FIREFLY
NEUROSCIENCE

Improving Mental Health Diagnosis and Treatment Through AI & Big Data

Forward-Looking Statements

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This presentation contains forward-looking information relating to capital expenditures, cash flow, investment payouts, valuations, and other matters ("forward-looking statements"). These statements relate to future events or future performance. Forward-looking statements are often, but not always, identified by the use of words such as "anticipate", "budget", "plan", "estimate", "expect", "forecast", "may", "will", "project", "potential", "target", "intend", "could", "might", "should", "believe" and similar expressions.

Forward-looking statements are based on the opinions, assumptions and estimates of management at the date the statements are made, and are subject to a variety of risks and uncertainties and other factors that could cause actual events or results to differ materially from those anticipated in the forward-looking statements. Although management believes that the expectations reflected in the forward looking statements are reasonable, there can be no assurance that such expectations will prove to be correct. These statements are not guarantees of future performance and involve known and unknown risks, uncertainties and other factors that may cause actual results or events to differ materially from those anticipated in the forward-looking information or forward-looking statements.

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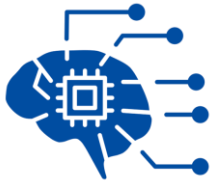
The forward-looking statements made herein relate only to events or information as of the date on which the statements are made. The reader is cautioned not to place undue reliance on forward looking statements.

Executive Summary

Why Now?

Achieved **FDA 510k** clearance

On the **cusp of commercialization**



Breakthrough AI Neuro-Technology

Largest **standardized, multi-task EEG & ERP** database

Software platform **FDA 510k** cleared

World Class Management

Jon Olsen, CEO, 25+ years in Medtech at Medtronic & Smith and Nephew

David DeCaprio, Director, AI healthcare thought leader (**Winner of CMS AI Healthcare Challenge**)

Problem

Today, mental illnesses are treated
based on "feelings" and **not brain function**

Current Gold Standard in Diagnosing and Treating Depression: *PHQ-9: a 9-item questionnaire*

Over the last 2 weeks, how often have you been bothered by any of the following problems?	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself – or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3

Guide for Interpreting PHQ–9 Scores		
Score	Depression Severity	Action
0 – 4	Non-minimal	Patient may not need depression treatment
5 – 9	Mild	Use clinical judgement about treatment, based on patient's duration of symptoms and functional impairement
10 – 14	Moderate	Use clinical judgement about treatment, based on patient's duration of symptoms and functional impairement
15 – 19	Moderately severe	Treat using antidepressants, psychotherapy or a combination of treatment
20 – 27	Severe	Treat using antidepressants with or without psychotherapy

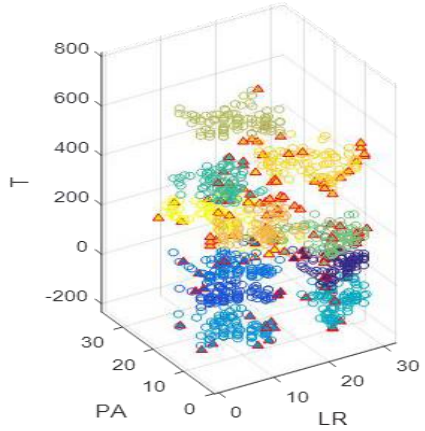
Our Solution

Step 1

Scan brain's **electrical** activity

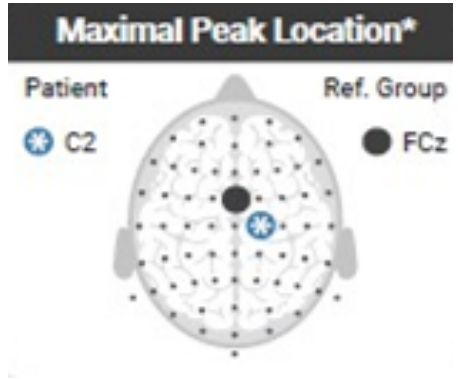
Step 2

Compare to our **foundational brain model**

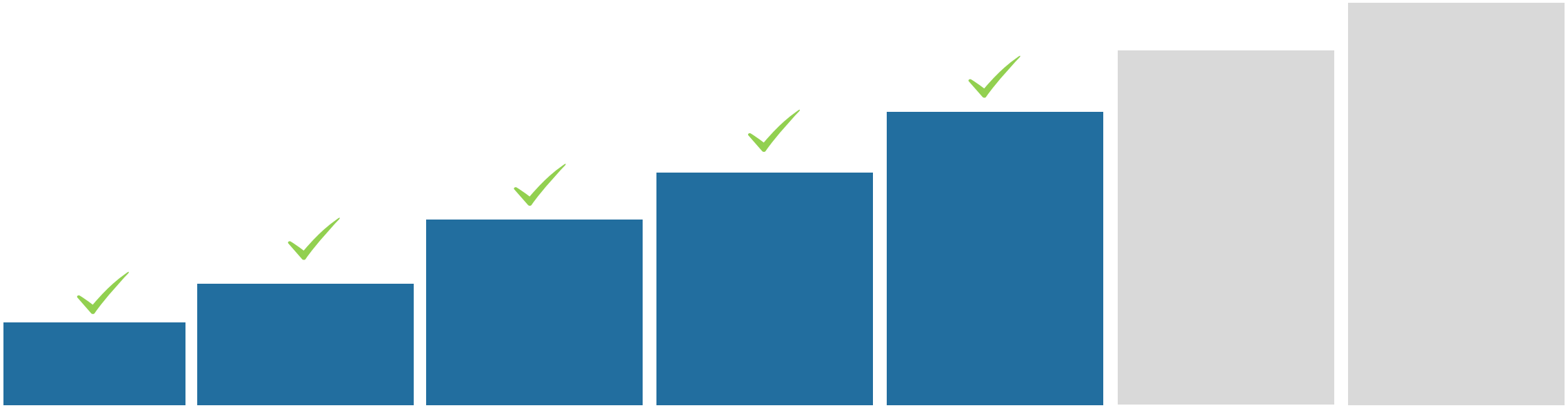


Step 3

Objectively **measure** cognition and **track** progression



FDA Cleared Data Platform is the Product of 15+ Years of Hard Science and $80M+, Backed up by 8 Patents



Researchers developed ***Deep Tech*** – understanding cognition

BNA™ is born to **objectively measure brain function**

Extensive research & clinical collaborations (**Takeda, Novartis**)

Significant data collection (**100+ sites**)

Software platform cleared by the **FDA**

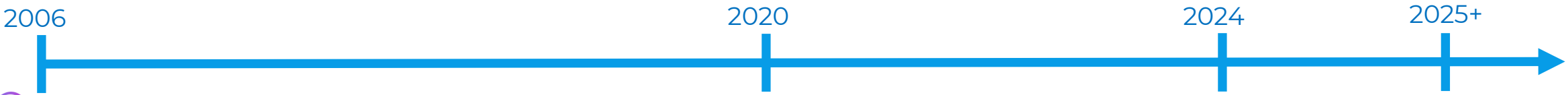
Clinical validation: **2,800+ patients** assessed in the US

Increase number of **neurology clinics** utilizing Firefly software

Increase **Pharma Partnerships**

Biomarkers & companion diagnostics

Expansion to medical professionals



Firefly's FDA-Cleared Proprietary Database Affords Unprecedented Insight into Brain Function

Largest Standardized, multi-task, EEG + ERP (brain function) database

>17,000 patients

5 different types of cognitive tasks

20 measures of cognitive function

3 avg. visits per patient (longitudinal data)

64 electrode (high fidelity)

77,000 brain scans

12 types of neuropsychiatric disorders

- Anxiety
- Dementia / Early Alzheimer's
- Depression
- Parkinson's
- Bi-Polar
- MCI
- Schizophrenia
- mTBI/TBI
- ADHD
- ASD
- PTSD
- Schizoaffective Disorder

Two Pathways for Success

Firefly Data Platform

Data

- Each incremental scan adds to database
- Negative cost per data acquisition
- Identification of biomarkers

Subscription or Per Use Fee

Biomarker Discovery Platform

- Accelerate and de-risk drug commercialization

Licensing, Equity, Royalty Fee

Clinicians

+$10B TAM in USA

Pharma

+$20B TAM

Software Platform to Enables Pharma Companies to Measure Treatment Impact & Enhance Patient Selection

Takeda

BNA™ was used to show SNRI drug **direct effects** on cognitive function

NOVARTIS

BNA™ was useful as a **primary endpoint** for developing **PK/PD model** for treatment-resistant depression drug

BNA™ was used to **quantify** depression objectively

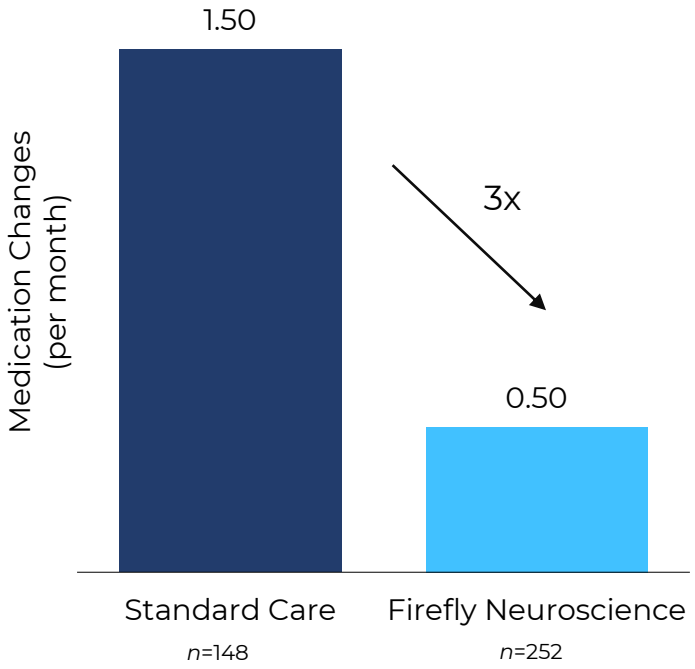
BRIGHT MINDS

BNA™ was used to show **central target engagement of BMB-101** (a candidate for the treatment of seizure disorders), and an **improved AED** (antiepileptic drug) principle over benzodiazepine (GABA receptor) AEDs

Firefly's BNA™ Platform has been Validated, Treating 2,800+ Patients in the United States

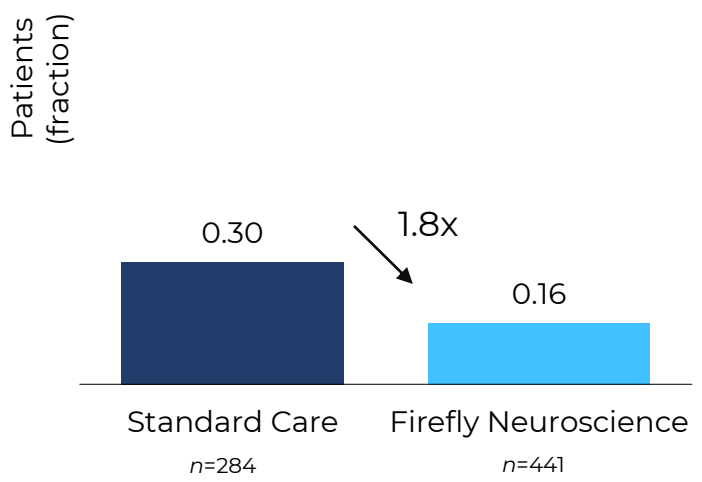
Informed treatment selection

Less medication changes



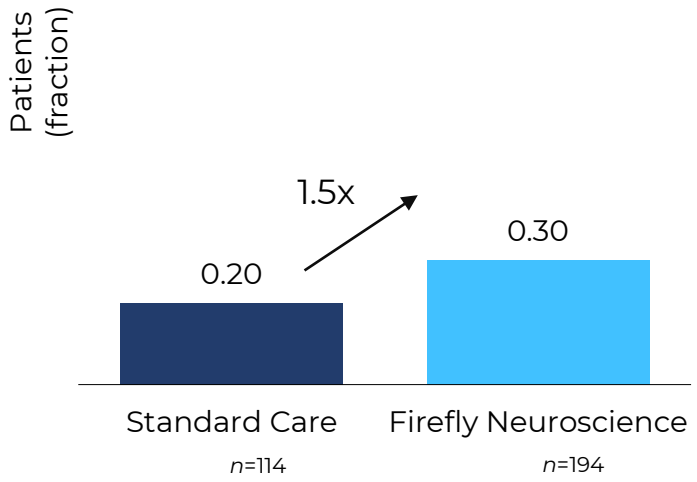
Increased compliance

Less discontinuation



Improved treatment outcomes

Increased response and remission rates



Leadership Team

Jon Olsen
CEO

- 25+ years of **global experience** in senior roles
- Managing Director Smith and Nephew (NYSE:SNN)
- Senior Director, Cardiac & Vascular Group at **Medtronic** (NYSE:MDT)

Dave DeCaprio
Director

- Co-founder ClosedLoop.ai. (Voted **#1 AI** Software Solution for Health Care '23/'22)
- **Winner** of the **CMS Artificial Intelligence** in **Healthcare** Challenge (#1 of 300 companies including IBM, McKinsey, Microsoft)
- Engineering lead for the **Human Genome Project** at the Broad Institute of **MIT** and **Harvard**
- BSc Electrical Engineering, **MIT**

Danelle James
VP of Clinical Development

- Clinical development, scientific, medical affairs leader through multiple biotech companies
- **Led global development** of **Imbruvica** (first BTK inhibitor) from first in human to 15 global registrations for 10 years spanning Pharmacyclics **acquired** by **Abbvie** (**$21 billion**)
- Hematologist and medical oncologist, formed UCSD faculty, **published 50+ articles** in peer reviewed journals

Medtronic
Smith+Nephew

Massachusetts Institute of Technology
ClosedLoop.ai

abbvie
pharmacyclics

Leadership Team

Gil Issachar
CTO

- **11+ years** software and algorithm developer, data science and research
- Masters Degree in Biomedical Engineering
- Masters Thesis focused on **signal processing and neuroscience**

Sagol School of Neuroscience
Tel Aviv University

Saleem Huda
AI Strategy & Innovation

- **25+ years** algorithmic trading; Fortress Investment Group, Deutsche Bank Global Markets, Canadian Pension Plan Investment Board,
- Interdisciplinary technical consultant for UCLA School of Medicine and Dept. of Tribology and coauthor for multiple biomedical grants from NIH, DARPA, U.S. Army
- BSc Mathematics **MIT**

Massachusetts Institute of Technology

FORTRESS

Jason Dubraski
Director BD

- Director of Sales at **Brainsway**
- Business Development at **Motus GI Holdings**
- **Medtronic:** Regional Sales Manager, Territory Manager, Senior Diagnostic Manager

Brainsway

Medtronic

World-Class Advisory Board

Robert T. Knight

- Professor of Psychology and Neuroscience, UC Berkeley
- Former Director of **Helen Wills Neuroscience Institute** (2001 – 2011), UC Berkeley
- Twice received the **Jacob Javits Award** for Distinguished Contributions to Neurological Research from the National Institute of Neurological Disorders and Stroke; IBM **Cognitive Computing Award; German Humboldt Prize** in Neurobiology; **Distinguished Career Contribution Award** from the Cognitive Neuroscience Society; **Education in Neuroscience Award** from the Society for Neuroscience; **Howard Crosby Warren Medal** for Distinguished Career Contributions from the Society of Experimental Psychologists

Berkeley Neuroscience
HELEN WILLS NEUROSCIENCE INSTITUTE

Adam Gazzaley

- Professor of Neurology, Physiology and Psychiatry, UC San Francisco
- Founder and Director, **Neuroscape**, UC San Francisco
- Co-founder, **Akili and Jazz Venture Partners**
- Filed multiple patents, authored **170+ scientific articles** and delivered **700+** invited presentations globally

NEUROSCAPE

Mohamed Shabana

- Epileptologist, Neurology Consultants of Dallas
- **Board Certified** in Neurology, Epilepsy and Neurophysiology
- Received **Resident Teacher Award**, UT Medical Branch at Galveston
- Dual fellowship-training in **Epilepsy and Neurophysiology**, UT Southwestern
- Affiliated with a **Level 4 Epilepsy Center**

NEUROLOGY
CONSULTANTS OF DALLAS

Chris Wilson

- Professor, Institute for Quantum Computing (IQC) University of Waterloo
- Recipient of the **Wallmark Prize** (2012) awarded by the **Royal Swedish Academy**
- Holds a BSc Physics from MIT; PhD Physics from Yale

Massachusetts Institute of Technology

Fabrizio Billi

- Director, **Musculoskeletal Devices and Technology Development** (MDTD) and Professor Dept. Orthopaedic Surgery UCLA School of Medicine
- Director, **Neuro-Musculoskeletal Health and Brain Plasticity Program**
- **50+ Journal Publications** and multiple grants from NIH, **DoD Industrial Partners**, ongoing collaboration with **LA Lakers and Bruins medical team** to develop custom treatments and novel surgeries

DAVID GEFFEN SCHOOL OF MEDICINE
UCLA

Appendix

Proprietary, Standardized, Medical-Grade Database

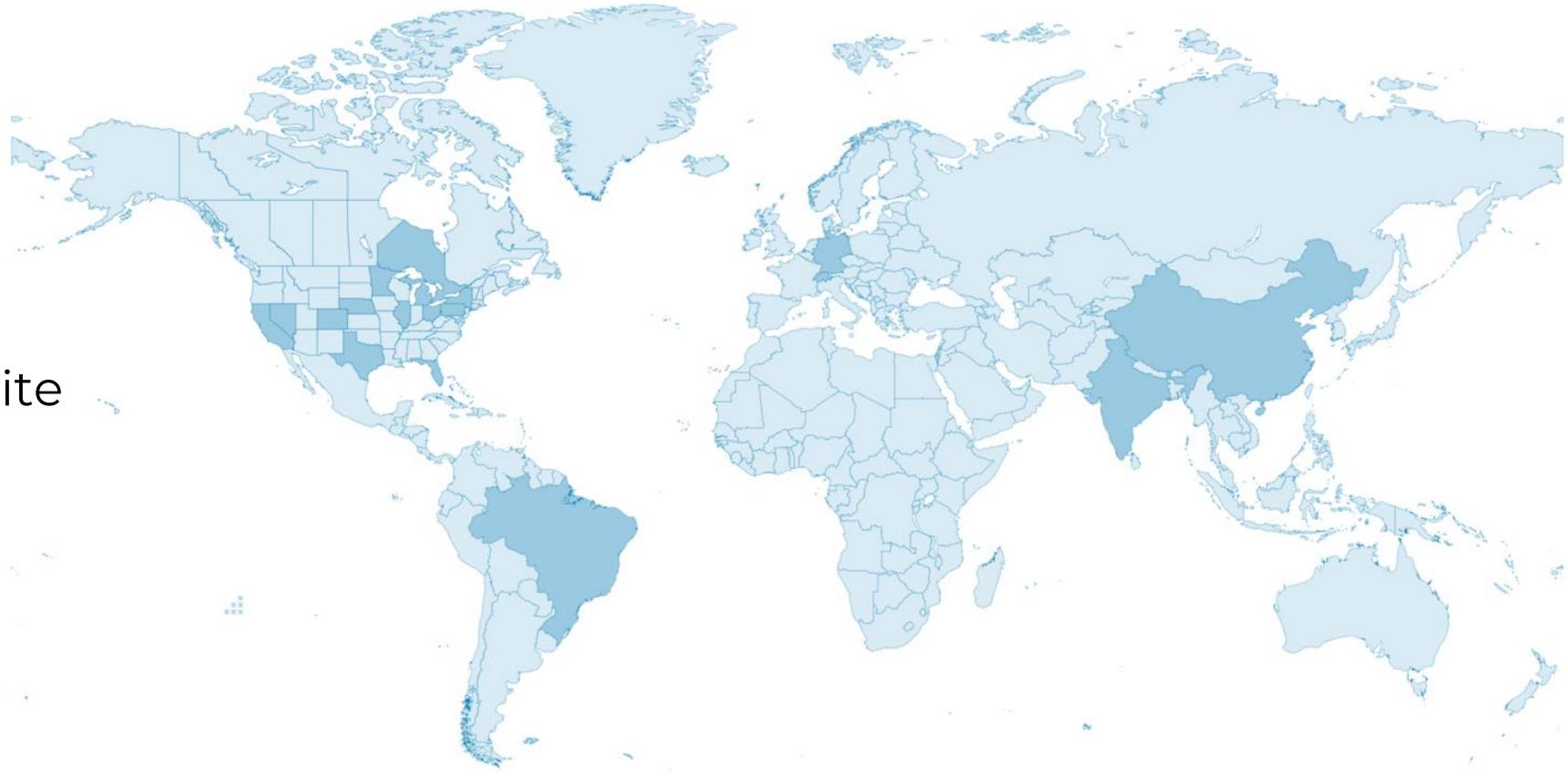
>17,000 patient multi-visit, longitudinal database ripe to develop disease biomarkers

- **9,400** clinically labeled patients between ages 12-85
- **7,800** clinically unlabeled patients with cognitive and meta-data labeling (useful for unsupervised/semi-supervised AI learning)

[1] – Management Estimates

Our Data is Proprietary and of High Quality

- ✓ The EEG and ERP data are **proprietary**
- ✓ Collected with our **standardized BNA platform**
- ✓ **106** sites
- ✓ **21** Countries
- ✓ **40** Studies
- ✓ **5** Commercial site



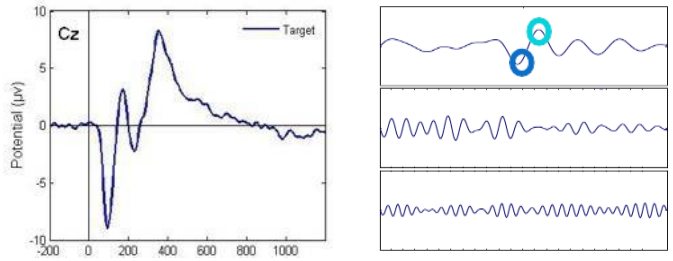
AI & Big Data Algorithms Drive Our Tech Platform

Advanced **Signal Processing** used for automatic cleaning and identification of relevant activity patterns

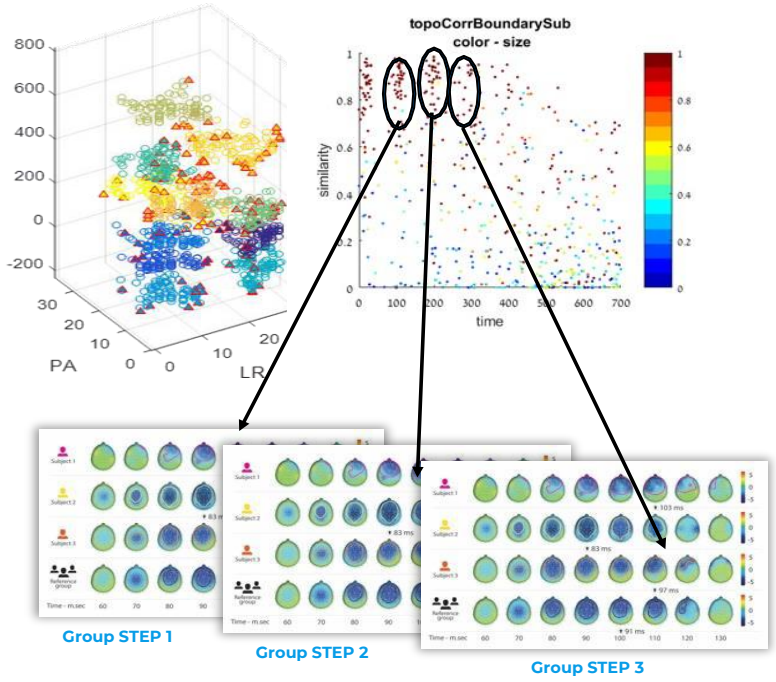
Machine Learning algorithms identify measures of cognitive functions in a patient-specific way based on our big data

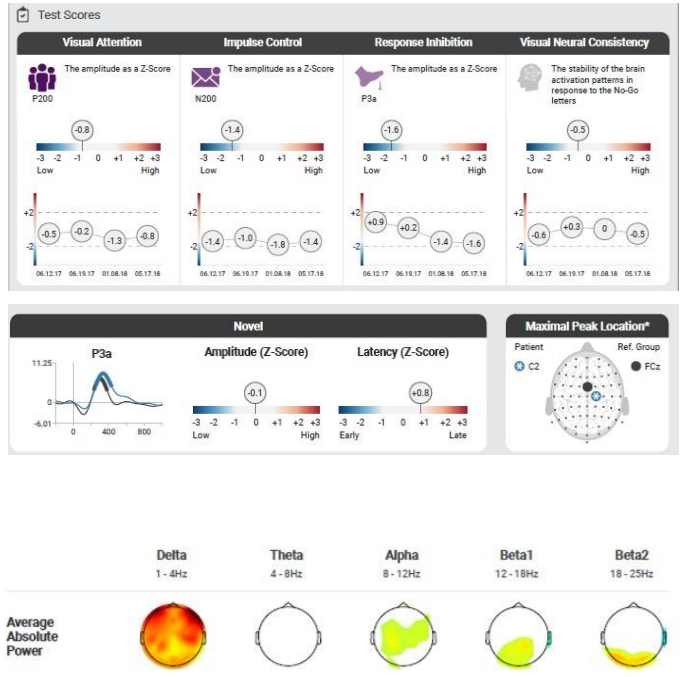
Leveraging our **Big Data** & normative database for a Comparative Analysis summarized in automatic report

Cleaning / Averaging / Filtering



Clustering of Spatiotemporal Parcellations (STEPS)





FDA 510k Labeling for BNA™

“The Brain Network Analytics (BNA™) Product is to be used by qualified medical professionals for the post-hoc statistical analysis of the human EEG, including event-related potentials (ERP).

This device is indicated for use in individuals 12 to 85 years of age.

The BNA™ Product is to be used with established testing tools (Auditory Oddball, Visual Go No-Go (age range of 25 to 85 years), and Eyes-Closed tasks).”

Barriers to Entry

FDA Cleared (510k)

FDA cleared (510k) software platform: highly regulated medical environment

Patents

Company has **8 patents,** and **trade secrets** based on **10+ years** of R&D and technical know-how

World's Largest Dataset of Standardized EEG & ERP Recordings

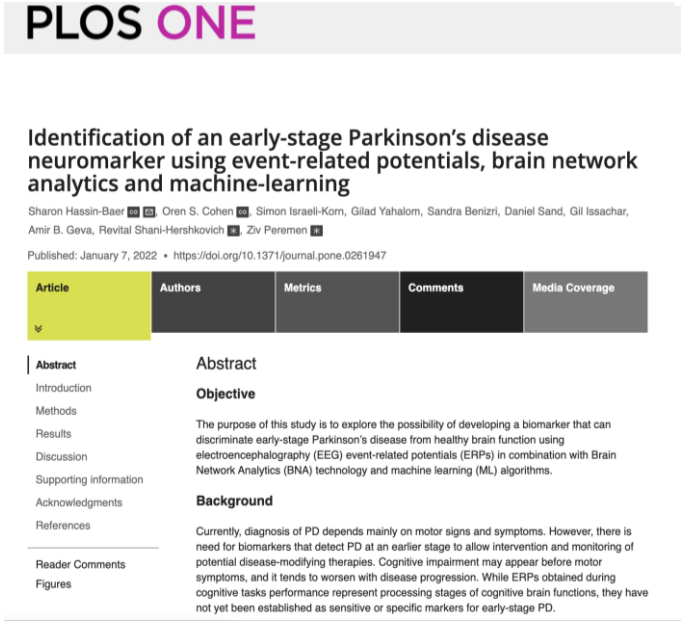
Comprehensive **longitudinal** standardized database across 12 disorders including normal

Patent Status

Patent Reference Number	Description	Status	Publication Date	Expiration Date
WO2018078619A1 US11400289B2	Apparatus and methods for predicting therapy outcome	GRANTED in US, Japan Pending in: Australia, China, Canada, EU, Israel	02-Aug-2022	02-Nov-2037
WO2015/071901 US Patent # 9,713,433	Method and system for managing pain.	GRANTED in the US	25-Jul-2017	11-Nov-2034
WO2014/076698 US Patent # 10,136,830	Neuropsychological Data analysis using spatiotemporal parcellation	GRANTED in US	27-Nov-2018	20-Aug-2034
WO2013/011515 US Patent # 9,839,392	Method and system for estimating brain concussion.	GRANTED in US	12-Dec-2017	10-Sep-2033
WO2011/086563 US Patent # 9,895,077	Method and system for weighted analysis of neurophysiological data.	GRANTED in US	20-Feb-2018	18-Jan-2031
WO2009/069134 US PATENT # 8,706,205	Functional Analysis of Neurophysiological Data.	GRANTED In the US	22-Apr-2014	28-Jun-2030
US Patent # 9,826,914	Functional Analysis of Neurophysiological Data.	GRANTED in the US	28-Nov-2017	30-Nov-2028
US Patent # 8,320,649	Neuropsychological spatiotemporal pattern recognition	GRANTED in the US	27-Nov-2012	27-May-2024

Notable Clinical Publications

Over 18 Peer Reviewed Publications



PLOS ONE

Identification of an early-stage Parkinson's disease neuromarker using event-related potentials, brain network analytics and machine-learning

Sharon Hassin-Baer, Oren S. Cohen, Simon Israeli-Korn, Gilad Yahalom, Sandra Benizri, Daniel Sand, Gil Issachar, Amir B. Geva, Revital Shani-Hershkovich, Ziv Peremen

Published: January 7, 2022 • https://doi.org/10.1371/journal.pone.0261947

Article | Authors | Metrics | Comments | Media Coverage

Abstract
Introduction
Methods
Results
Discussion
Supporting information
Acknowledgments
References
Reader Comments
Figures

Abstract

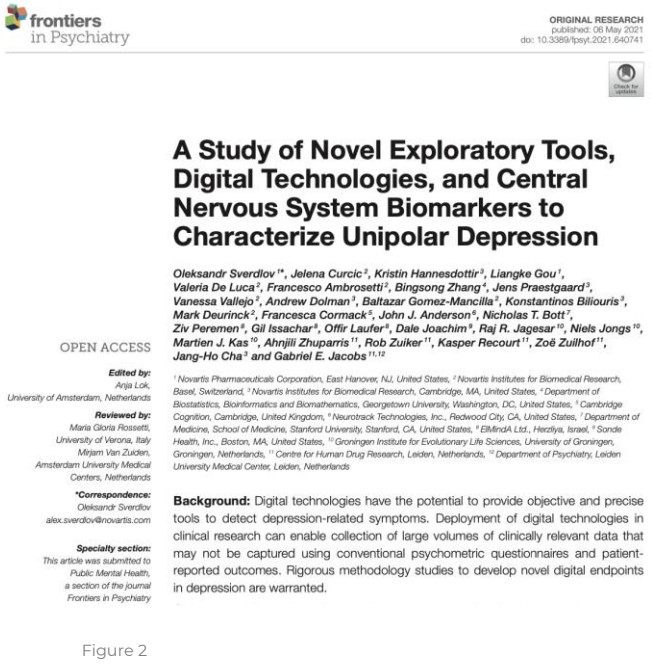
Objective

The purpose of this study is to explore the possibility of developing a biomarker that can discriminate early-stage Parkinson's disease from healthy brain function using electroencephalography (EEG) event-related potentials (ERPs) in combination with Brain Network Analytics (BNA) technology and machine learning (ML) algorithms.

Background

Currently, diagnosis of PD depends mainly on motor signs and symptoms. However, there is need for biomarkers that detect PD at an earlier stage to allow intervention and monitoring of potential disease-modifying therapies. Cognitive impairment may appear before motor symptoms, and it tends to worsen with disease progression. While ERPs obtained during cognitive tasks performance represent processing stages of cognitive brain functions, they have not yet been established as sensitive or specific markers for early-stage PD.

Figure 1



frontiers in Psychiatry

ORIGINAL RESEARCH
published: 06 May 2021
doi: 10.3389/fpsyt.2021.640741

A Study of Novel Exploratory Tools, Digital Technologies, and Central Nervous System Biomarkers to Characterize Unipolar Depression

Oleksandr Sverdlov, Jelena Curcic, Kristin Hannesdottir, Liangke Gou, Valeria De Luca, Francesco Ambrosetti, Bingsong Zhang, Jens Praestgaard, Vanessa Vallejo, Andrew Dolman, Baltazar Gomez-Mancilla, Konstantinos Biliouris, Mark Deurinck, Francesca Cormack, John J. Anderson, Nicholas T. Bott, Ziv Peremen, Gil Issachar, Offir Laufer, Dale Joachim, Raj R. Jagesar, Niels Jongs, Martien J. Kas, Ahnjili Zhuparris, Rob Zuiker, Kasper Recourt, Zoé Zuilhof, Jang-Ho Cha and Gabriel E. Jacobs

OPEN ACCESS

Edited by: Anja Lok, University of Amsterdam, Netherlands

Reviewed by: Maria Gloria Rossetti, University of Verona, Italy; Mirjam Van Zuiden, Amsterdam University Medical Centers, Netherlands

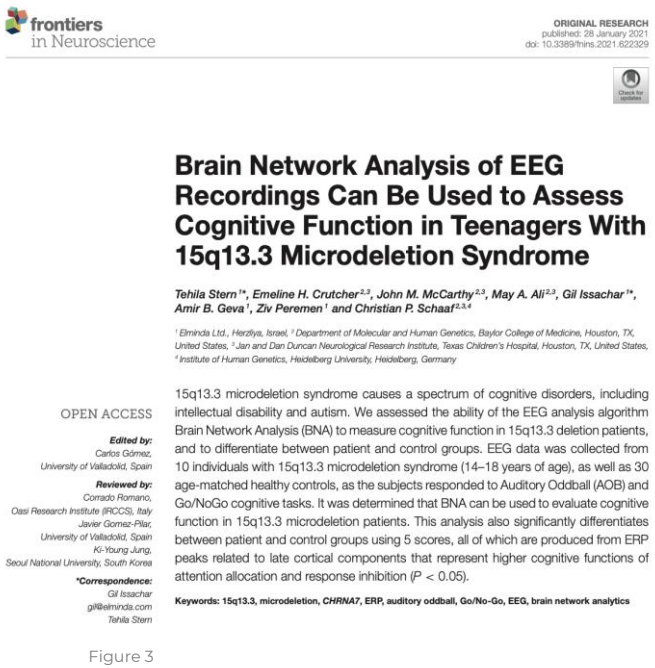
*Correspondence: Oleksandr Sverdlov, alex.sverdlov@novartis.com

Specialty section: This article was submitted to Public Mental Health, a section of the journal Frontiers in Psychiatry

Novartis Pharmaceuticals Corporation, East Hanover, NJ, United States; Novartis Institutes for Biomedical Research, Basel, Switzerland; Novartis Institutes for Biomedical Research, Cambridge, MA, United States; Department of Biostatistics, Bioinformatics and Biomathematics, Georgetown University, Washington, DC, United States; Cambridge Cognition, Cambridge, United Kingdom; Neurotrack Technologies, Inc., Redwood City, CA, United States; Department of Medicine, School of Medicine, Stanford University, Stanford, CA, United States; ElMindA Ltd., Herzliya, Israel; Sonde Health, Inc., Boston, MA, United States; Groningen Institute for Evolutionary Life Sciences, University of Groningen, Groningen, Netherlands; Centre for Human Drug Research, Leiden, Netherlands; Department of Psychiatry, Leiden University Medical Center, Leiden, Netherlands

Background: Digital technologies have the potential to provide objective and precise tools to detect depression-related symptoms. Deployment of digital technologies in clinical research can enable collection of large volumes of clinically relevant data that may not be captured using conventional psychometric questionnaires and patient-reported outcomes. Rigorous methodology studies to develop novel digital endpoints in depression are warranted.

Figure 2



frontiers in Neuroscience

ORIGINAL RESEARCH
published: 28 January 2021
doi: 10.3389/fnins.2021.622329

Brain Network Analysis of EEG Recordings Can Be Used to Assess Cognitive Function in Teenagers With 15q13.3 Microdeletion Syndrome

Tehila Stern, Emeline H. Crutcher, John M. McCarthy, May A. Ali, Gil Issachar, Amir B. Geva, Ziv Peremen and Christian P. Schaaf

OPEN ACCESS

Edited by: Carlos Gómez, University of Valladolid, Spain

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ElMinda Ltd., Herzliya, Israel; Department of Molecular and Human Genetics, Baylor College of Medicine, Houston, TX, United States; Jan and Dan Duncan Neurological Research Institute, Texas Children's Hospital, Houston, TX, United States; Institute of Human Genetics, Heidelberg University, Heidelberg, Germany

15q13.3 microdeletion syndrome causes a spectrum of cognitive disorders, including intellectual disability and autism. We assessed the ability of the EEG analysis algorithm Brain Network Analysis (BNA) to measure cognitive function in 15q13.3 deletion patients, and to differentiate between patient and control groups. EEG data was collected from 10 individuals with 15q13.3 microdeletion syndrome (14–18 years of age), as well as 30 age-matched healthy controls, as the subjects responded to Auditory Oddball (AOB) and Go/NoGo cognitive tasks. It was determined that BNA can be used to evaluate cognitive function in 15q13.3 microdeletion patients. This analysis also significantly differentiates between patient and control groups using 5 scores, all of which are produced from ERP peaks related to late cortical components that represent higher cognitive functions of attention allocation and response inhibition ($P < 0.05$).

Keywords: 15q13.3, microdeletion, *CHRNA7*, ERP, auditory oddball, Go/No-Go, EEG, brain network analytics

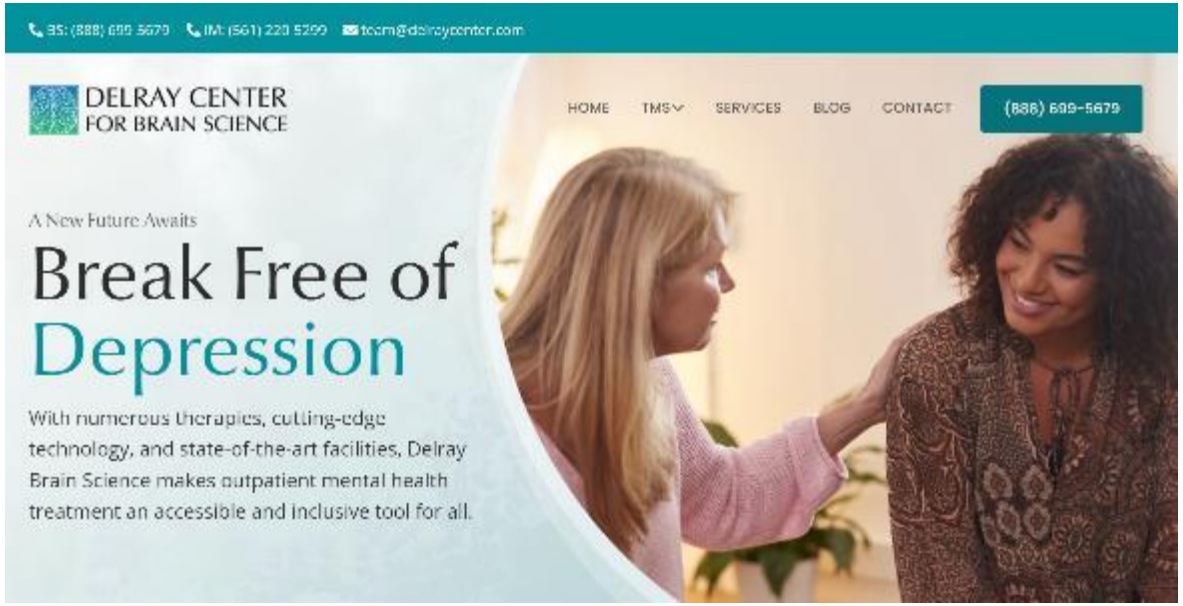
Figure 3

Firefly Neuroscience is Transforming Mental Health Standard of Care

Standard Procedure		Firefly Neuroscience
Undiagnosed pre-symptomatic stages (e.g., preclinical AD)	Pre-clinical	**Detection of pre-symptomatic pathology** (e.g., Early prediction of cognitive decline)
Diagnosis based on subjective symptoms	Diagnosis	**Diagnosis is supported with objective brain measures**
A trial-and-error strategy Low remission rates[1], increased health care costs	Treatment Selection	**Informed treatment selection** (e.g., SSRI, TMS)
High drop-out rates, low adherence[1]	Treatment compliance	**Increased compliance**
Subjective assessment of treatment effect	Follow-up	**Objective monitoring of treatment effect**
Poor outcomes, increased costs		**Improved outcomes, lower costs**

[1]28% remission rate, 21% dropout rate (STAR*D level 1)

Testimonial - Delray Center for Brain Science



"We're able to get information right away, information that we never had before, and we can see at the neurophysiologic functional level of the brain [and] how that brain is firing.

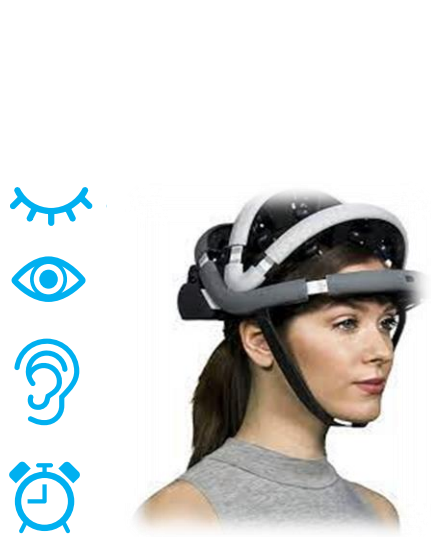
That really helps guide us in terms of what condition are we dealing with, what are the complexities of this case, what is unique about this case, how might we cater this person's treatment to help their particular case based on both what they report and based on also what we see now on the BNA™ report."

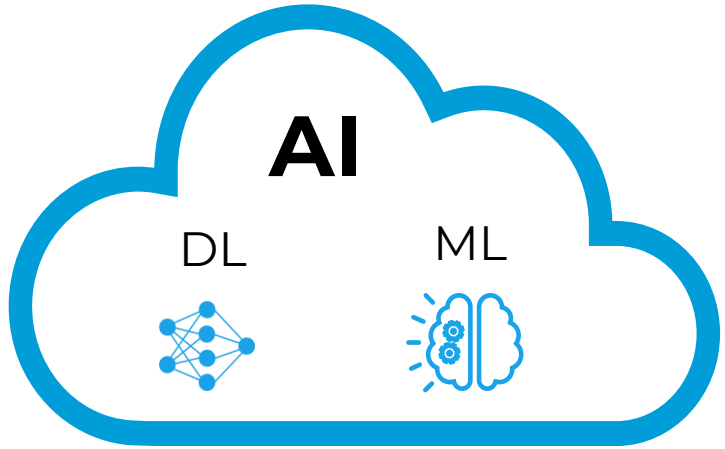
– **Dr. Raul Rodriguez** of Delray Center for Brain Science

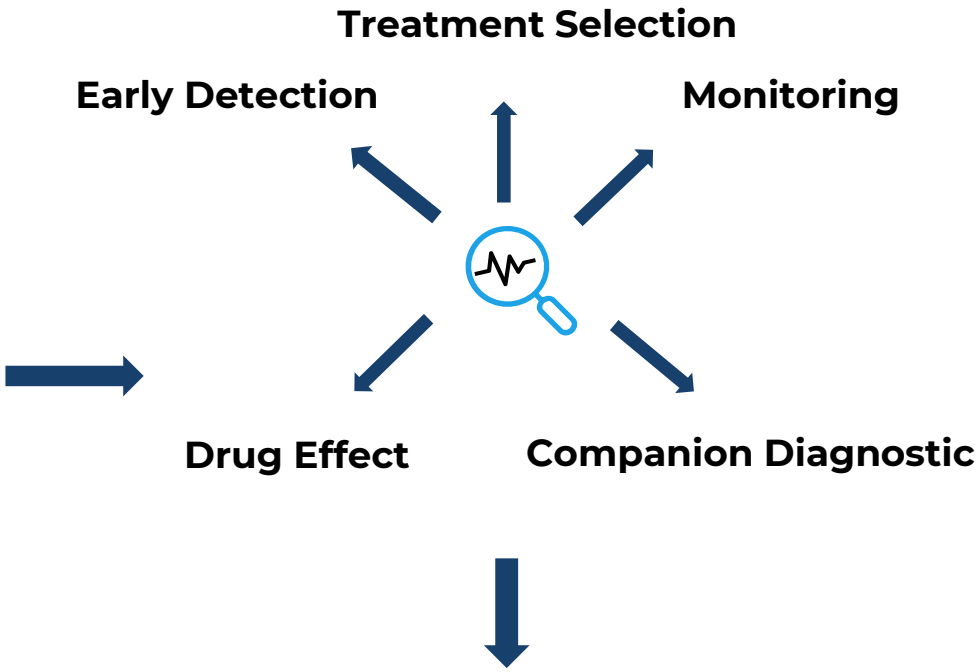
Full Interview

Identifying Neuro Biomarkers

Brain Network Analytics (BNA™)	Improved outcomes by using EEG Based Biomarkers







✓ Reduced costs ✓ Better Efficacy ✓ Reduce time