

Digital Biomarkers for earlier intervention of Autism Spectrum Disorder

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Autism Spectrum Disorder

Early intervention benefits

Early intervention ESDM : Intensive 2 years program

Highest brain neuroplasticity level

- Better socialization level
- Better communication skills
- Control stereotyped behaviour

A More Independent Life

Impact on Society Dependency Cost

\$203.148,00 Average Lifetime Savings from 28 months earlier intervention

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Early Detection

1 year old

Average detection of the first observable symptoms



4 years old

Average age of diagnosis and intervention



Diagnostic is Subjective and Experts Intensive

"...we had many different people observing the same child and **came up with different outcomes**... the examiner's **clinical skill and experience** with this tool is extremely important."

> Sofia Rocha, Occupational Therapist in Portugal and UK

Clinical Pathway



A Pathway Limited by Delays



To enable Autism Spectrum Disorder (ASD) early intervention, we need to reduce delays through diagnosis pathway with an **easy**, **accurate**, and **affordable early-stage screening**

Accelerating the path to intervention



- 10min test
- Objective

Value for Diagnostic Centers

Resources (Cost per diagnosticated child)



50% faster

Value for Healthcare System

With the Same Diagnostic and Intervention Budget





necessary Intervention

Value for Healthcare System





€36.024/kid savings in lifetime caregiver cost

from 28 months earlier intervention

Already reimbursed in the US

 CPT Code
 Medicare (2019)

 96112 (Screening)
 \$130,10

 97151 (Monitoring)
 \$82,50 per 15min



Source: JAMA Pediatr. 2017;171(1):23-30. doi:10.1001/jamapediatrics.2016.2695 JACA Psychiatry. 2017:56(9):777-783. doi: https://doi.org/10.1016/j.jaac.2017.06.007

How dnosis works?



Off-the-shelf Eye Tracking Equipments

Biomarker: Gaze Path to Video Stimuli

AI ASD Classifier

24 Months Autism Spectrum Disorder

6 Months Typical Development

dnosis Screening Report

TYPICAL DEVELOPMENT



Computer-aided Diagnosis (CADx) for Differential Diagnostic of Autism Medical Device Class IIa

State-of-the Art Technology

Biomarker supported by latest scientific research

95% Accuracy with 300 kids

Preliminary study in partnership with





Background

is a target for treatments for the disorder. Measures of social attention, assessed via eye-gaze tracking (RGT), have been proposed as an early efficacy biomarker for clinical trials targeting social communication skills. EGT measure have been shown to differentiate children with ASD from typical children, however, there is less known about the relationships with social communication outcome measures that are typically used in ASD clinical trials. In the present study, an EGT task involving viewing a videotane of an actor making bids for a child's attention was evaluat in 25 children with ASD aged 24-72 months. Children's attention to the actor during the dyadic bid condition me. sured via EGT was found to be strongly associated with five well-validated caregiver-reported outcome measures that are commonly used to assess social communication in clinical trails. These results highlight the convergent validit of EGT measures of social attention in relation to caregiver-reported clinical measures. EGT holds promise as a non invasive, quantitative, and objective biomarker that is associated with social communication abilities in children w ASD. Autism Res 2017, 0: 000-000. © 2017 International Society for Autism Research, Wiley Periodicals, Inc.

comes in clinical trials investigating interventions to treat autism spectrum disorders. In this study, an EGT task wa evaluated in children with ASD, who watched a video with an actor talking directly to them. Patterns of eye-gan were associated with caregiver-reported measures of social communication that are used in clinical trials. We show EGT may be a promising objective tool measuring outcomes.

tal disorder characterized by social communication these assessments are meaningful sources of info

Innovative Technology



Provisional Patent on

Stimuli Processing

AI Model Agnostic to Video Stimuli Variations

Competitive Landscape

	Accuracy	Minimum Age	Cost	Duration	Subjectity	Specialist	Training
ADOS	96%	1 year	45€	60 min	Yes	Yes	Yes
		_					
Cognoa	93%	2 years	-	10 min	Yes	Yes	No
Playcare	95%	3 years	-	10 min	No	No	No
ক্ষ dnosis	95%	6 months	40€	10 min	No	No	No

Business Model



B2B Pricing Pay per report Or Annual License

Market Size



Of the population is impacted



7,5 millions

in Europe

TAM \$**3**B* SAM \$780m* **Autism Diagnostics** SOM \$**30**M

Market Entry

(Q1 21') Portugal/Spain/France/UK (New Borns: 2M/year)

7.250€ (Annual Licence) + 40€ (per report)

(Q3 21') USA (New Borns: 4M/year)

11k\$ (Annual Licence) + 80\$ (per report)

Financials

	2019	2020	2021	2022	2023	2024
Tests Per Year	0	0	6937	45482	138790	274504
Installed Equipments	10	20	40	70	110	160
Average Price per Test	€0.00	€0.00	€107.18	€73.04	€68.13	€66.75
Revenue	€0	€0	€743,456	€3,321,865	€9,455,223	€18,322,229
Gross Profit	-€180,000	-€210,000	€323,456	€2,661,865	€8,525,223	€17,092,229
Fixed Costs	€127,000	€1,238,500	€1,380,000	€1,560,000	€2,150,000	€2,680,000
Net Profit	-€307,000	-€1,448,500	-€1,056,544	€1,101,865	€6,375,223	€14,412,229
Investment	€2,000,000	€0	€1,000,000	€0	€0	€0
Cash Flow	€1,693,000	€244,500	€187,956	€1,289,821	€7,665,043	€22,077,273

Rate 12.00% Valuation (DCF) €9,438,542

Roadmap

• October 2018 First Eye tracking Screening		Q4 2 First di Deploy	Q4 2019 First dnosis Equipment Deploy		Q3 2020 Al training and Retrospective Clinical Trials		Q3 2021 FDA Approval USA Market entry		1 ral : entry		Q1 2022 Early Diagnos Test with Pediatricians	is	
		Pre	-Seed €	75k	EIT H	lealtl	h Wild Card - € 2M				Series	A € 8M	
				EU	J/USA Data		Early Diagr	nosis D	ata				
	Re Pa	search Si rtnership	tes s	Data c Softwa	ollection are developm	ent	CE Mark Class IIa Market Entry PT / S	P / FR /	UK	ASD F Test	Profiling]	
1	Today			Q1 2	020		Q1 2021			Q4 :	2021		

EIT Health Wild Card Accelerator

Who is the Team?



Cognitive/AI Engineer MSc MBA in Entrepreneurship Founder of B.Mind



Andreu Oliver-Moreno CEO

Cognitive Psychologist PhD Eye Tracker Technical and Sales Expert



Miguel Amador COO

Biomedical Engineer MSc PhD Candidate Health Data and Innovation Previous Scale-up COO

Partnerships



Technology Development Partners



Eye-Tracking Partners



Incubation



Parc Científic de Barcelona UNIVERSITAT DE BARCELONA

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Addition Ser

biocat



Digital Biomarkers for earlier intervention of Autism Spectrum Disorder

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Our vision is to use digital biomarkers to empower people with developmental disorders

Pipeline

Multimodal Biomarkers for Automated Profile Report





Provisional Patent

Integrated Therapy Management and Monitoring



ASD Depency Costs

Dependency Cost for Society till 65 years on Intervention Delay

Current Delay (32 months)	\$2,483,300
Half Delay (16 months)	\$2,371,732
No Delay (2 months)	\$2, <mark>280,152</mark>

Dependency Cost for Healthcare till 65 years on Intervention Delay

Current Delay (32 months)	€504,892	
Half Delay (16 months)	€484,964	
No Delay (2 months)	£468,868	

Clinical Trial



Dataset - 300 (Balanced cohorts)

460.000€*

*Recruitment, Data Collection and Validation Test

AI Classifier



IP Strategy

There is freedom to Operate in the use of Eye Tracking for Autism Diagnostic **Apparatus Patents**

Al Model / Dataset -Trade Secret

2 Provisional Patents on Al Model technological limitations

Clinical Certification

Early Stage Denver Methodology (ESDM)

Promote development start using the child's first interests as a beginning to help him discover human interaction through imitation.

2 years intensive programme Fully personalized From 1 year old Parents are key

Alternatives Landscape

Ongoing Research of Objective Tests

No single test can stratify diagnostic. Not yet one objective test in clinical use

Name	Туре	Biomarker	Tech	Clinical Validation
Cognoa	Diagnosis	Parental inputs and diagnostic data and responses to therapeutics	AI	FDA Breakthrough Designation
Playcare Diagnosis		App Interaction	AI	Class 1 Medical Device
SensPD	Diagnosis	Oto-Acoustic-Emission (OAE)	AI	Research
SynapDX	Diagnosis	Blood comprising 24 metabolites	AI	Research
Akili Labs	Treatment Diagnosis	Cognitive Behaviour	AI	Autism Clinical Validation with Pfizer

Our Tech

Response

Stimuli



Computer Assisted Diagnosis Software (CADx) for Differential Diagnostic of Autism

Medical Device Class IIa



The best way to manage Autism Spectrum Disorder (ASD) is to detect it early.

...quick and cheap...

by just sitting in front of a computer