blinklab *(ASX:BB1)*

For Early and Accurate Diagnosis of Autism & ADHD

Introducing an AI-powered smartphone platform for neurological testing

Brokers meet Biotech, 20 March 2025
Henk-Jan Boele, MD PhD

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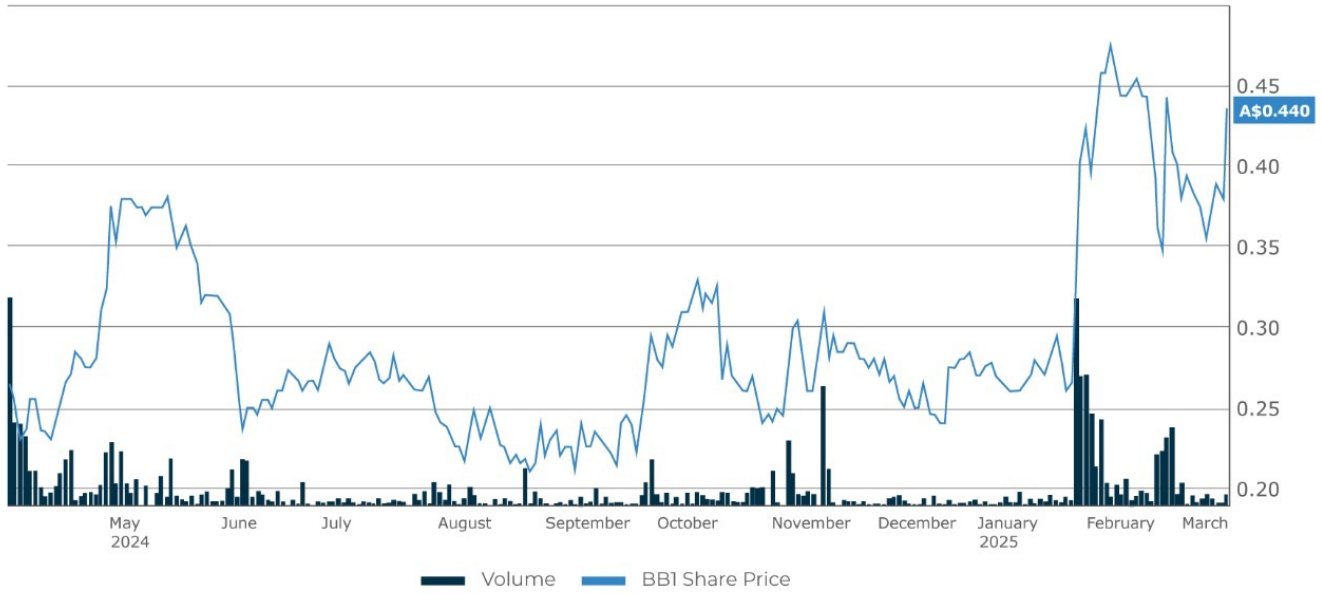
Corporate Snapshot

blinklab

Next-Generation Digital Solutions for Neurodevelopmental Health

CAPITAL STRUCTURE	
ASX Code	BB1
Shares on Issue	99.2M
Options on Issue (31 December 2024)	39.5M
Founders'/ Directors' shareholding %	37%
Market Cap (19 March 2025)	$43.6M
Cash (31 December 2024)	$4.4M



Henk-Jan Boele, CEO

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

Anton Uvarov, COO & Executive Director

MBA, PhD, Biotech Analyst with Citibank

Bas Koekkoek, CSO

PhD, Assistant Prof. of Neuroscience, Erasmus MC

Peter Boele, CTO

MA, PhD Candidate at Erasmus MC

Brian Leedman, Chair

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.

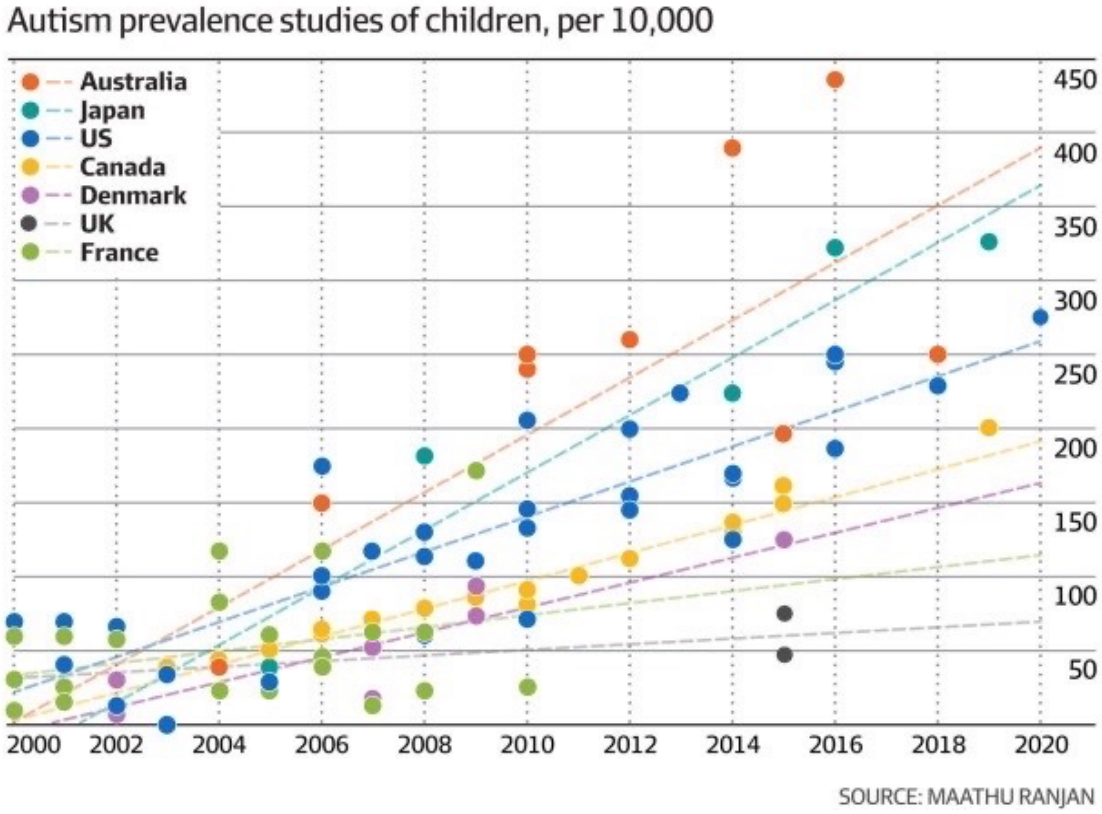
Autism can impact:

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

Economic Burden of Autism in USA – $700B in 2024

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

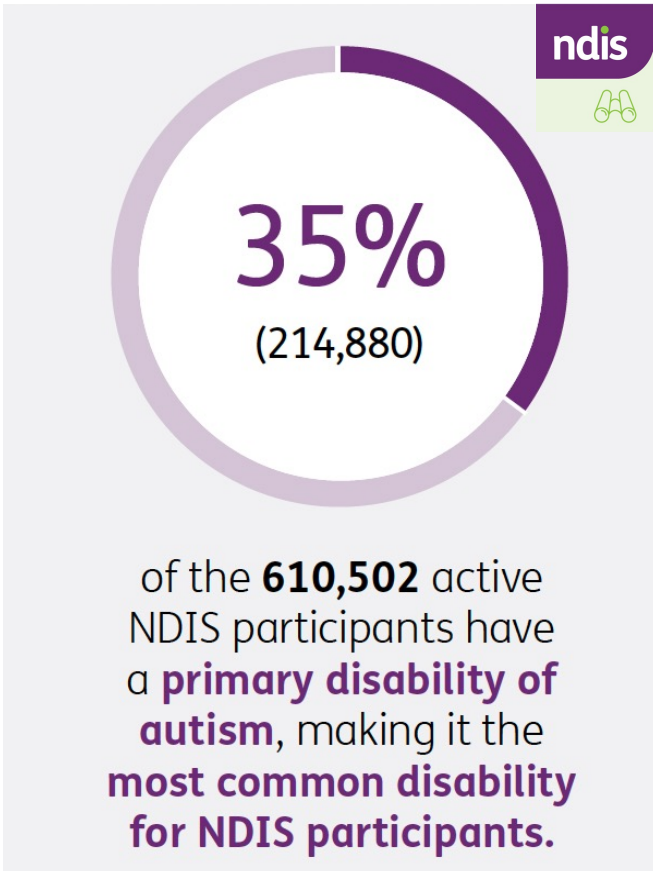
- **Prevalence has grown up to 2-4% among children**[2]
- **Autism healthcare expenses are soaring**[3]
  - *USA: Costs for an autism diagnostic evaluation:* ***$1,000 to $7,000***
  - *USA: Lifetime cost for individual with ASD:* ***$3.6M***[3]
  - *AUS: 35% of NDIS participants have autism accounting for* ***$8.4B***[4]

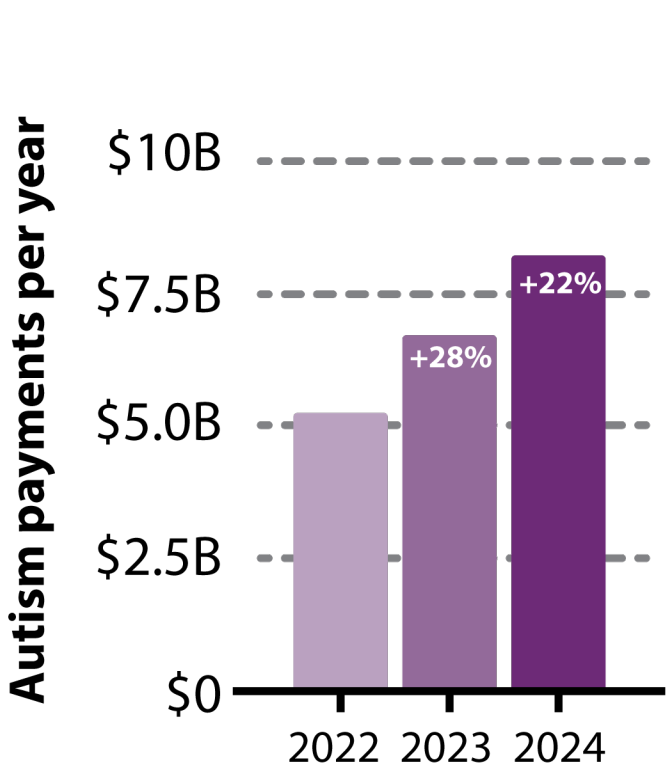


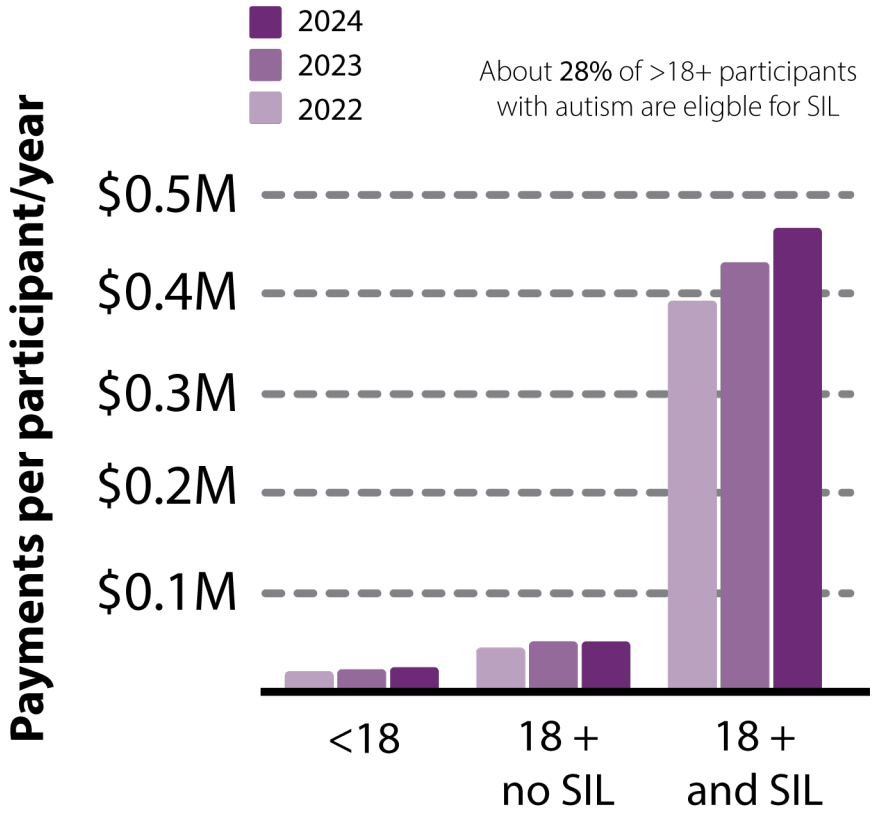
[1] *Leigh and Du (2015), Forecasting the economic burden of autism in 2015 and 2025 in the US, Journal of Autism and Developmental Disorder*
[2] *Center for Disease and Control, World Health Organization*
[3] *Cakir et al. (2020) The lifetime social cost of autism: 1990-2029, Research in Autism Spectrum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

NDIS Payments for Autism: 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).







Data extracted and visualized by BlinkLab. Extracted from National Disability Insurance Scheme (NDIS).

Consensus: Early diagnosis and intervention enhance independent living skills in children with autism.

- **Recommendation by American Association for Psychiatry:**

  "The AAP recommends that all children be screened for ASD at ages 18 and 24 months"

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®

- **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 challenge: No medical test available for autism

Governments and healthcare providers are on the lookout for disruptive technologies

THE AUSTRALIAN

YOUNG CHILDREN JOINING SCHEME 400 PER CENT HIGHER THAN EXPECTED

NDIS misses autism checks

EXCLUSIVE

STEPHEN LUNN
SARAH ISON

Thousands of children with autism or developmental delay who should not be on the $42bn National Disability Insurance Scheme are still getting taxpayer support because public servants are failing to reassess their cases.

The NDIS caseload surged last year, as the number of children up to six years old who joined the scheme skyrocketed 400 per cent more than expected.

In the latest NDIS annual financial sustainability report, scheme actuary David Gifford notes greater numbers of children with developmental delay joining the scheme in 2022-23 pushed numbers significantly higher than anticipated.

More than 16,500 0 to 6-year-olds joined the NDIS last financial year, 415 per cent greater than the 3211 expected. An additional 23,766 people across all age groups joined the scheme in 2022-23 with developmental delay as their primary disability, when just 5440 were anticipated.

Despite the National Disability Insurance Agency's inability to predict the recent massive increases, the scheme actuary still projects between five and six per cent of the 300,000 children aged 0-14 on the NDIS are likely to be removed each year for the next three years as staffing resources ramp up. The revelations came as NDIS executives fronted parliament on Wednesday and conceded $60bn in projected savings would likely disappear altogether if Labor's efficiency measures fail.

Former NDIS minister Linda Reynolds led a united front of Coalition and Greens senators attacking the Albanese Government's secrecy over its plans to contain the scheme's growth over the next decade.

Senator Reynolds grilled officials on whether the scheme was still running "above expectations", to which she was told the cost of the NDIS was 0.9 per cent above expectations as of last September.

The WA senator also asked the NDIS executives what would happen if Labor's $720m in budgeted "efficiency measures" – which the government says will get the scheme's growth down to 8 per cent a year – was not successful.

"It will result in $60bn in savings not being realised? In us being $60bn ... in the black?" Senator Reynolds said.

Mr Gifford replied "based on quick calculations, yes, it would be something like that".

Despite admitting that the NDIS's third quarter report was available and in the hands of commonwealth and state governments, the officials refused to table the documents or provide budget data over the past four months.

lescent cases saw an overall increase in NDIS participant numbers 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 paper says.

Freed non-citizen detainees accused of 27 crimes

DAVID MURRAY
JESS MALCOLM

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

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 detainees. Seven were commonwealth prosecutions, 18 were state and territory prosecutions and one matter was under consideration.

FULL REPORT P5
COMMENT P5

Average wait time for autism assessments in children is over 3 years

THE UNIVERSITY OF SYDNEY

6 February 2023

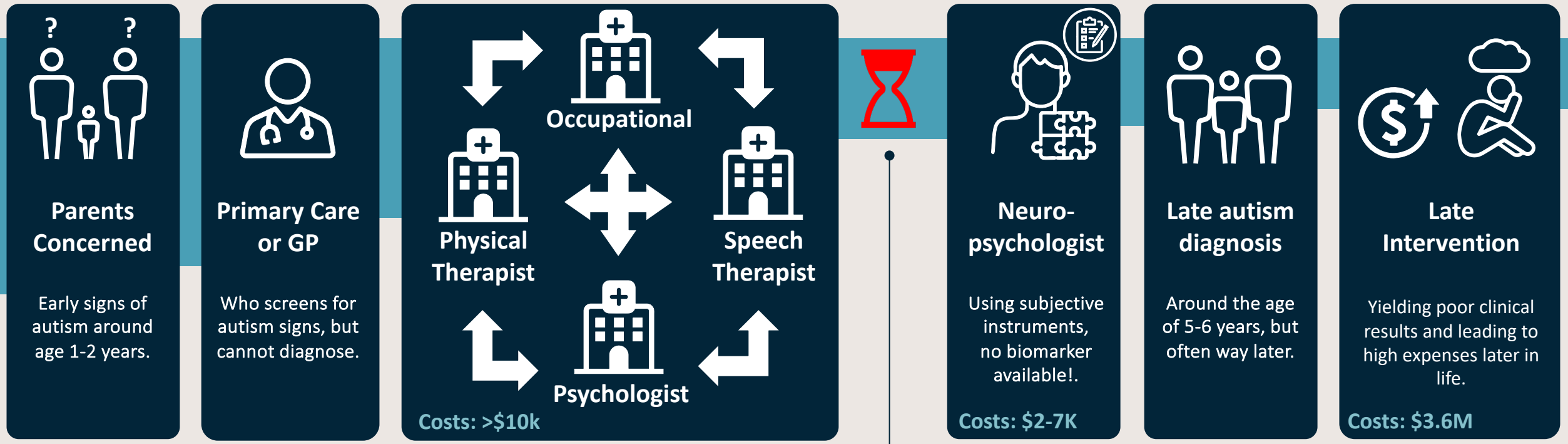
New research has revealed that children wait 3.5 years on average for neurodevelopment assessments.

Sources: Left up - The Australian 15 February 2014; Right down- Sydney University 6 February 2023, www.sydney.edu.au/brain-mind;

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



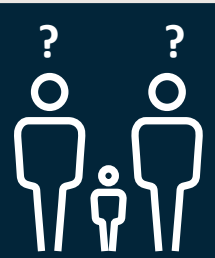
Currently, a clinical autism diagnosis requires input from multiple disciplines.

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.

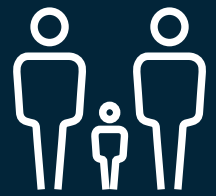
Primary Care or GP

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

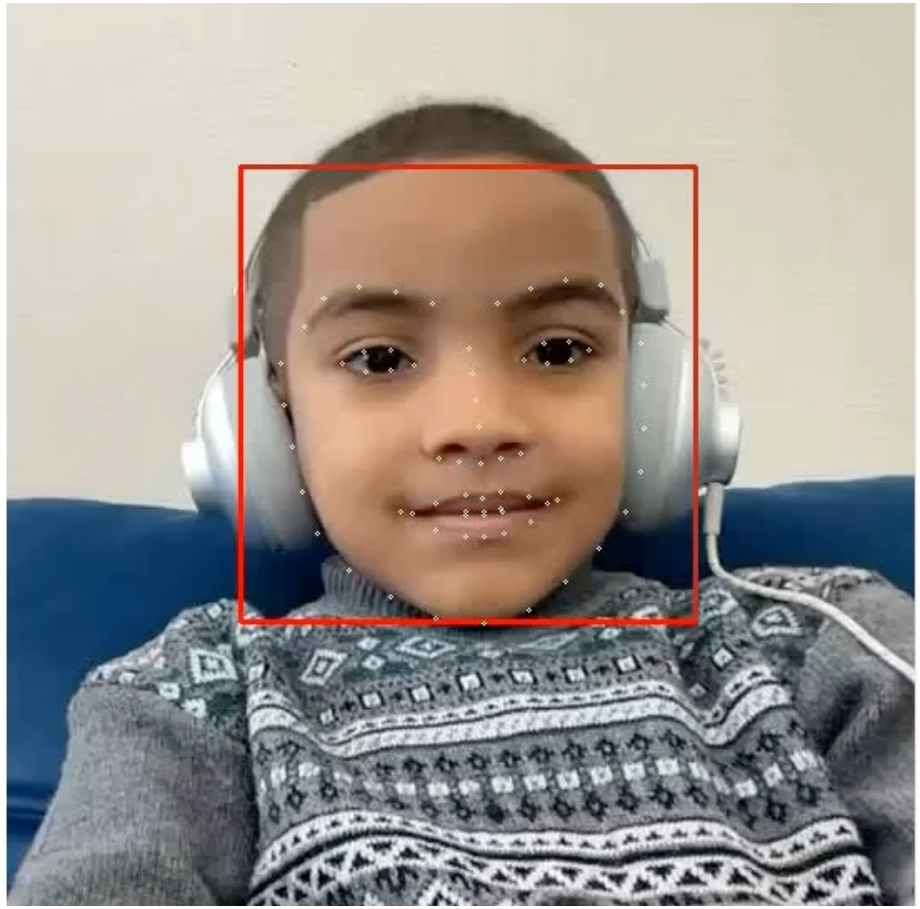
Early therapy improve outcomes, helping children develop crucial skills and reducing long-term support needs. This will significantly reduce in costs by 40-60% later in life.

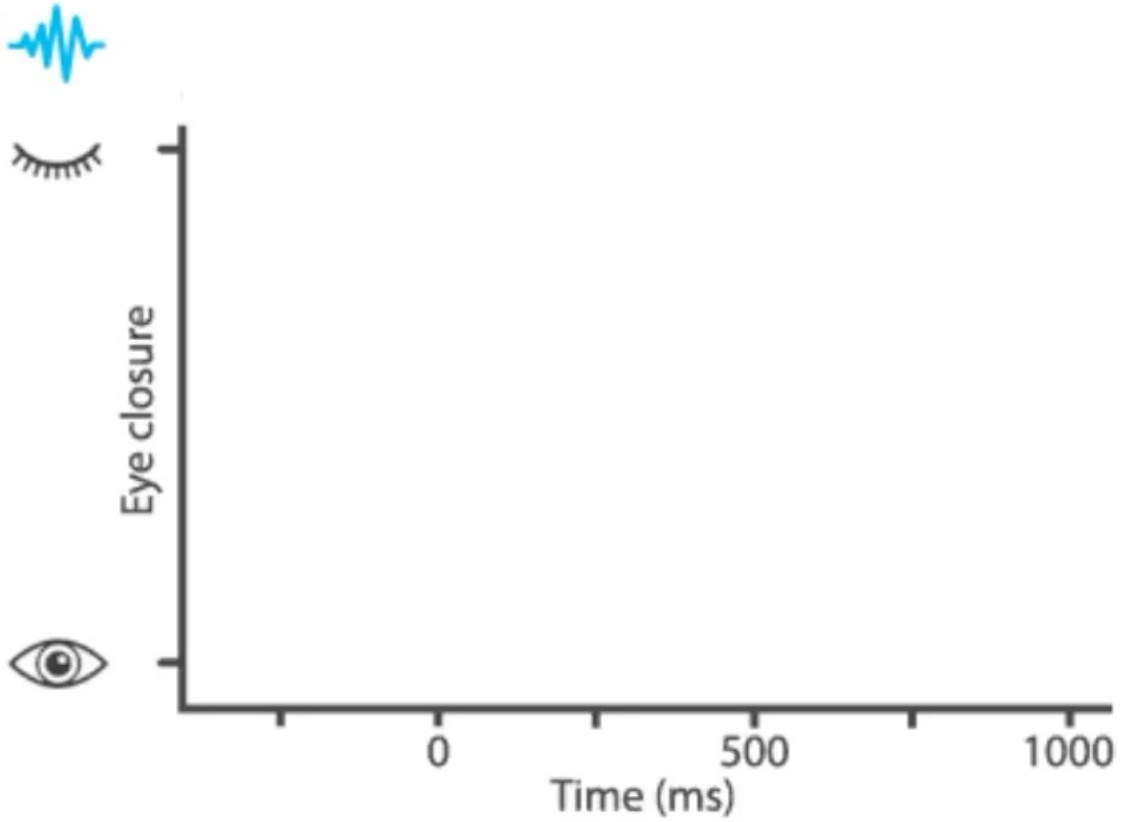
BlinkLab diagnosis is instantaneous after completing the two 15-minute video session. Only necessary specialists will need to be consulted. BlinkLab is currently conducting an FDA 510(k) study.


BlinkLab’s AI-enabled
Smartphone-based Assessment
blinklab

BlinkLab PPI test – Neurotypical Control (4 years old)

Patent: PCT/US2021/058698

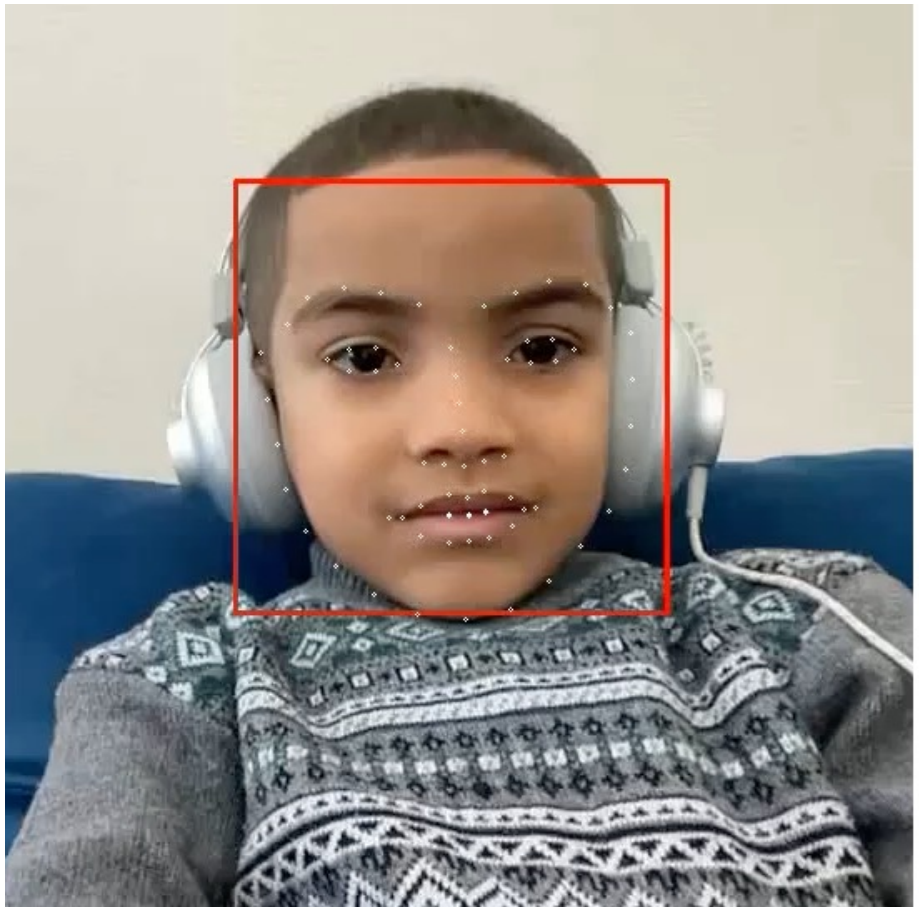


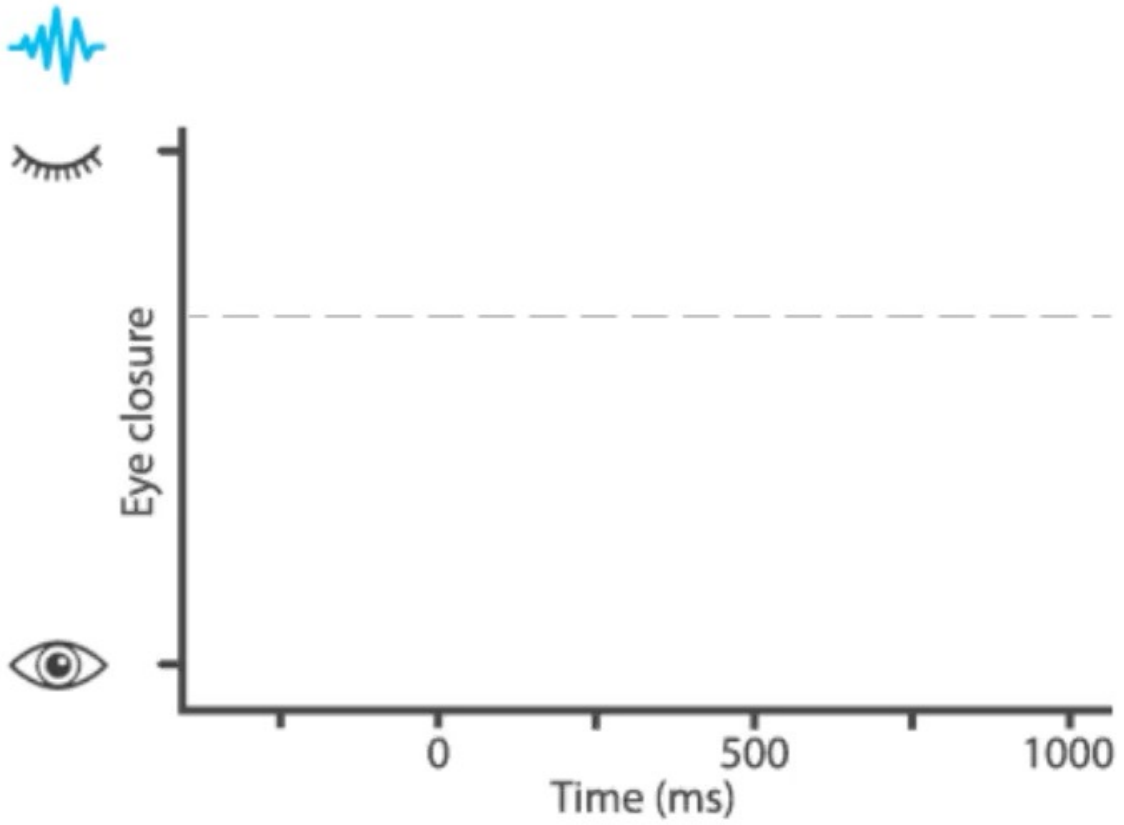


Video used with permission of caregiver

BlinkLab PPI test – Neurotypical Control (4 years old)

Patent: PCT/US2021/058698

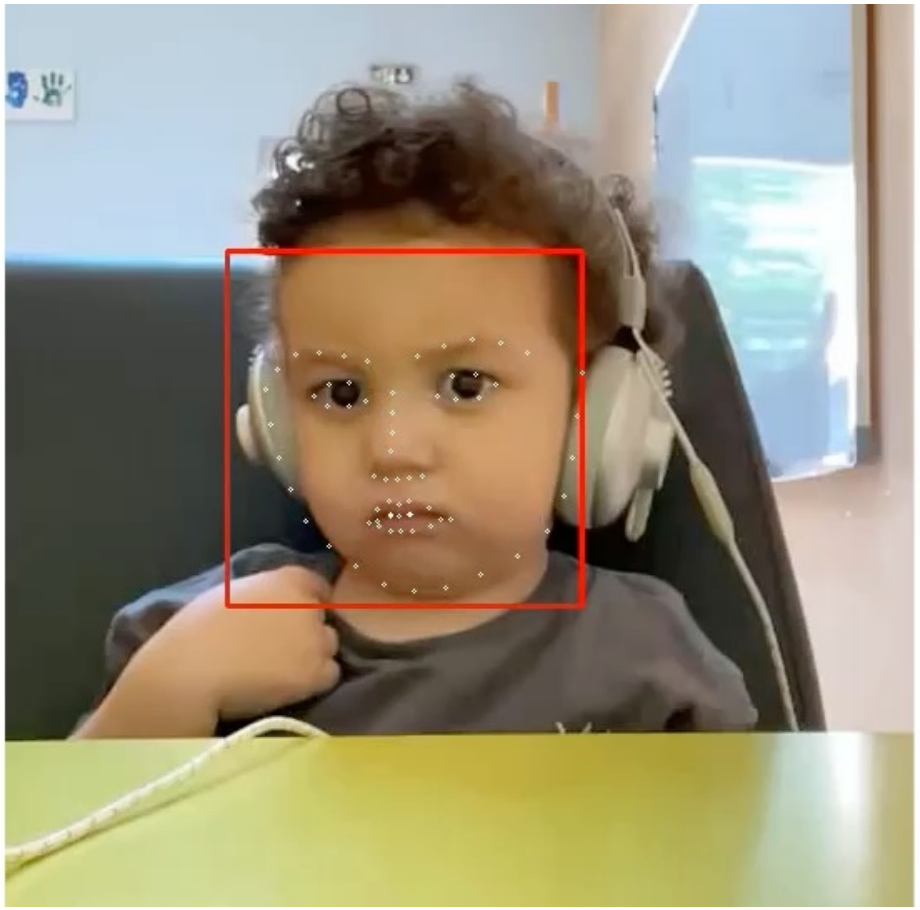


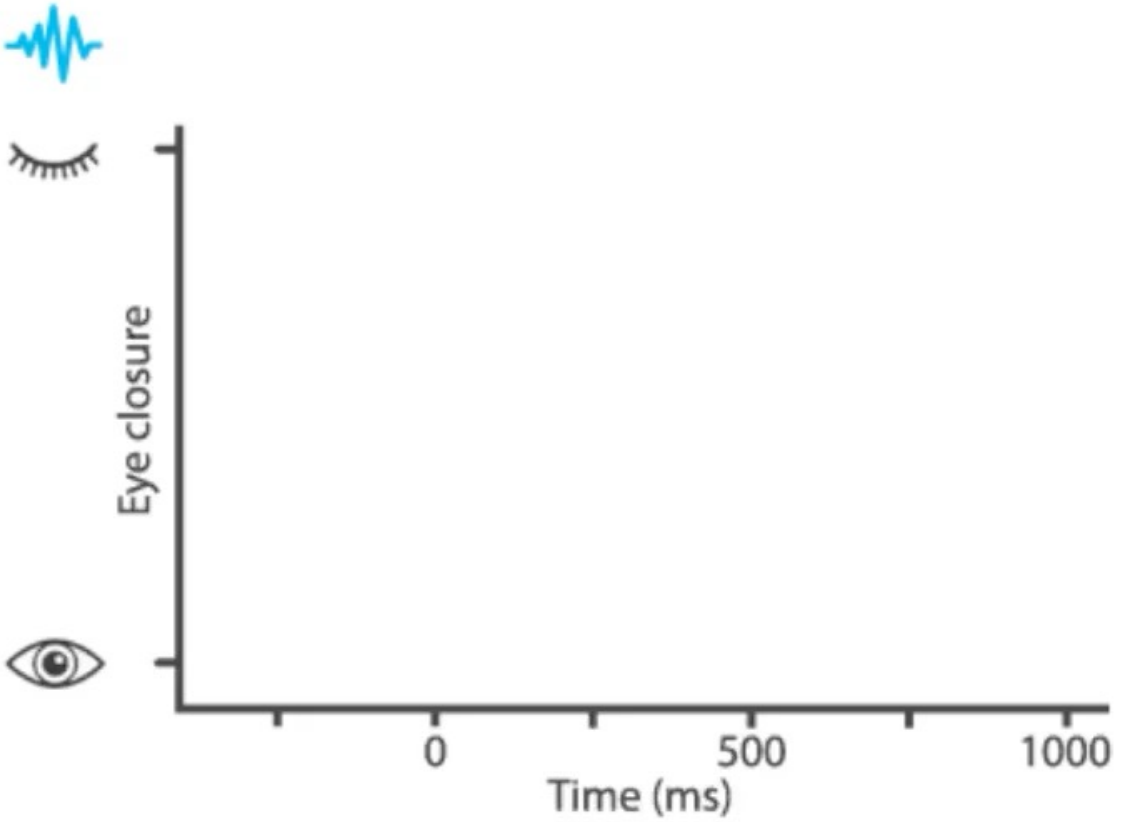


Video used with permission of caregiver

BlinkLab PPI test – Autism Spectrum (2 years old)

Patent: PCT/US2021/058698





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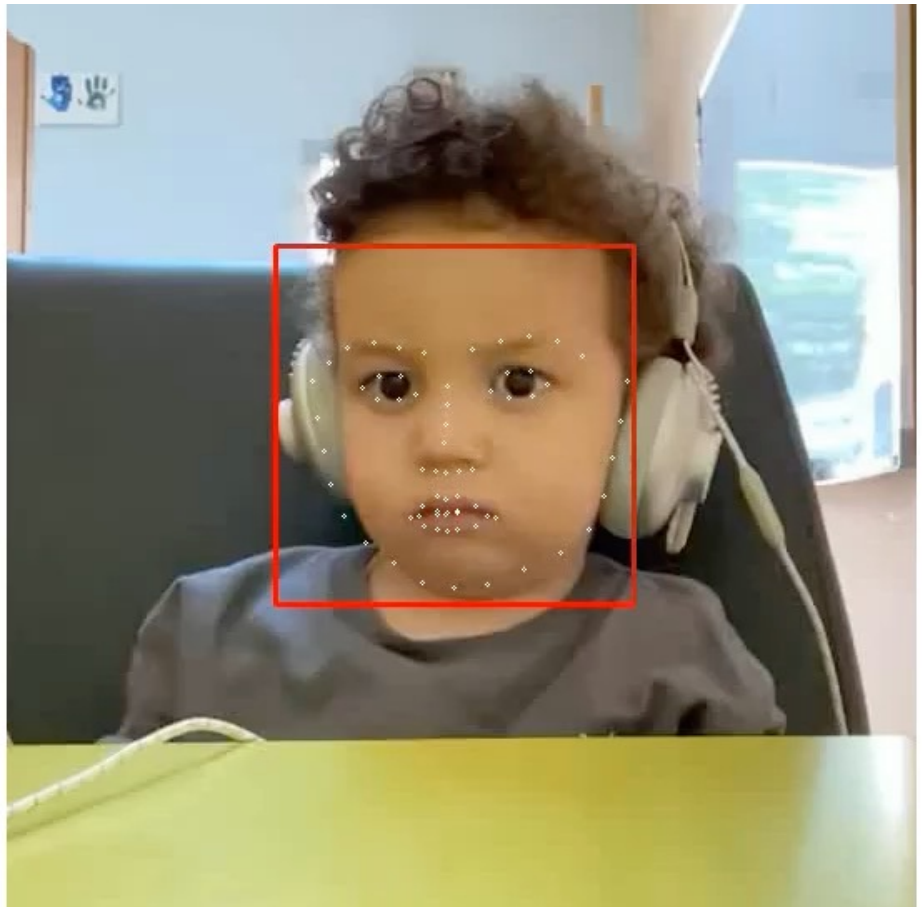
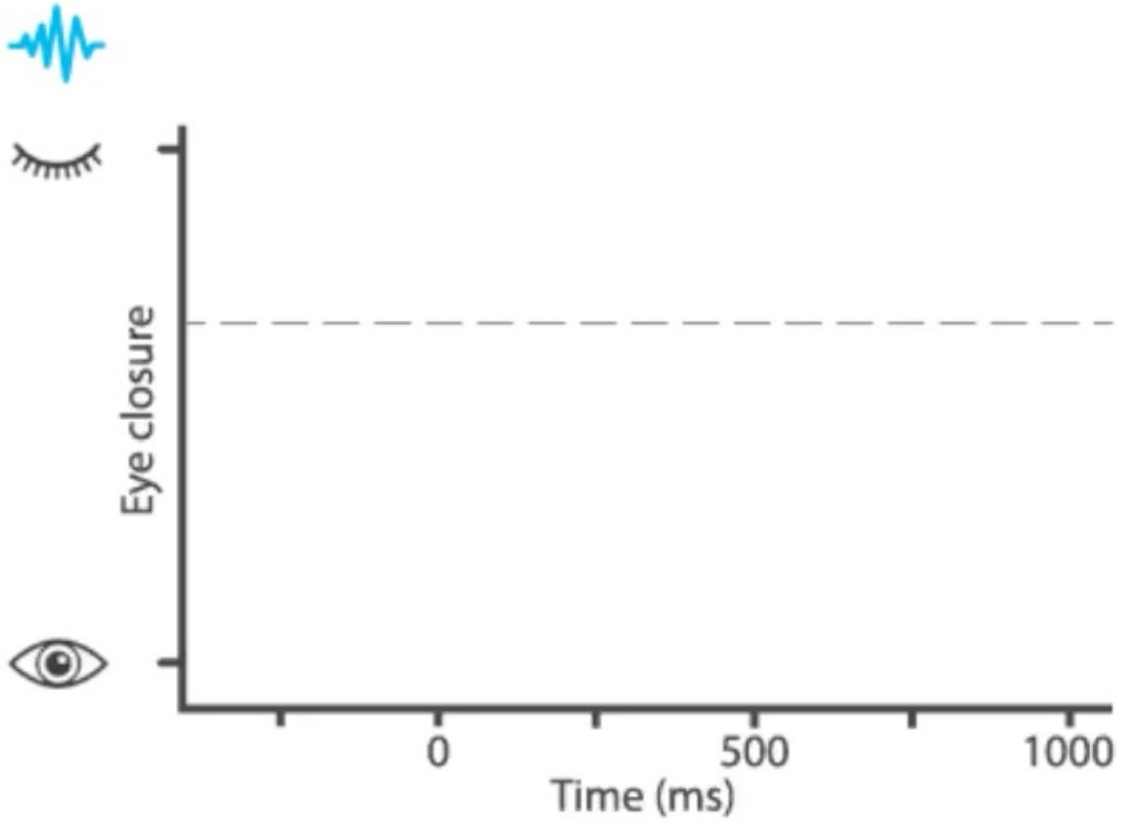
BlinkLab PPI test – Autism Spectrum (2 years old)

Patent: PCT/US2021/058698





Video used with permission of caregiver

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.

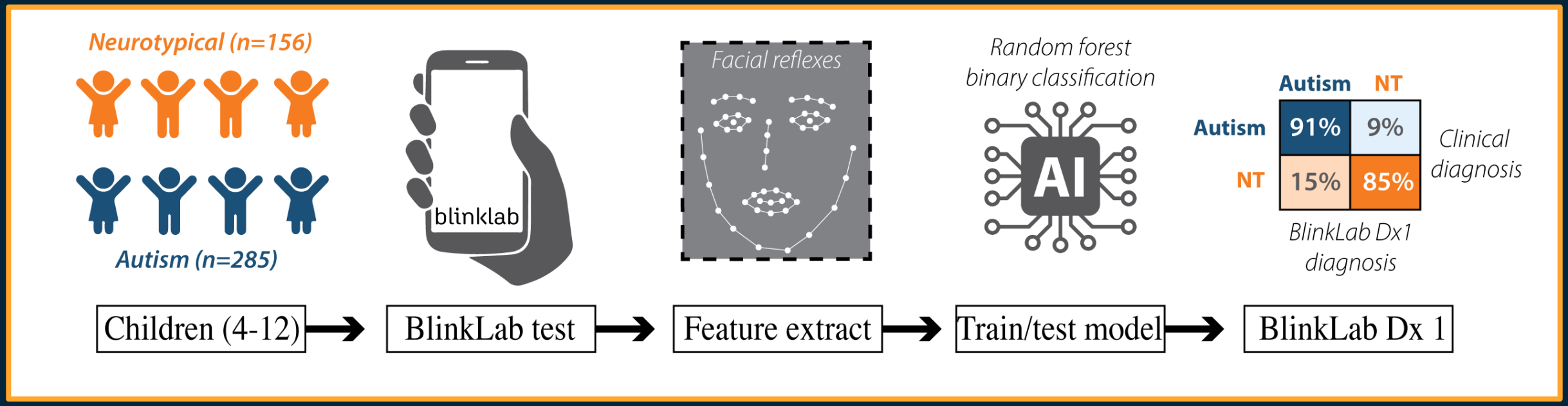
Evaluates brain function

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

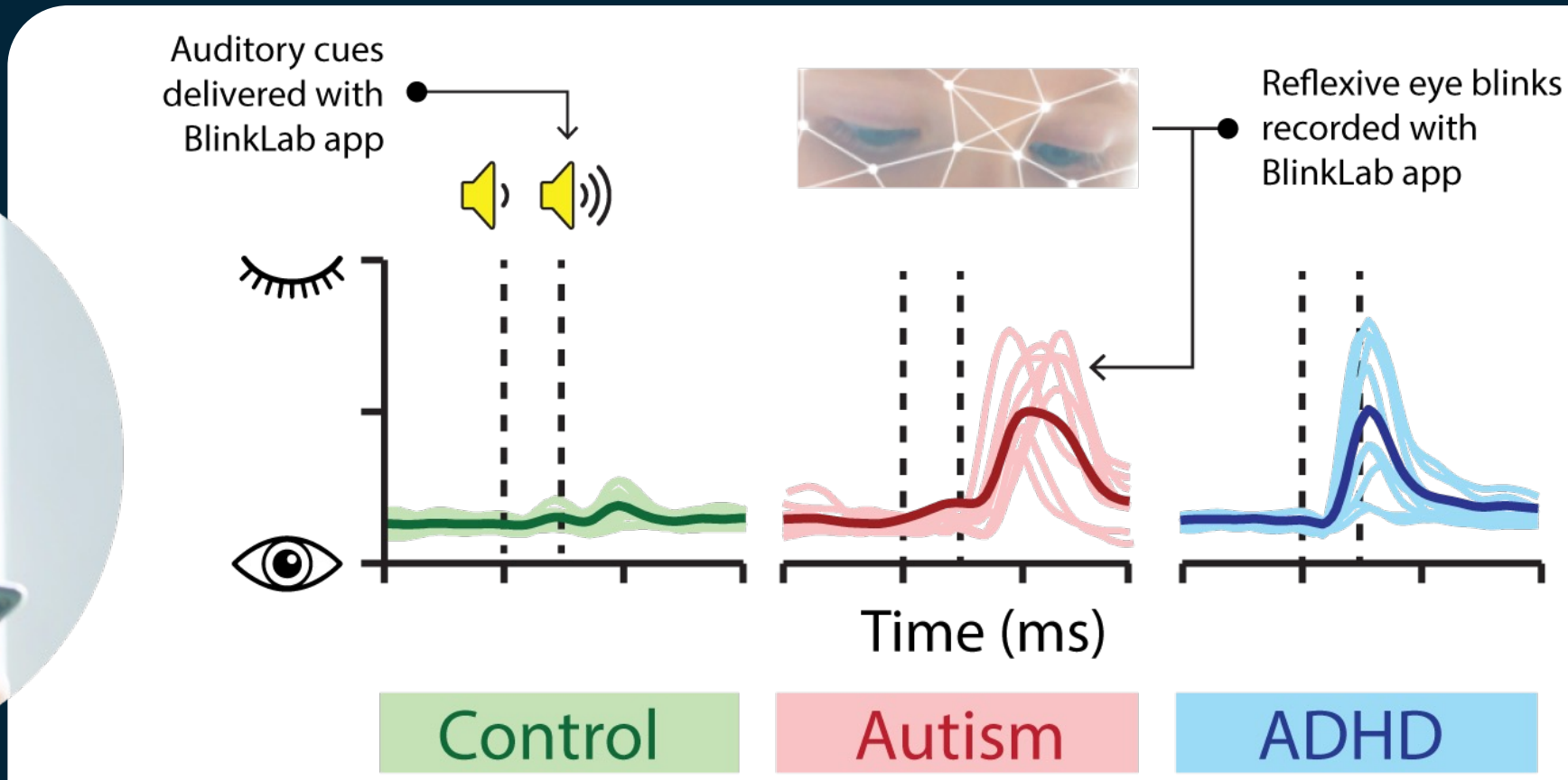
Large Study Validates and Enhances BlinkLab's Accuracy in Detecting Autism in Children

Released on 18 November 2024



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

Our AI technology detects autism and ADHD



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

BlinkLab Outperforms FDA-approved Digital Peers

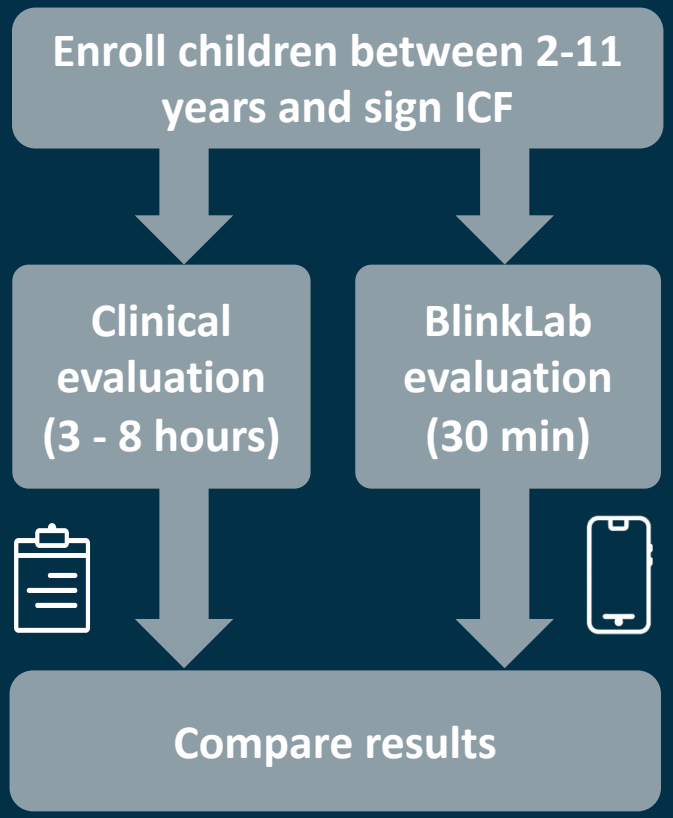
We are leaders in the digital diagnostics and therapeutics space

	blinklab	cognoa	EarliTec Diagnostics Inc.
Sensitivity	91%	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

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



Main study: n = 230 children with autism, and n = 230 children without autism.

Total n based on expected autism prevalence at sites: 750-1000

Q4 2024	- CRO assigned*
	- IRB approval *
	- Pre-submission meeting with FDA*
Q1 2025	- Onboarded two US clinical sites for initial (100-participant) study: PriMED and NorthShore Pediatrics*
	- Compliant with HIPAA 21 and CRF parts 11, 820*
	- Started data collection for initial study*
Q2 2025	- Results from initial study
	- Onboarding clinical and research sites for main study
Q3 2025	- Start main study
Q4 2025	- Results from main study
Q1 2026	- Submission to FDA
Q3 2026	- Outcome from FDA 510(k) submission

* completed

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.

Investment Highlights

blinklab

Breakthrough AI-Powered Solution

- *Rapid, accurate results for early detection and diagnosis of autism and ADHD*

Significant Need & Market Opportunity

- *Addressing $700B autism and $122B ADHD markets (USA), with global potential*

Clinically-Validated & Patent-Protected

- *Clinical data demonstrating a leading 91% sensitivity and 85% specificity*

FDA Pathway

- *Registrational studies underway and 510(k) submission expected late-2025*

Leading Clinical Partnerships

- *Between Princeton University (USA), Monash University (AU), and leading US pediatric clinical sites.*

blinklab *ASX:BB1*

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The formal presentation concludes here. The following slides are for discussion and Q&A purposes only.

FY2025 Milestones Achieved

Nov 2024

Large-Scale Pivotal Study Validation

Study demonstrates 91% Sensitivity and 85% Specificity for Dx1 tool – outperforming competitors

Monash MAGNET Study Launch

Secured participation with Monash University study on deep phenotyping and AI-driven biomarkers

Nov 2024

Dec 2024

FDA Pre-Submission Meeting Success

FDA Approval for Clinical Study Design, essential to next steps for 510(k) clearance

Launch of Registrational Study

US-based clinical study with PriMED Clinical Research (Ohio) and North Shore Pediatric Therapy (Illinois)

Feb 2025

Mar 2025

First Child Tested

First US Patient successfully tested at PriMED Clinical Research – a major milestone for FDA Approval

Important milestones

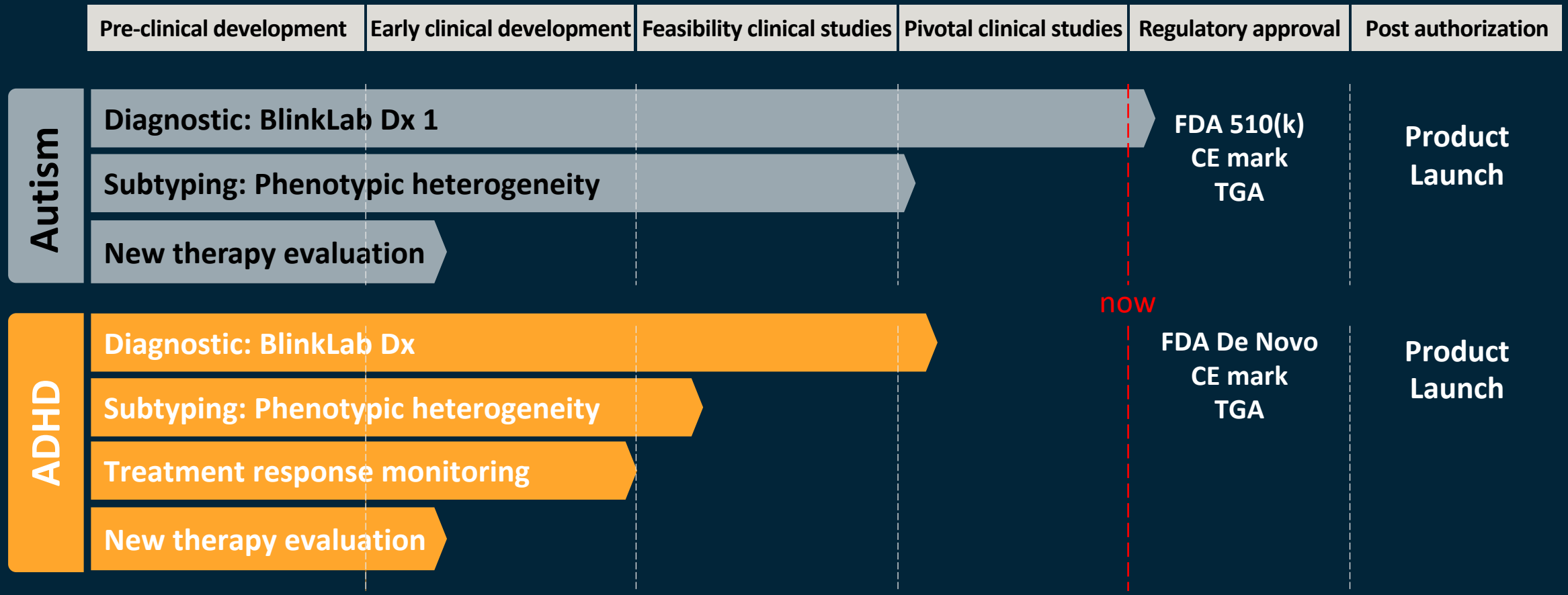
News pipeline: Updates on regulatory studies on autism and ADHD and new partnerships

Milestone	Timeframe
Start of activities for FDA registrational study in autism	*2Q 2024
Interim data from ADHD clinical study in EU	*3Q 2024
Appointment of US based CRO to conduct FDA registrational study in Autism	*4Q 2024
Final data from large clinical study in autism (Morocco/US clinical sites)	*4Q 2024
Selection of US clinical trial sites for FDA registrational study	*4Q 2024
First subjects tested in FDA registrational study	*1Q 2025
Update on CE/ISO certification in EU	1Q 2025
Completion of ADHD clinical study in EU (final data)	2Q 2025
Initiation of FDA registrational study in ADHD	3Q 2025
FDA registration study in Autism complete	4Q 2025
510k FDA submission is Autism	4Q 2025
510k FDA approval in Autism (approx. 6 months after submission)	2Q 2026
Ongoing partnerships updates / new partnerships	Ongoing

*Achieved

R&D Pipeline

Our R&D pipeline is focused on obtaining FDA 510(k) clearance and EU regulatory approval for BlinkLab as a diagnostic adjunct for autism and ADHD.



BlinkLab is collaborating with world-leading institutions

Since our product launched in 2022, we have established global partnerships academic and clinical institutes.

2022	2023	2024	ongoing	
Princeton University				**Proof-of-concept** of smartphone-based neurometric evaluations.
	Mohammed V Foundations for solidarity			Multi-center **autism** study in Morocco on BlinkLab's diagnostic accuracy.
		ESPOCH		Multi-center study in Ecuador on brain development, nutrition, and **autism.**
			Scanner Consortium Europe	Large European consortium, awarded 5.3M euro's, on **autism** in women.
			Turning Pointe Autism	**Autism** study in United States on BlinkLab's diagnostic accuracy.
			Erasmus University	Large study on early detection of **Alzheimer's** and **Frontotemporal Dementia.**
			Bates College	Objective biomarkers for **Functional Neurological Disorders.**
			Columbia University	Effects of physical activity on **Spinocerebellar Ataxia (SCA).**
			Mental Care Group	**Research and commercial partnership** with the fifth largest provider of mental health care in EU.
			Monash Univ.	Study on the pharmacology of human decision making and effects of **ketamine.**
			INTER-PSY	Prospective study on diagnostic accuracy for **autism** in young children.

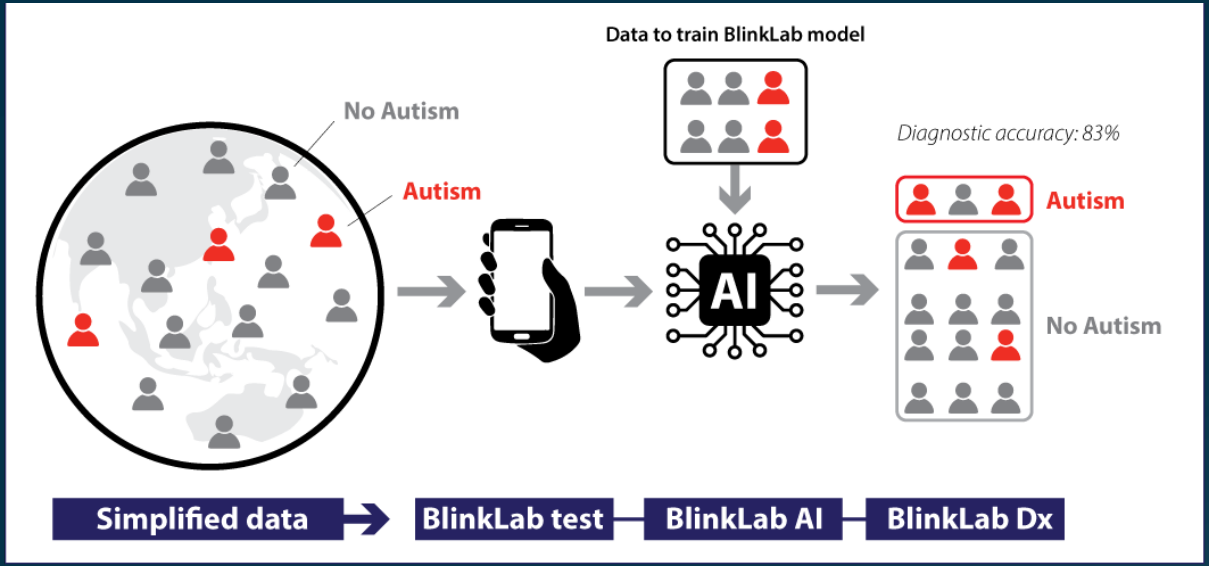
Prof. Samuel S. H. Wang
(Princeton University)

"The BlinkLab app is easy to operate, substantially reduces the costs of diagnosis, and produces reliable and reproducible results."

Optimizing AI and machine learning for BlinkLab Dx

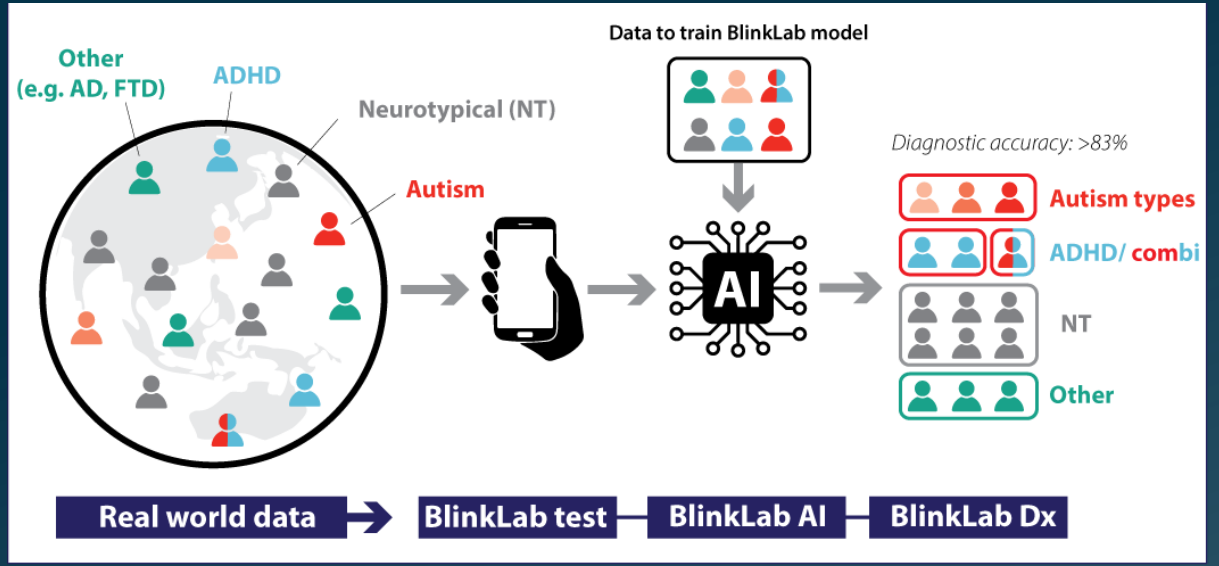
Establishing academic partnerships is crucial not only for academic and clinical adoption, but also for training our ML models with diverse datasets that reflect real-world data.

PREVIOUS STUDIES



Our binary AI classification model, which categorizes individuals into 'Autism' and 'No Autism,' achieved an 83% diagnostic accuracy. However, this model's assumption of only these two categories oversimplifies the complexity of real-world diagnoses.

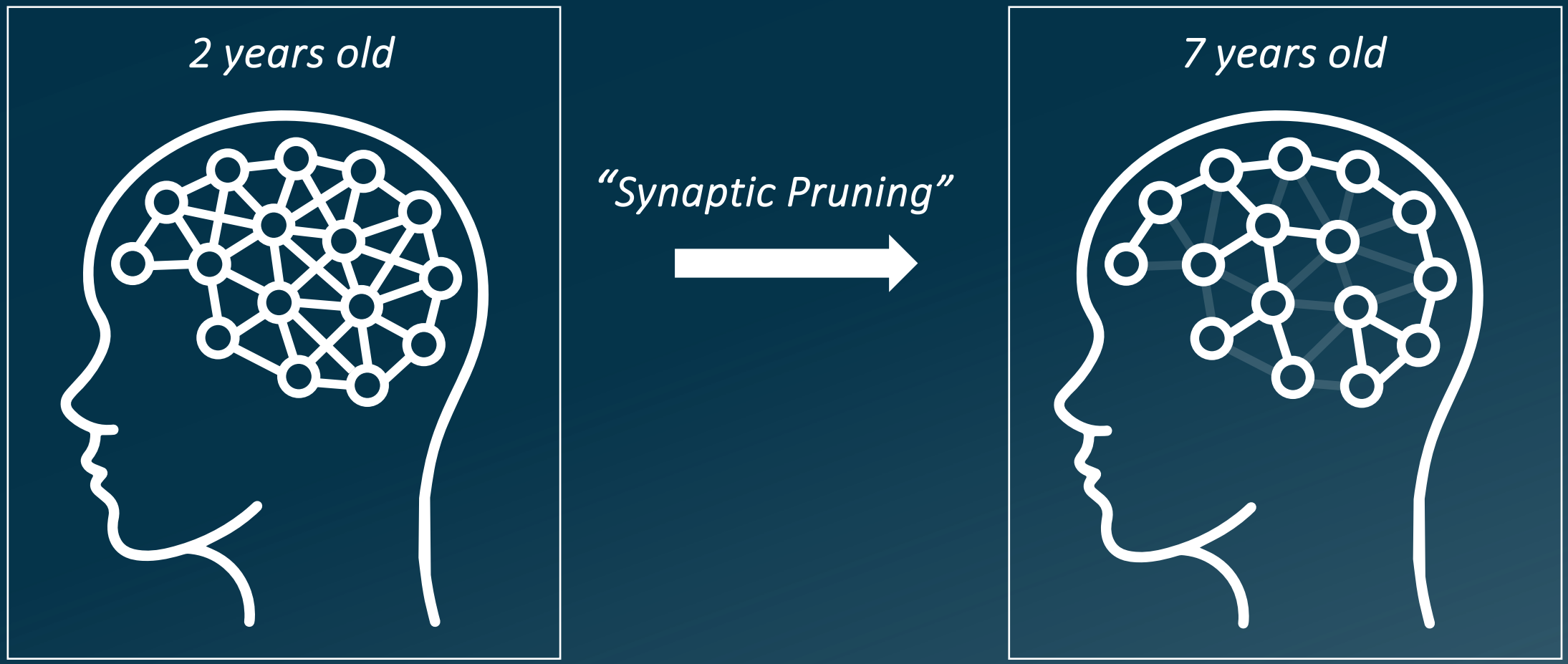
CURRENT WORK



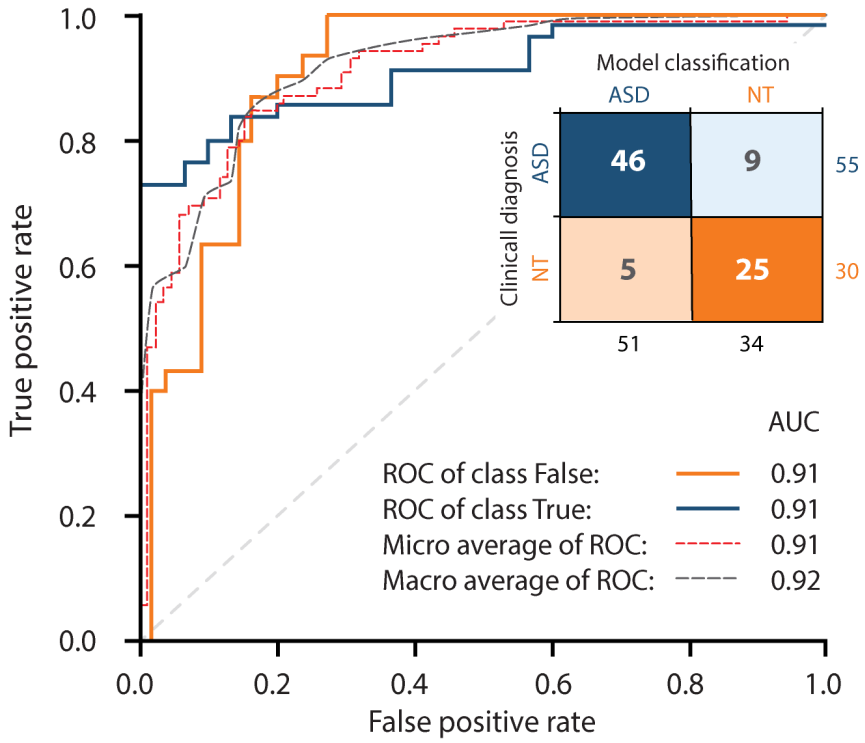
We are currently training our AI model with data that more accurately reflects real-world diversity, including other neuropsychiatric conditions such as ADHD, Alzheimer's (AD) and frontotemporal dementia (FTD). This enhances the model's performance in identifying autism subtypes and ADHD.

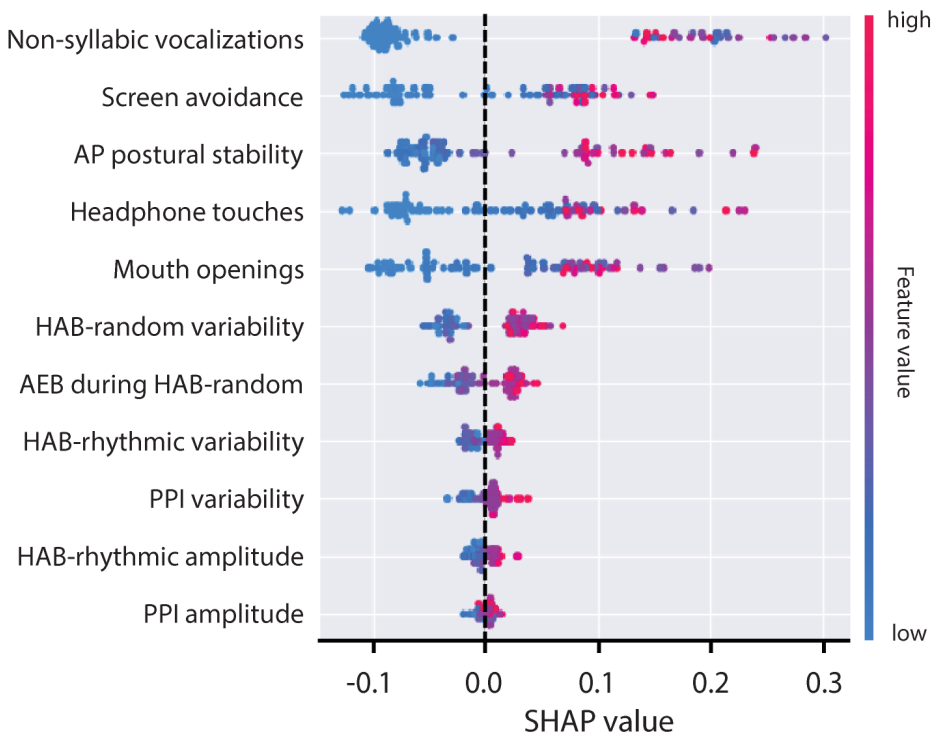
Why is early intervention key?

Young brains have high plasticity, allowing therapies to shape neural connections, improve communication and social skills, and maximize long-term potential.



Binary classification using random-forest model gave us a sensitivity of 85% and specificity of 84%.

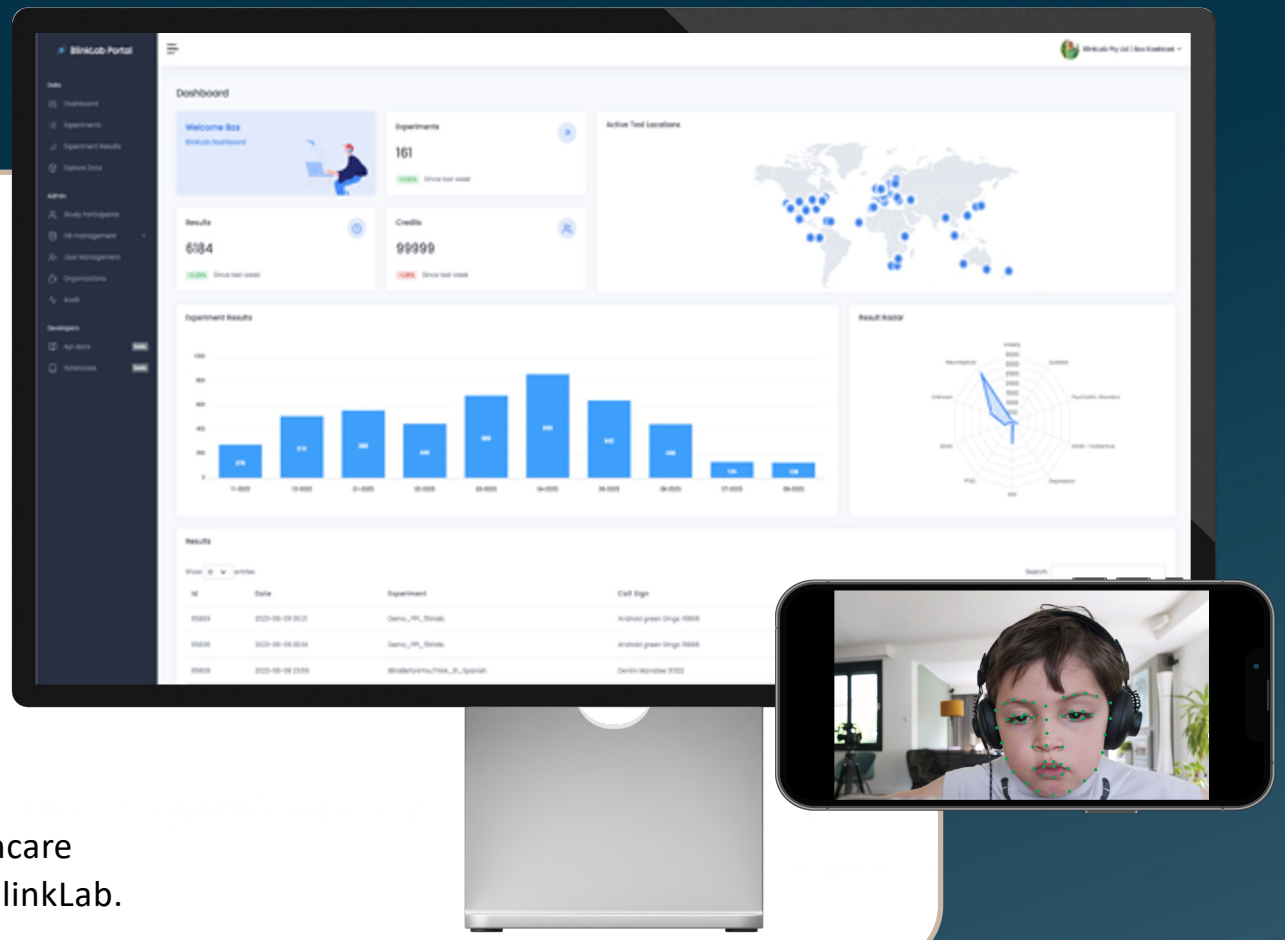




BlinkLab App & Online Portal Fully-Developed

Validated in >12,000 subjects tested globally, including people with limited healthcare access

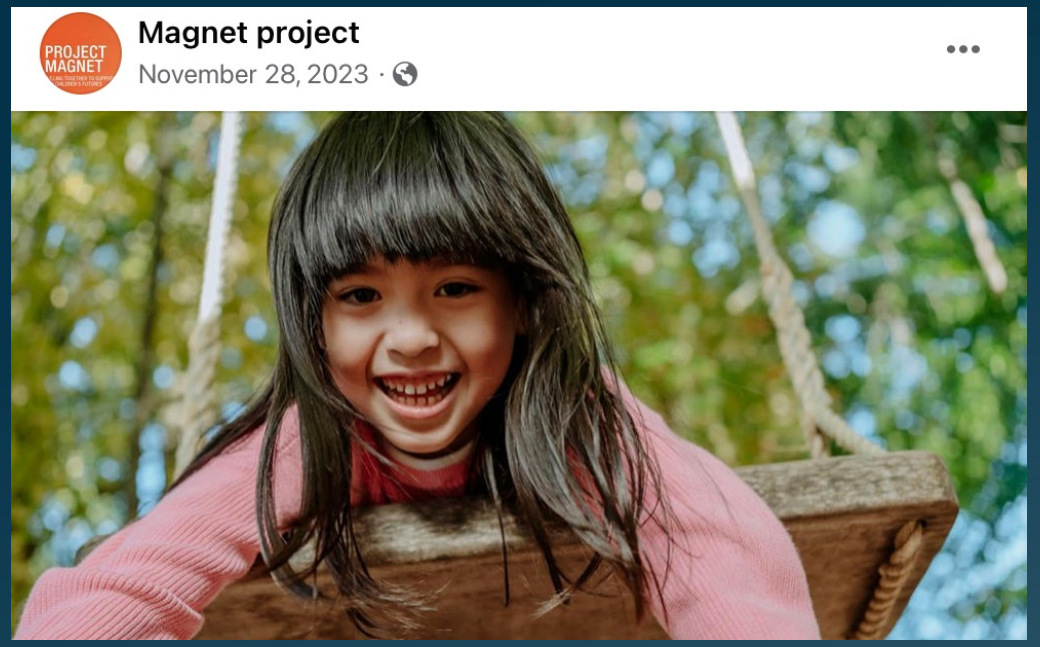
- **Remote testing**
  Enables accessible and global diagnostics.
- **Scalable solution**
  Easily adaptable for clinical and diverse research needs.
- **Real-time analysis**
  Immediate insights in user tests and biomarker scores.
- **Rapid global adoption**
  Academic and clinical institutes, special schools and, large healthcare providers around the globe already have started implementing BlinkLab.



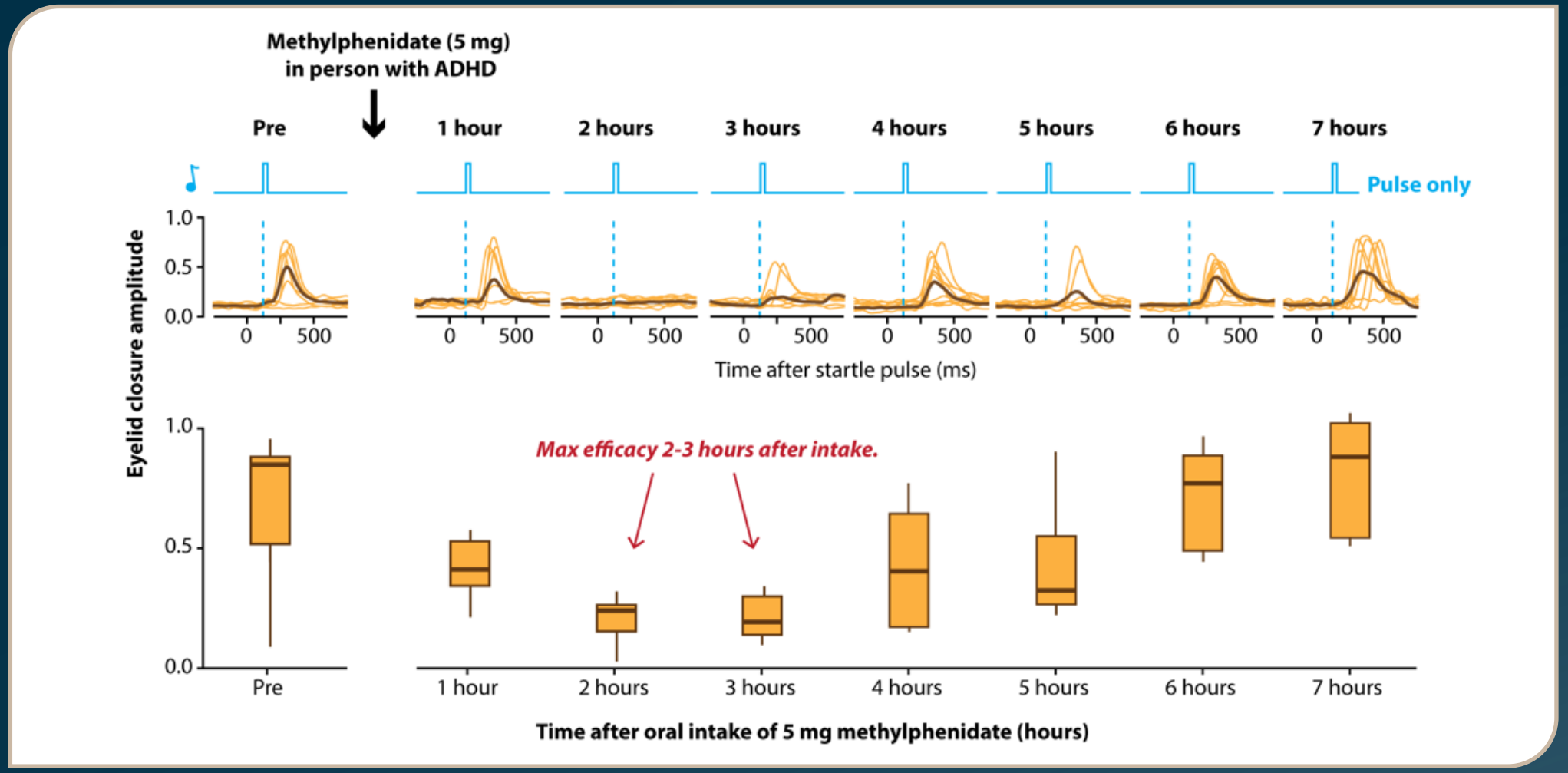
BlinkLab to Participate in the Landmark Monash University Autism/ADHD MAGNET Project

News announcement 13 November 2024

- The MAGNET project is an ongoing large cohort study aiming to enroll **1,000 families** with children diagnosed with autism, ADHD, or both autism and ADHD.
- MAGNET is utilizing a novel **family-based trial design** where the parents, affected child and siblings are all enrolled in the same study.
- The aim of the study is to identify novel data-driven autism and ADHD subtypes using **deep phenotyping data**, including the BlinkLab Dx 1 biomarkers, that may outperform current categorical diagnoses with potential future implications for better and more personalized autism and ADHD diagnosis and treatment.



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.

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”