

## blinklab (ASX:BB1)

# Early and Accurate Diagnosis of Autism and ADHD

Introducing an Al-powered smartphone platform for neurological testing



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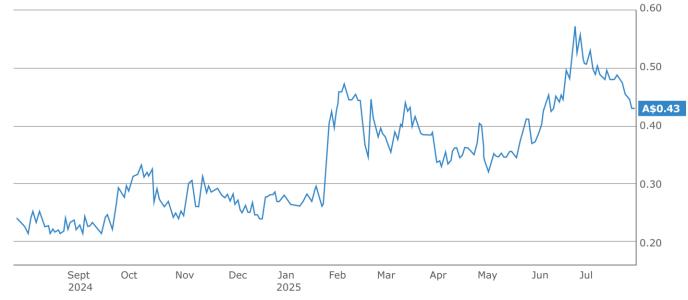
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### **Corporate Snapshot**

## blinklab

#### Next-Generation Digital Solutions for Neurodevelopmental Health

CAPITAL STRUCTURE	
ASX Code	BB1
Shares on Issue	124.2M
Options on Issue	39.3M
Founders'/ Directors' percentage	24%
Market Cap (30 July 2025)	\$55.7M
Cash	\$8.7M





Henk-Jan Boele, Cofounder & 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 & CSO

PhD, Assistant Prof. of Neuroscience, Erasmus MC



Peter Boele Cofounder & CTO

MA, Startup Entrepreneur, PhD Candidate at Erasmus MC



Brian Leedman
Non-Executive Chairman

Experienced Chairman and Co-Founder of six 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:**

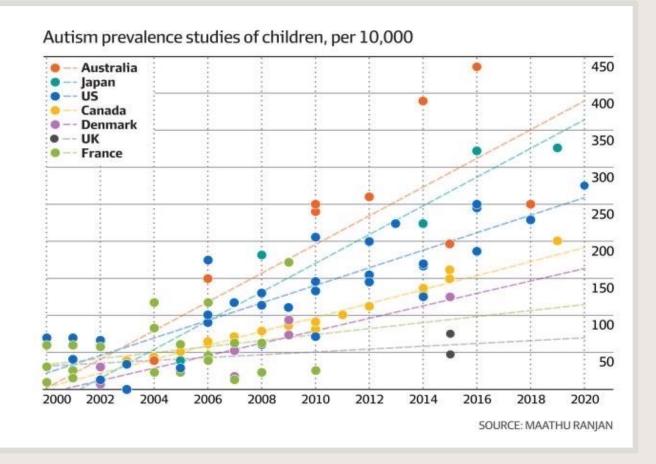
- Social development
- Language development
- Sensory processing
- Behavior and interests



## **Economic Burden of Autism in USA: \$700B in 2024**

"The economic burden is significant and alarming" 1

- Prevalence has grown up to 2-4% among children<sup>2</sup>
- Autism healthcare expenses are soaring<sup>3</sup>
  - Costs for an autism diagnostic evaluation:
     \$1,000 to \$7,000
  - Lifetime cost for individual with ASD:
     \$3.6M<sup>3</sup>



<sup>&</sup>lt;sup>1</sup> Leigh and Du (2015), Forecasting the economic burden of autism in 2015 and 2025 in the US, Journal of Autism and Developmental Disorder

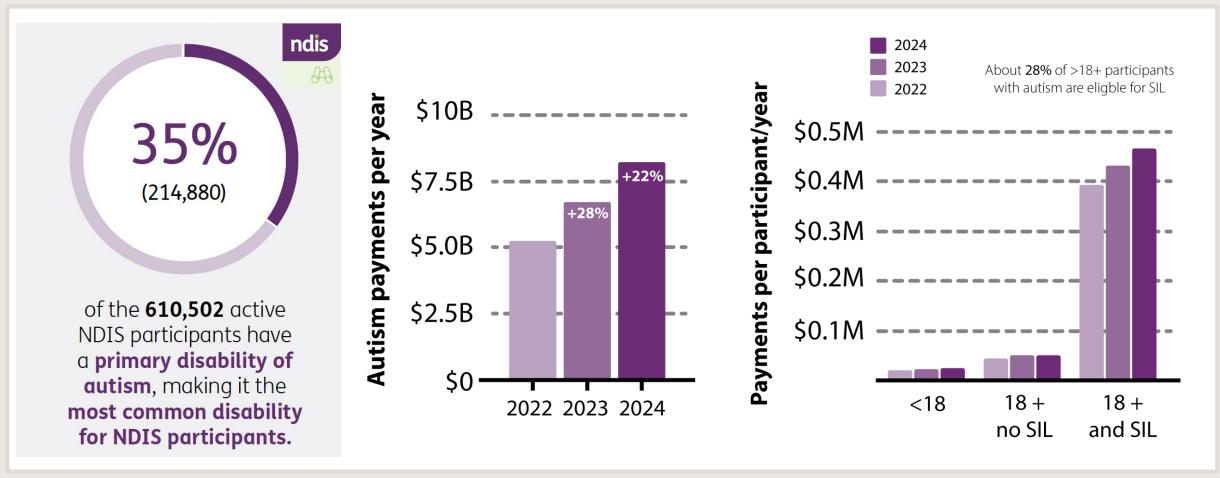
<sup>&</sup>lt;sup>2</sup> Center for Disease and Control, World Health Organization

<sup>&</sup>lt;sup>3</sup> Cakir et al. (2020) The lifetime social cost of autism: 1990-2029, Research in Autism Spectrum Disorder

<sup>&</sup>lt;sup>4</sup> National Disability Insurance Scheme (NDIS)

## NDIS Payments for Autism in Australia: A\$8.4B in 2024

NDIS payments for autism rise by more than 20% annually, with the largest share allocated to Supervised Independent Living (SIL).



# Consensus: <u>Early diagnosis</u> and intervention enhance independent living skills in people with autism.





"All children must be screened for autism at ages 18 and 24 months"

➤ Market size = Total number of children born each year: - US 3.6M

- EU 3.8M

- AU 287K

#### More reading:

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.

# THE AUSTRALIAN

YOUNG CHILDREN JOINING SCHEME 400 PER CENT HIGHER THAN EXPECTED

## NDIS misses autism checks

#### EXCLUSIVE

STEPHEN LUNN SARAH ISON

autism or developmental delay 3211 expected. An additional who should not be on the \$42bn 23.766 people across all age groups National Disability Insurance joined the scheme in 2022-23 with Scheme are still getting taxpayer - developmental delay as their prisupport because public servants many disability, when just 5440 are failing to reassess their cases.

The NDIS caseload surged last year, as the number of children up Insurance Agency's inability to to six years old who joined the predict the recent massive inscheme skyrocketed 400 per cent - creases, the scheme actuary still more than expected.

nancial sustainability report, 0-14 on the NDIS are likely to be ment on Wednesday and con- Reynolds led a united front of scheme actuary David Gifford removed each year for the next ceded \$60bn in projected savings. Coalition and Greens senators atnotes greater numbers of children three years as staffing resources would likely disappear altogether tacking the Albanese Covern-

with developmental delay joining the scheme in 2022-23 pushed numbers significantly higher than anticipated

More than 16,500 0 to 6-yearolds joined the NDIS last financial Thousands of children with year, 415 per cent greater than the were anticipated.

Despite the National Disability

#### Freed non-citizen detainees accused of 27 crimes

DAVID MURRAY JESS MALCOLM

Non-citizens released into the community after the High. Court's "NZYO" ruling in November have since been accused of committing 27 crimes, with more than 100 of

The Australian Federal

Police's Grant Nicholls told a Senate estimates committee on Tuesday night that as of last Friday, the AFP had received 27 reports of crimes involving former detainces, Seven were commonwealth prosecutions, 18 were state and territory prosecutions and one matter was under consideration.

FULL REPORT P5 COMMENT P5

projects between five and six per ramp up. The revelations came as if Labor's efficiency measures fail. In the latest NDIS annual fi- cent of the 300,000 children aged NDIS executives fronted parlia- Former NDIS minister Linda

contain the scheme's growth over something like that". the next decade.

Senator Reynolds grilled officials on whether the scheme was still running "above expectations". to which she was told the cost of ments the officials refused to table the NDIS was 0.9 per cent above - the documents or provide budget expectations as of last September. data over the past four months.

The WA senator also asked the NDIS executives what would John criticised the agency for sethappen if Lahor's \$720m in bud-ting a "dangerous precedent". geted "efficiency measures" - while Senator Reynolds blasted which the government says what she called an "unprewill pet the set ------

to 8 per cer successful. "It will re

ima not bein \$60bn ... in Reynoldssai Mr Giffo

them receiving welfare benefits. ment's secrecy over its plans to quick calculations, yes, it would be lescent cases saw an overall in-

NDIS's third quarter report was available and in the hands of commonwealth and state govern-

Greens senatur Jordon Steele-papersays.

crease in NDIS participant num-Despite admitting that the bers in 2022-23 of 75,847, 32 per cent more than the 57,639 the actuary had expected.

> "New entrants with developmental delay and autism accounted for 70 per cent of total new entrants in 2022-23," the actuary's

About 12 per cent of all boys aged5-7 are on the NDIS.

Total scheme numbers set at 610,500 at the end of 2022-23 and

#### Average wait time for autism THE UNIVERSITY OF SYDNEY assessments in children is over 3 years

6 February 2023

New research has revealed that children wait 3.5 years on average for neurodevelopment assessments.

## Autism diagnosis is expensive, inefficient, and often late

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

#### 3-5 years of uncertainty for family and child



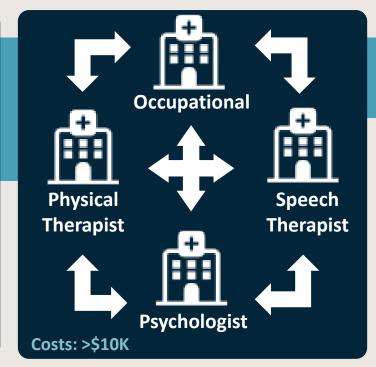
Parents Concerned

Early signs of autism around age 1-2 years.

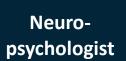


Primary Care or GP

Who screens for autism signs but cannot diagnose.



X



Using subjective instruments, no biomarker available!.

**Costs: \$2-7K** 



Late autism diagnosis

Around the age of 5-6 years, but often way later.



Late Intervention

Yielding poor clinical results and leading to high expenses later in life.

Costs: \$3.6M

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** 



#### Neuropsychologist

Using clinical judgement and subjective rating instruments.



### Early autism diagnosis

Diagnostic certainty at the age of 2-3 years.



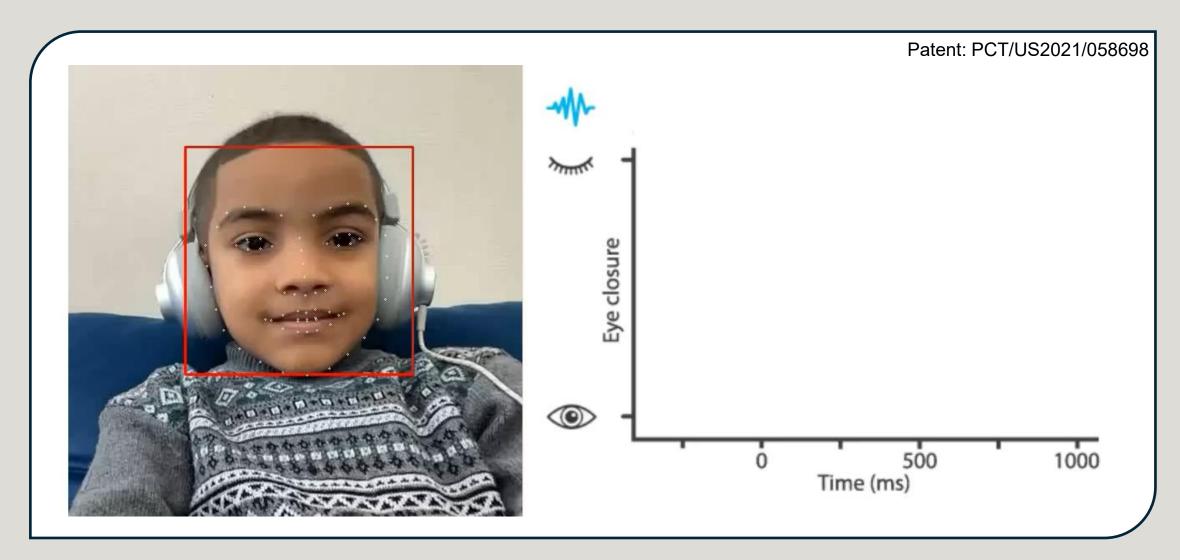


## Early and personalized intervention and accurate treatment monitoring

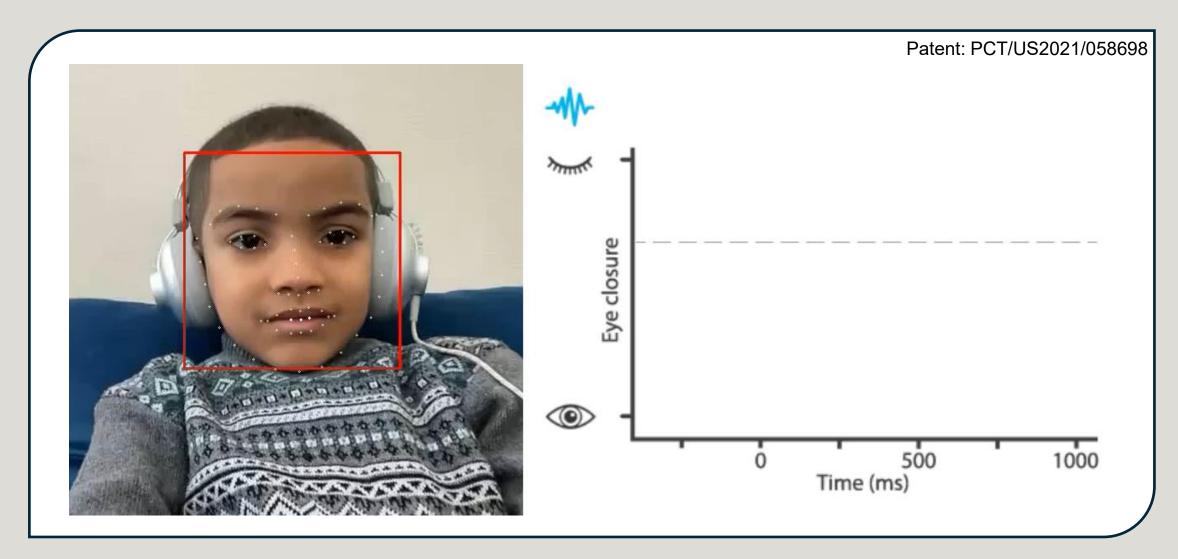
Early therapy improve outcomes, helping children develop crucial skills and reducing long-term support needs. This will significantly reduce in costs by 40-60% later in life.

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.

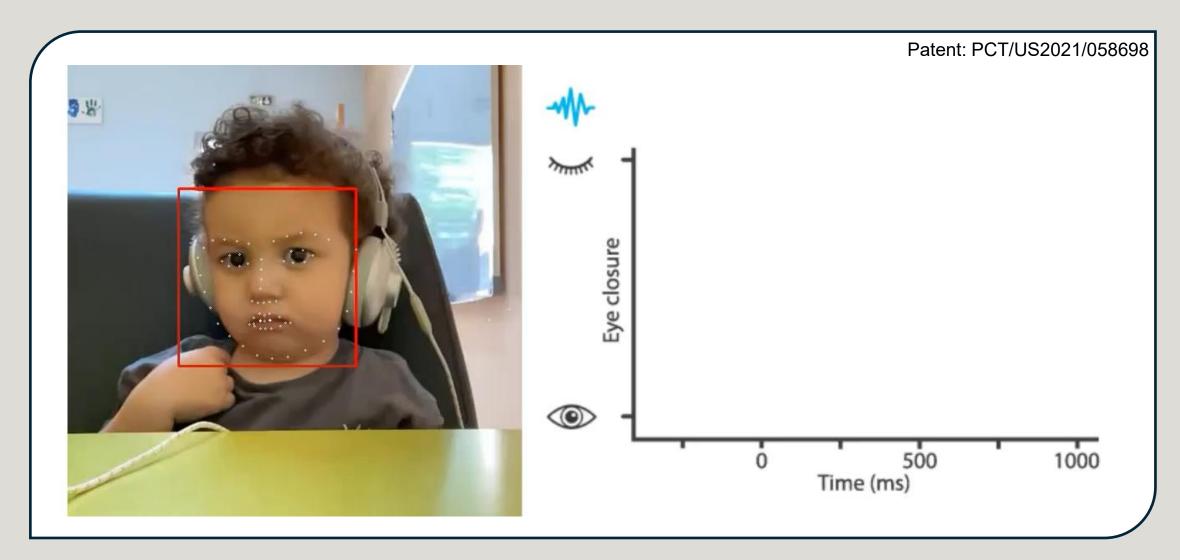
## BlinkLab PPI test – Neurotypical Control (4 years old)



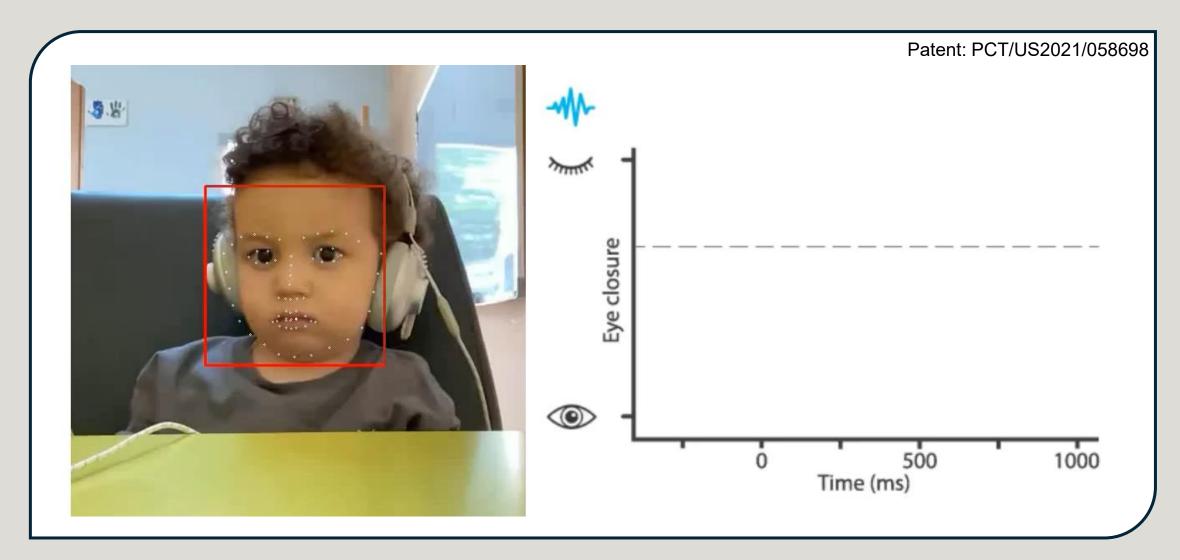
### BlinkLab PPI test – Neurotypical Control (4 years old)



## BlinkLab PPI test – Autism Spectrum (2 years old)



## BlinkLab PPI test – Autism Spectrum (2 years old)



## 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**.

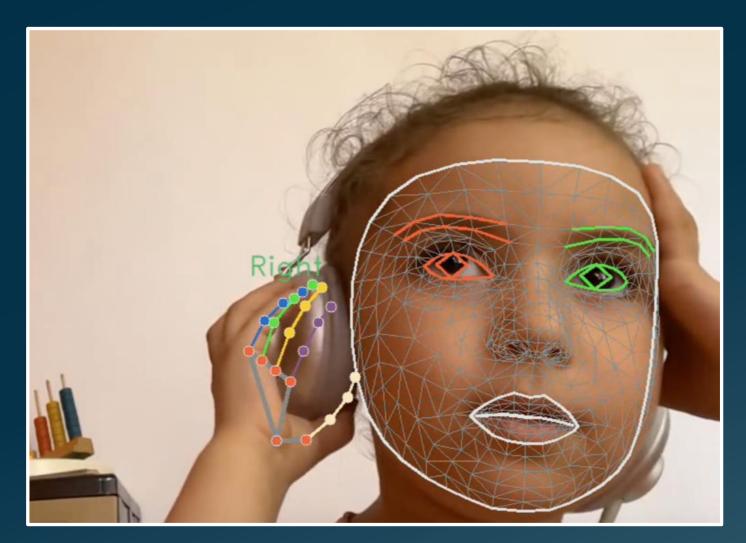
#### **Biomarker Detection**

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

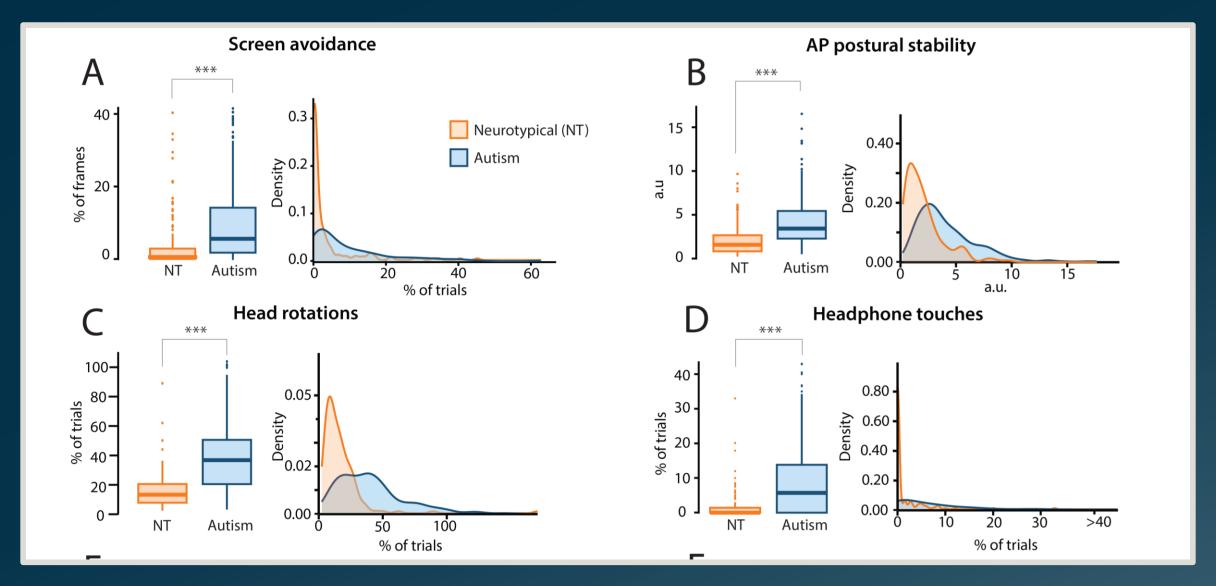
#### **Evaluates brain function**

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

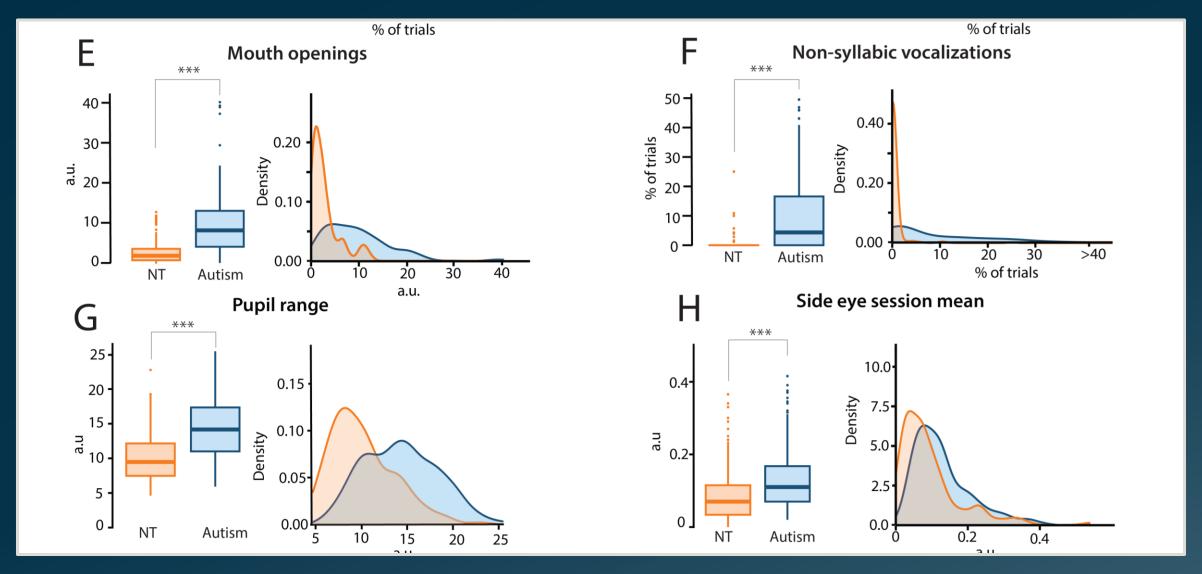
# Beyond blinks: Tracking of vocal responses and hand/head movements as objective markers for autism



### General behavioral measures



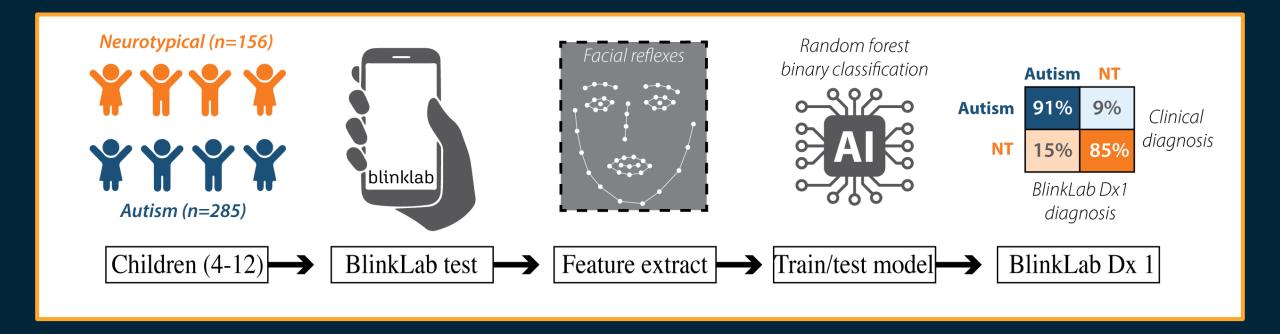
## **Vocalizations and Eye Movements**





# Large Study Validates and Enhances BlinkLab's Accuracy in Detecting Autism in Children

Released on 18 November 2024



In a sample of 441 children, BlinkLab achieved a sensitivity of 91% and specificity of 85%

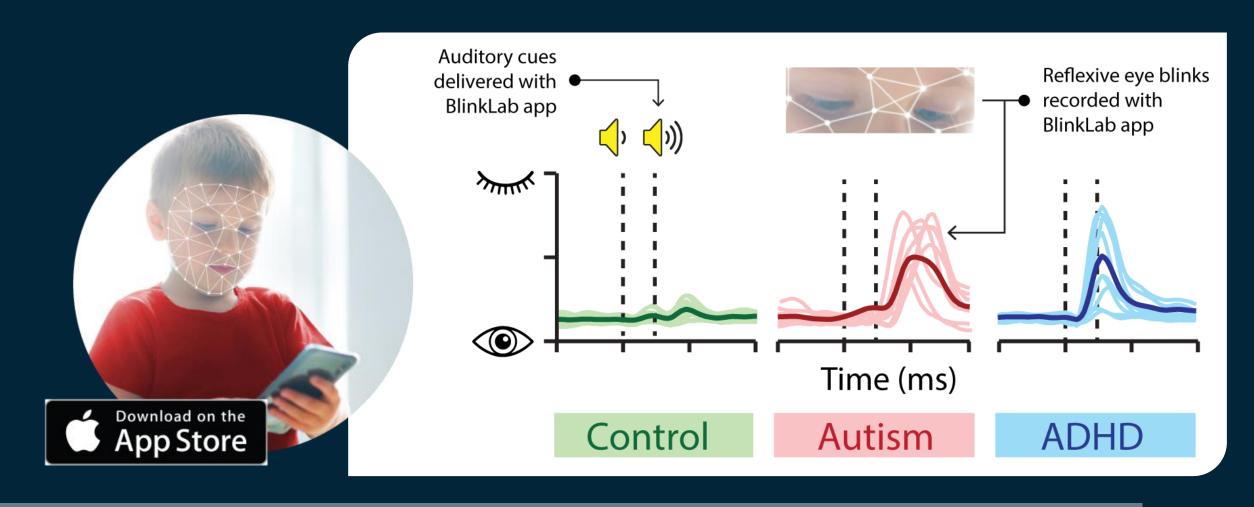
## BlinkLab Outperforms FDA-approved Digital Peers

We are leaders in the digital diagnostics and therapeutics space

	blinklab	cognoa	EarliTec Diagnostics Inc.
<b>Sensitivity</b>	91%	52%*	71%
Specificity	85%	19%*	81%
Smartphone-based	Yes	Yes	No
FDA approval	No - 510(k)	Yes - De Novo	Yes - 510(k)

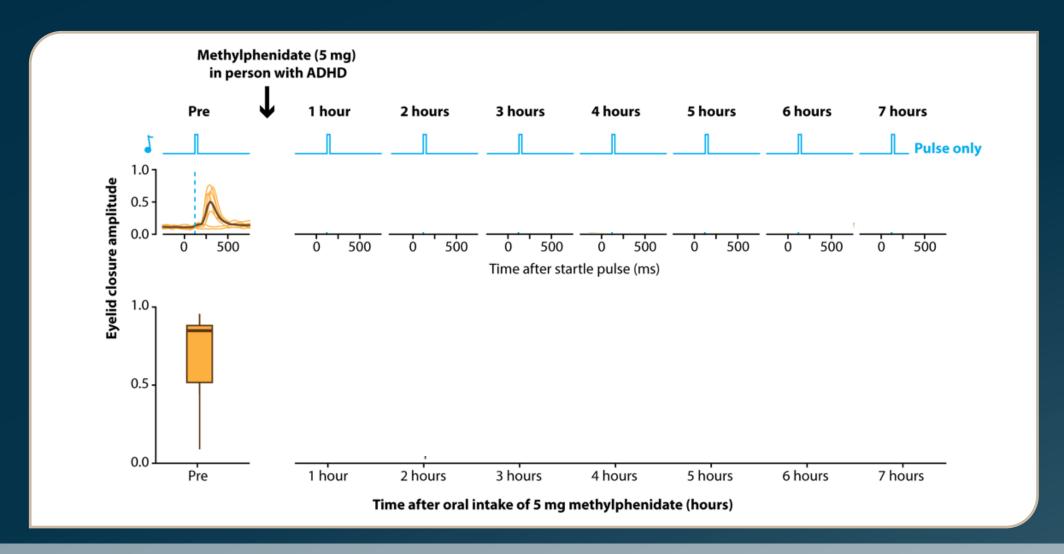
<sup>\*</sup> Calculated over all study completers (Cognoa's device yielded indeterminate results in 68% of cases)

## Our AI technology detects autism and ADHD



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

## First product to monitor the effect of therapy in real-time



Real-time drug monitoring offers a path to even larger recurring revenues via subscription-based models.

### 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 six ASX listed healthcare companies including digital healthcare company ResApp Health, acquired by Pfizer for \$180M in 2022.





#### **Company Director**



Jane Morgan

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



#### **Company Director**



**Richard Hopkins** 

Experienced biopharmaceutical executive with over 20 years in corporate leadership roles with public biotechnology companies.





#### Scientific advisor



**Prof. Samuel Wang** 

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



#### Scientific advisor



Prof. Chris De Zeeuw

Professor of Neuroscience at Erasmus MC and vicedirector of the NIN (Netherlands Institute of Neuroscience).



#### Scientific advisor



**Prof. Javier Medina** 

Professor in neuroscience at Baylor College of Medicine in Houston.



### 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:

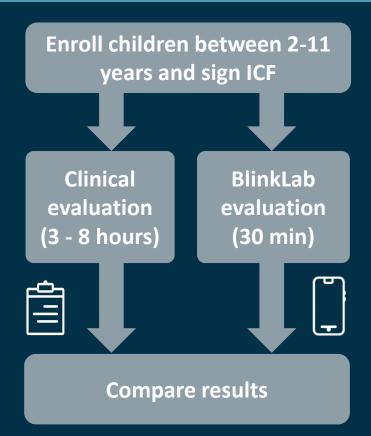
- US Provisional patent application number 63/218,607 Filed on November 30, 2022, entitled "Psychopharmacological System and Method Using Eyelid Tracking"
- US Provisional patent application number 63/460,451 Filed on April 19, 2023, entitled "Method And System For Measuring Emotional Engagement"
- US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

# Discuss the progress and the structure of the US FDA study. What is the timing of the US FDA study?



\* completed

510(k) Trial: Prospective, multicenter, doubleblinded, within-subject comparison study



Main study: N = 260 children with autism, and N = 260 children without autism.

Q4 2024 - CRO assigned\* - IRB approval for initial 100-patient study\* - 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 initial study\* Q2 2025 - IRB approval for main 520-patient study - Onboarding clinical and research sites for main study Q3 2025 - Results from initial study - Start main study Q2 2026 - Results from main study - Submission to FDA

Q3 2026 - Outcome from FDA 510(k) submission

# What learnings are expected from the FDA Pilot Study first 100 participants?



- Final validation of BlinkLab Dx 1 in a 'real-FDA-study-situation' (to be announced Q3 2025)
- Optimize SOPs for clinicians and families protocals
- Optimize recruitment strategies
- Evaluate and optimize usability of the Blinklab platform



North Shore Pediatric Therapy (Chicago, Illinois).



#### PriMED Clinical Research Autism Device Study

Study Name: The Evaluation of the Diagnostic Accuracy of BlinkLab's Digital Assessments for Autism

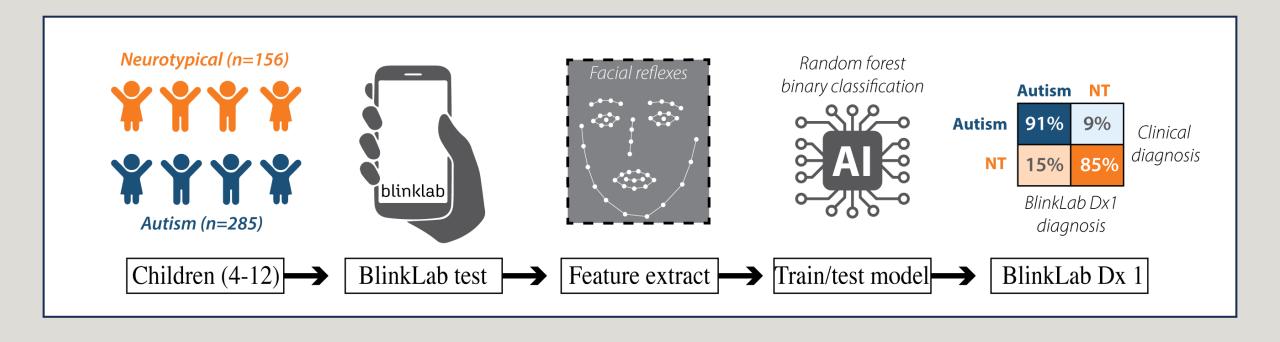
#### Purpose:

PriMED is hosting a research study that is to validate whether BlinkLab's (Name of Sponsor) neurobehavioral assessments, using a computer program to measure how a child responds to different sights, sounds, and touches, as well as their repetitive behaviors. By analyzing these responses with smart computer programs (machine learning), they can reliably tell apart children with autism from those without it.

## What is the minimum level of accuracy - sensitivity & specificity? Which is more important? What has been achieved to date?



- For FDA approval, minimum requirement for both is 65%
- From clinical perspective, specificity is more important. Current questionnaire screeners aim for high sensitivity at the expense of specificity.
- To date: BlinkLab Dx 1 Sensitivity 91% and Specificity 85% based on 441 patients



## Why is there a difference between diagnosing autism in adults and in children?



	Children	Adults
Observation Source	Parents, teachers, clinicians	Self-report, limited external observation
Tools Used	ADOS, M-CHAT, Vineland	Limited, AQ, RAADS-R, interviews
Symptom Presentation	More visible behaviors	Masked, internalized symptoms
Developmental History	Actively observed	Retrospective or missing
Diagnostic Challenge	Early recognition	Masking, co-morbidity, late awareness

BlinkLab is running study with University of Amsterdam and Netherlands Autism Register on adult diagnosis, with focus on women. There is no masking possible in BlinkLab's sensory assessments.





# Discuss other applications for the technology and other trials underway.



### European ADHD Study

- o Collaborator: Mental Care Group
- o Goal: Develop BlinkLab Dx 2 ADHD Model
- Status: Recruiting. Recently expanded from 1 to 5 ADHD clinical sites, 300 children will have completed all testing in mid-Q4



### European Dementia Study

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



#### Australian MAGNET Study

- Collaborator: Monash University
- Goal: Genotyping and deep behavioral phenotyping of autism and ADHD
- Status: Recruiting in the 1,000-family study



## blinklab ASX:BB1

### For further information please contact:



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