselling books.

PRINCETON UNIVERSITY

Scientific advisor

Prof. Chris De Zeeuw

Professor of Neuroscience at Erasmus MC and vice-director of the NIN (Netherlands Institute of Neuroscience).

Erasmus MC

Scientific advisor

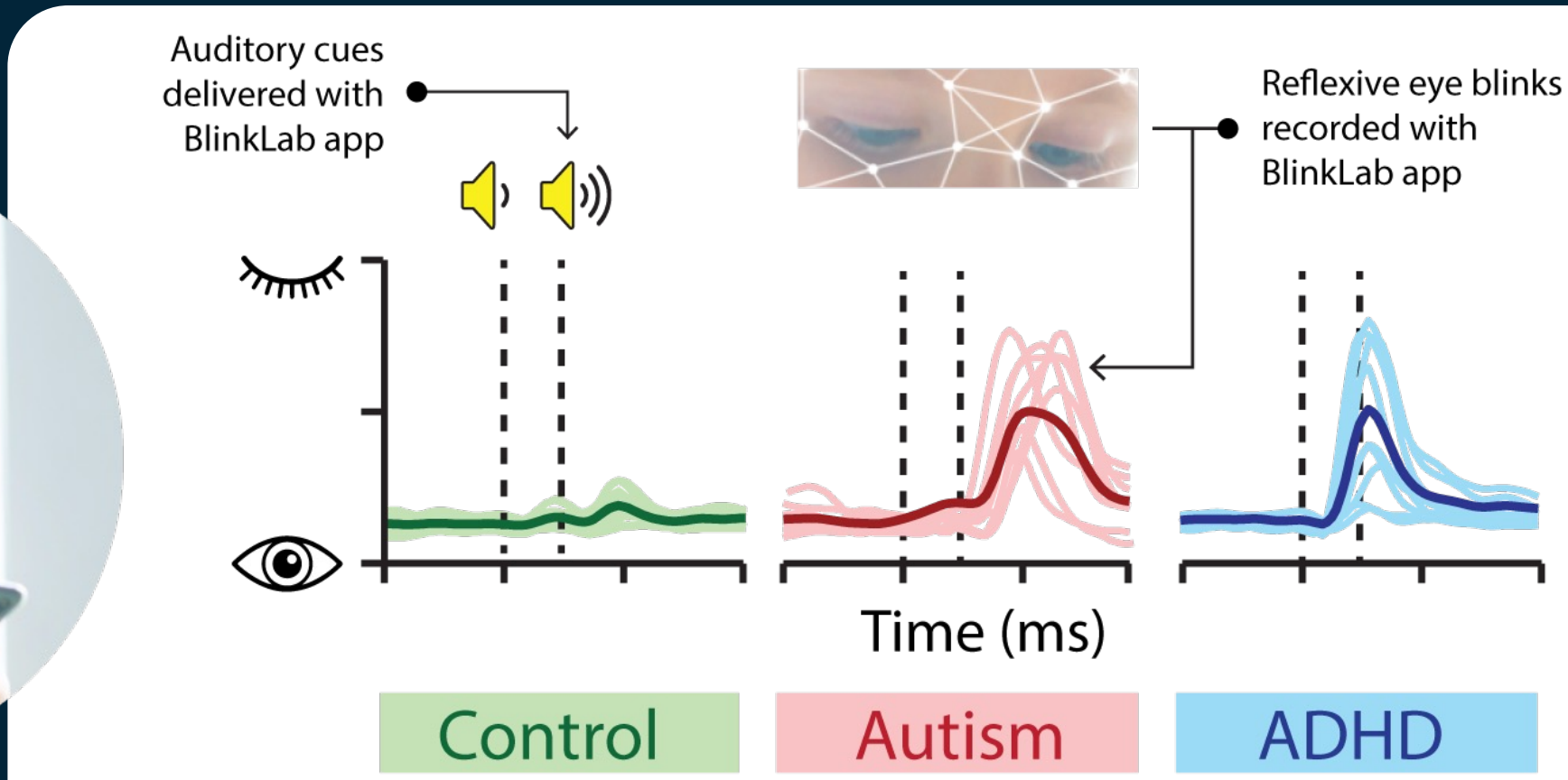
Prof. Javier Medina

Professor in neuroscience at Baylor College of Medicine in Houston.

BCM Baylor College of Medicine

World leading scientists, strategic and commercial advisors.

Our AI technology detects autism and ADHD



BlinkLab precisely measures sensory sensitivity in people with autism and ADHD.

Catalysts and milestones for Dx 1 autism and Dx 2 ADHD models

News pipeline on updates our regulatory studies on autism and ADHD and new partnerships

	BlinkLab Dx 1 – Autism Model	Calendar Year
Pilot Study	Release of Pilot Study Results	4Q 2025
Pilot Study	Submit Pilot Study results for CE/MDR clearance	2Q 2026
Pivotal Study	Finish onboarding of US clinical sites for Pivotal Study	4Q 2025
Pivotal Study	Start Pivotal Study (i.e. first patient tested)	1Q 2026
Pivotal Study	Complete Pivotal Study (i.e. last patient tested)	3Q 2026
Pivotal Study	Submit Pivotal Study results to FDA	4Q 2026
Pivotal Study	Milestone: FDA responses on 510(k) clearance for Dx 1	1Q 2027

BlinkLab Dx 2 – ADHD model	Calendar Year
Complete European ADHD Study	1Q 2026
Submit ADHD study results for CE/MDR clearance	2Q 2026
Onboarding of US clinical trial sites for Pivotal Study	3Q 2026
Start Dx 2 Pivotal Study (i.e. first patient tested)	1Q 2027
Complete Dx 2 Pivotal Study (i.e. last patient tested)	3Q 2027
Submit Dx 2 Pivotal Study results to FDA	4Q 2027
Milestone: FDA responses on 510(k) clearance for Dx 2	1Q 2028

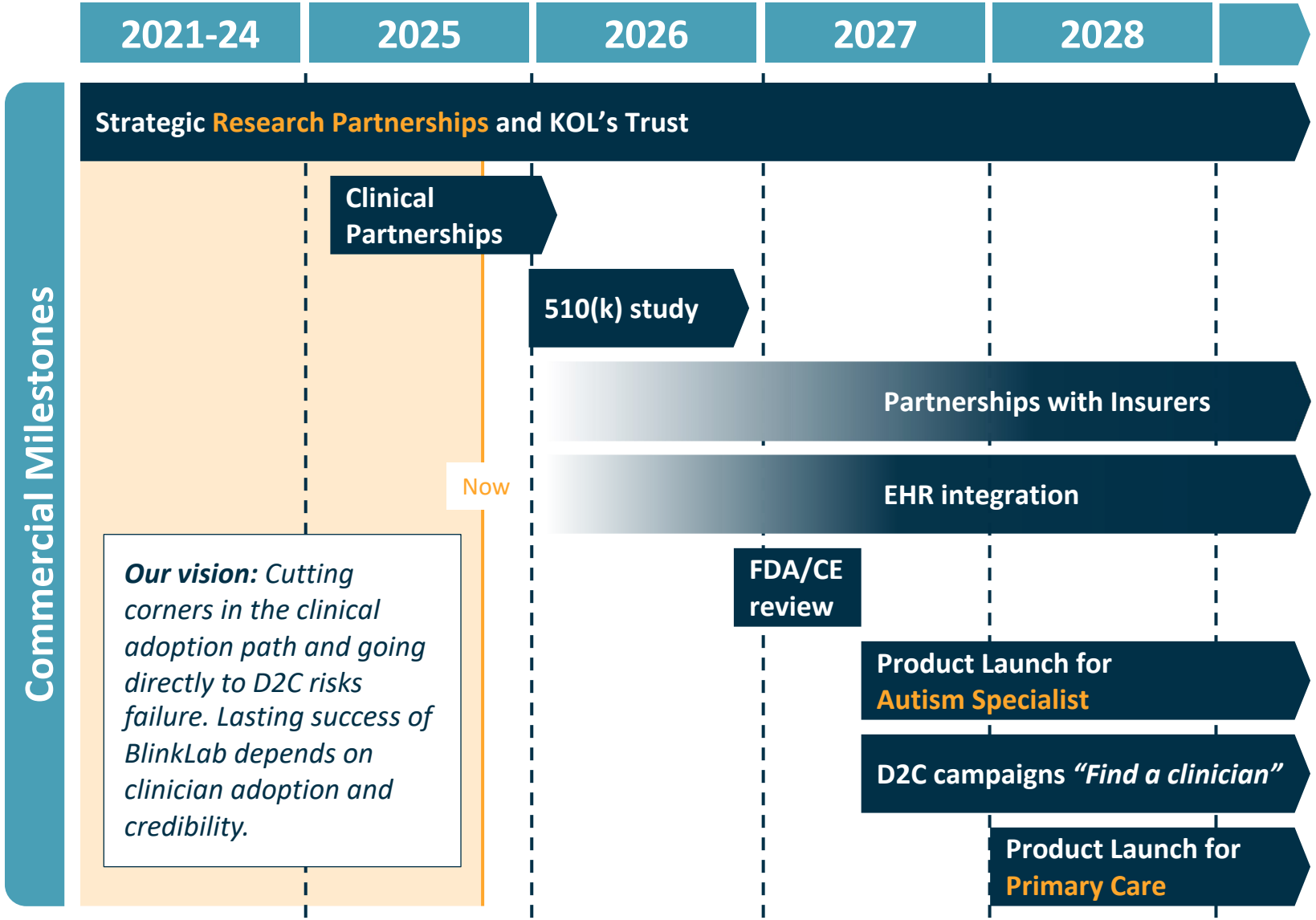
Note: This news pipeline excludes updates from the ongoing European Adult Autism Study, the Australian Monash Magnet Study, and the European Dementia Study.

blinklab

BlinkLab's GTM strategy follows a traditional medical adoption curve

Research -> Autism Specialist -> Primary Care (GP/PCP)

** The GTM plan shown on this slide applies to Dx 1 in the US market only. The GTM approach for Dx 2 and/or non-US markets will follow a similar structure.*



Since its foundation, BlinkLab is building trust through strategic collaborations with leading research centers and KOLs, driving early adoption and clinical credibility via **free SaaS access**. Research adoption will smoothen clinical adoption.

Onboarding leading centers is essential for post-clearance adoption. All autism centers participating in the 510(k) trial are strategically chosen for their research expertise and leadership within the field.

The 510(k) trial will be conducted with a leading CRO, following the same rigorous standards and tools used by major pharma-research companies. This approach ensures high data integrity and makes BlinkLab an attractive acquisition target.

Early engagement (prior to regulatory clearance) to **establish reimbursement pathways.** Pursue CPT/HCPCS codes and demonstrate cost-effectiveness through health economics and outcomes research (HEOR).

Strategic Electronic Health Record (HER) partnerships, such as Epic integration, enhance adoption by fitting seamlessly into existing clinical workflows. No new tools or logins required for healthcare providers.

Clinical validation, risk analysis, and compliance documentation, ensuring patient data is encrypted, securely stored, and integrated into the FDA post-market registry (PUPIL) to support ongoing regulatory review.

B2B commercialization pathway leveraging initial pilot access for early adopters, transitioning to paid institutional licenses. Market size: 600K children annually. Adoption among autism specialists will enable future expansion to GP/PCP users.

D2C campaigns will inform parents which centers use BlinkLab, highlighting faster diagnostic outcomes and driving competition among sites. A *"Find a Clinician"* tool will capture caregiver leads and auto-match them to local providers.

B2B expansion into primary care targets a market of 3.6M children in the U.S. born annually. Empowering primary care pediatricians (PCPs) and GPs aligns with the ongoing trend of shifting diagnosis from specialists to primary care.

Intellectual property

Our patents prohibit other parties to conduct neurometric testing using mobile devices.

BlinkLab has consistently prioritized the development and protection of its intellectual property since its seed funding round in August 2021. Our capital investments sourced from seed investors, government funding, and industry sponsorships - have been primarily utilized for IP and software development.

We are represented by the US-based law firm, Meagher Emanuel Laks Goldberg & Liao, LLP, which ensures our IP protection. We have filed National Stage Applications for 2020-2021 patents across various jurisdictions including the United States, Japan, Canada, Australia, Korea, and the European Patent Office (EPO) in March 2023.

Our portfolio comprises patents filed both by Princeton University, under an exclusive license agreement, and BlinkLab itself. These patents range from systems for neurobehavioral testing to methods for measuring emotional engagement, all of which firmly establish our innovation and leadership in the field.

Patents filed by Princeton University, with an exclusive license agreement in place between Princeton University and BlinkLab:

- PCT application number PCT/US2021/058698 Filed November 10, 2021, entitled “System and Method for Remote Neurobehavioral Testing”
- US patent application number 18/036,009 Filed May 9, 2023, entitled “System and Method for Remote Neurobehavioral Testing”
- European patent application number 21892692.1 Filed March 31, 2023, entitled “System and Method for Remote Neurobehavioral Testing”
- Japanese patent application number 2023-528017 Filed May 10, 2023, entitled “System and Method for Remote Neurobehavioral Testing”
- Canadian patent application number 3,195,596 Filed April 13, 2023, entitled “System and Method for Remote Neurobehavioral Testing”
- Korean patent application number 10-2023-7018839 Filed June 2, 2023, entitled “System and Method for Remote Neurobehavioral Testing”
- Australian patent application number 2021378273 Filed May 23, 2023, entitled “System and Method for Remote Neurobehavioral Testing”

Patents filed by BlinkLab:

- US Provisional patent application number 63/218,607 Filed on November 30, 2022, entitled “Psychopharmacological System and Method Using Eyelid Tracking”
- US Provisional patent application number 63/460,451 Filed on April 19, 2023, entitled “Method And System For Measuring Emotional Engagement”
- US Provisional patent application number 63/548,542 Filed on February 1, 2024, entitled “System And method For Detecting Neurological Condition”

Other Applications for BlinkLab and Trials Underway

➢ European ADHD Study

- **Collaborator:** Mental Care Group
- **Goal:** Develop BlinkLab Dx 2 - ADHD Model
- **Status:** Recruiting - 300 children will have completed all testing in mid-Q4

ASX Announcement, 30th Jul 2024;
BlinkLab Partners with Mental Care Group in Europe

➢ European Dementia Study

- **Collaborator:** Erasmus University Medical Center
- **Goal:** Early neurometric markers for frontotemporal and Alzheimer's dementia
- **Status:** Recruiting presymptomatic and symptomatic participants

ASX Announcement, 5th Jun 2024;
BlinkLab signs Clinical Study Partnership with Erasmus MC

➢ Australian MAGNET Study

- **Collaborator:** Monash University
- **Goal:** Genotyping and deep behavioral phenotyping of autism and ADHD
- **Status:** Recruiting in the 1000-family study

ASX Announcement, 13th Nov 2024;
BB1 to Participate in Monash Uni Autism/ADHD MAGNET Project

➢ European Adult Autism Study

- **Collaborator:** Amsterdam University
- **Goal:** Exploring BlinkLab neurometrics in adults with autism
- **Status:** Recruiting in 200-participant study

ASX Announcement, 19th Mar 2025;
Blinklab Expands Autism Diagnostics into Adults

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For further information please contact:

Henk-Jan Boele, MD, PhD

Cofounder and CEO

henkjan@blinklab.org

M: +31 (0) 611 132 247

Brian Leedman

Non-Executive Chairman

brian@blinklab.org

M: +61 (0) 412 281 780

info@blinklab.org

@BlinkLab.App

@Blink_Lab

BlinkLab Limited (ASX:BB1)

@BlinkLab Ltd

@BlinkLab2193