

# **Revolutionizing Brain Health**

**AI-Powered Precision Neuropsychiatry** 





## The problem: Patient needs outpace clinical innovation

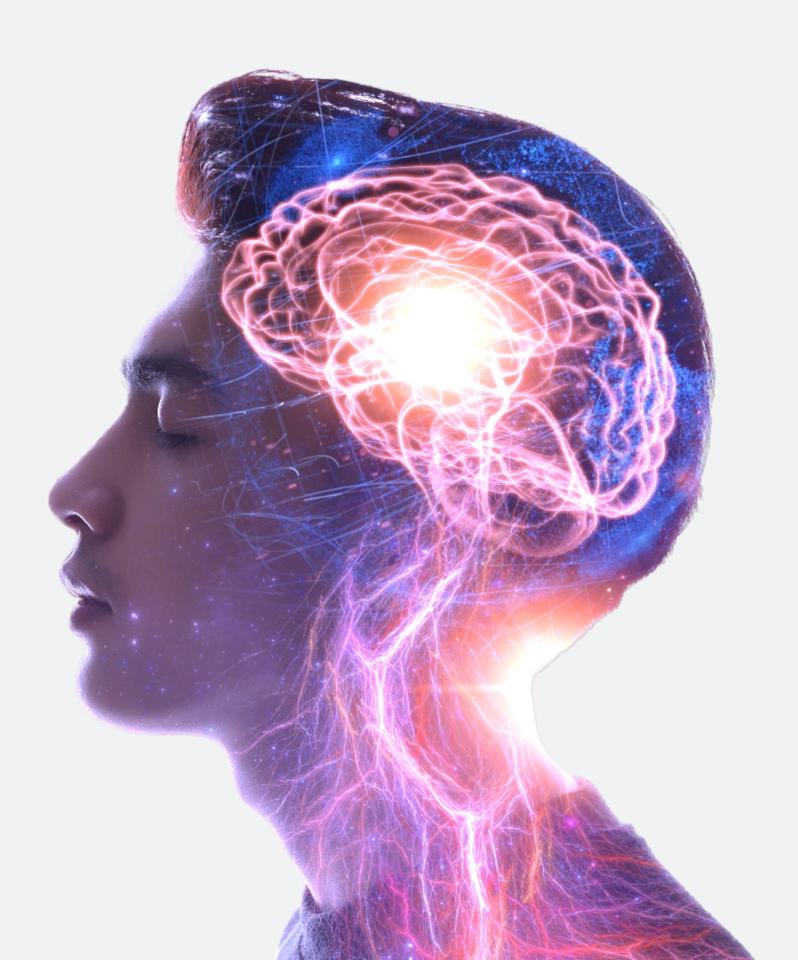
### ~1B mental health patients worldwide

- \$2.5T cost to economy (\$16T by 2030)
- 30+% of healthcare spending is waste
- Trial & error is standard of care
- 30-40% of patients are treatment-resistant

- R&D costs \$2-3B
- Takes 12-18 years
- 25-35% clinical trial participant attrition rate
- 8% success rate

### Therapy development is inefficient

## Neuropsychiatric clinical trials have the highest cost, time to market, and failure rate of all disciplines



2X

## Al/Precision Biomarker return on investment

**Precision oncology proves feasibility** 

Probability of clinical trial success with biomarkers

**25%** Decreased cancer trial mortality using AI prediction models (1) using AI prediction models (1)

Increase in overall ROI (2) on clinical pipeline & IP portfolio

## The solution: Bringing precision to neuropsychiatry

**Preclinical foundation** 



## Fundamental neuroscience





**Biomarker synthesis** 

Therapeutic strategy

## Sama fuses generative Al with computational neuroscience

**Extensive intellectual property portfolio and** *software as medical device* regulatory pathway:

- First "transprognostic" algorithms optimize treatment of major psychiatric disorders ~50% better than standard of care
- **Rigorous independent replications: #1 team** on the Brainclinics Foundation international biomarker prediction challenge (3)
- Structure-function deep learning foundation models trained on >15,000 patients for classification & digital twins
- Accuracy of our iMAGiNE<sup>™</sup> precision neuropsychiatry platform ranks alongside billion dollar incumbents in the space
- **Diverse, curated data:** reduce bias,  $\uparrow$  positive predictive value

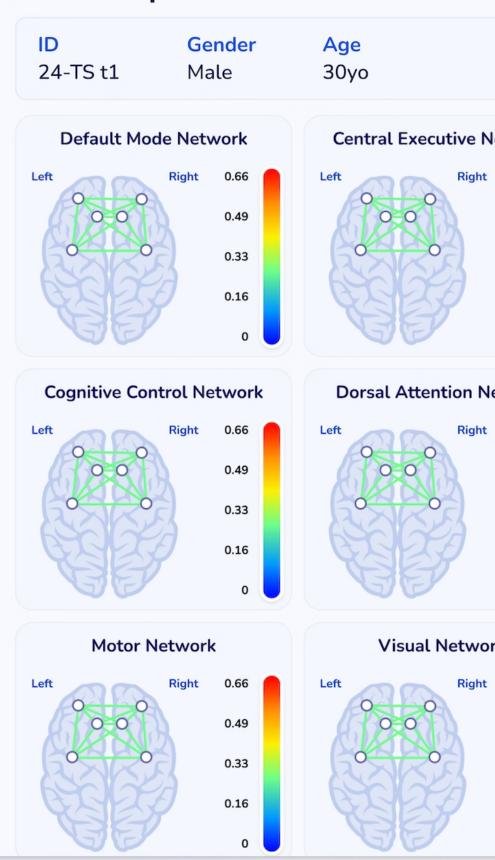
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#### platform.sama

#### Sama

- C Dashboard
- Patients
- Settings

#### **Patient Report**



😥 Dr. Harrison L. Montague



Individual baseline — ketamine infusion



Nale XX-15 KJ

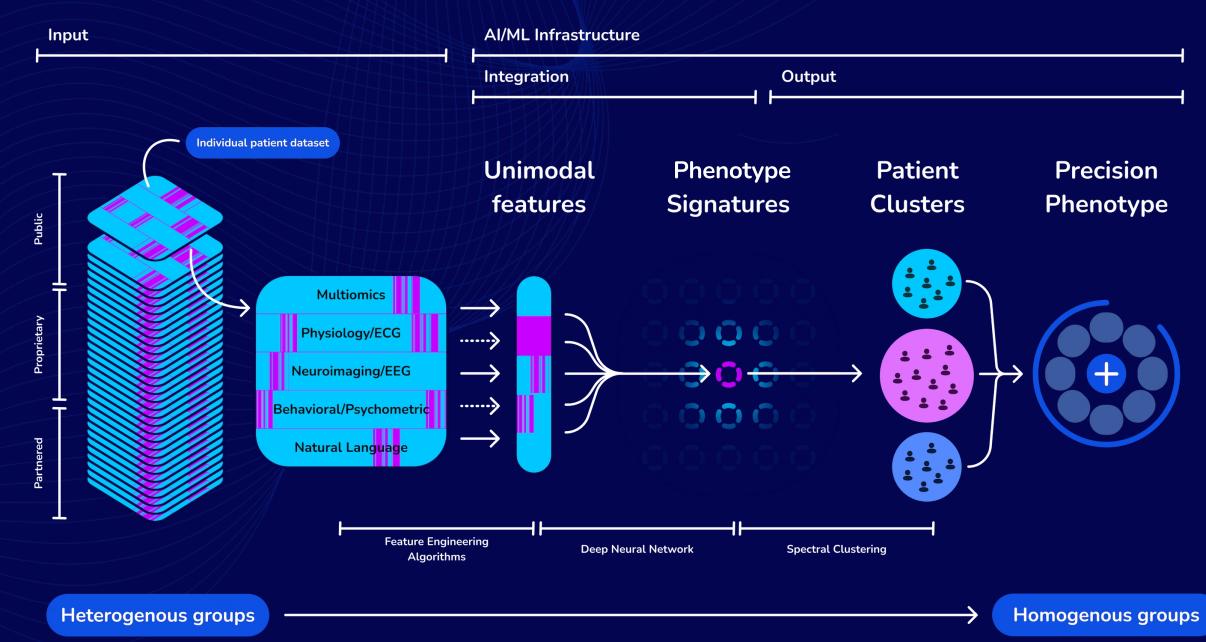
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Central Attention New

## Our mission: eliminate trial-and-error in neuropsychiatry

- 10 patents pending: cross-validated, harmonized, longitudinal & clinical datasets are feature engineered for multimodal AI/ML and deep learning
- Phenotype signatures: precision platform generates compact, highdimensional embeddings which systematically uncover clinicallyactionable biomarkers
- Normative baselines: clustering patients reduces heterogeneity for treatment matching, placebo models & digital twins



#### Protocol, Screening, Recruitment

Prior to the trial, sponsors use our platform to create protocols using precision biomarker-driven subgroups, modeling placebo neuroscience, digital twins, etc with fully encrypted HIPAA compliance.

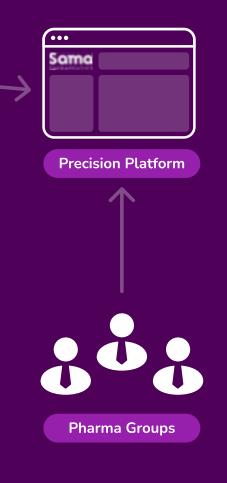
#### Site user **Existing Clinical Trials** AI / Algorithms / Data **Ecosystems / Platforms** 15 Manage patients ... Create groups Sama Handle study **Precision Platform** Mobile e **Cloud Server** Chatbot Survey VR $\boldsymbol{\sim}$ ~~~~ ~~~~ ~~~~ ~~~~ $\sim\sim\sim$ Group of patients ~ 0 0 C Patient **EEG** Acquisition **EEG Server**

#### **Decentralized Operations**

In this phase, interim analytics are delivered as patients interact with mobile neurotechnology, chatbots, telemedicine, home nursing, and virtual reality interfaces through the precision platform.

### **Clinical Trial Readout**

The final phase hinges on intensive platform analytics for Go/No-Go decisions. Cohorts are processed through *interactive* AI and biostatistics algorithms on the cloud for stakeholders to review.





### Maximize success through patient stratification

- and after dosing

## We maximize success at each step in clinical development

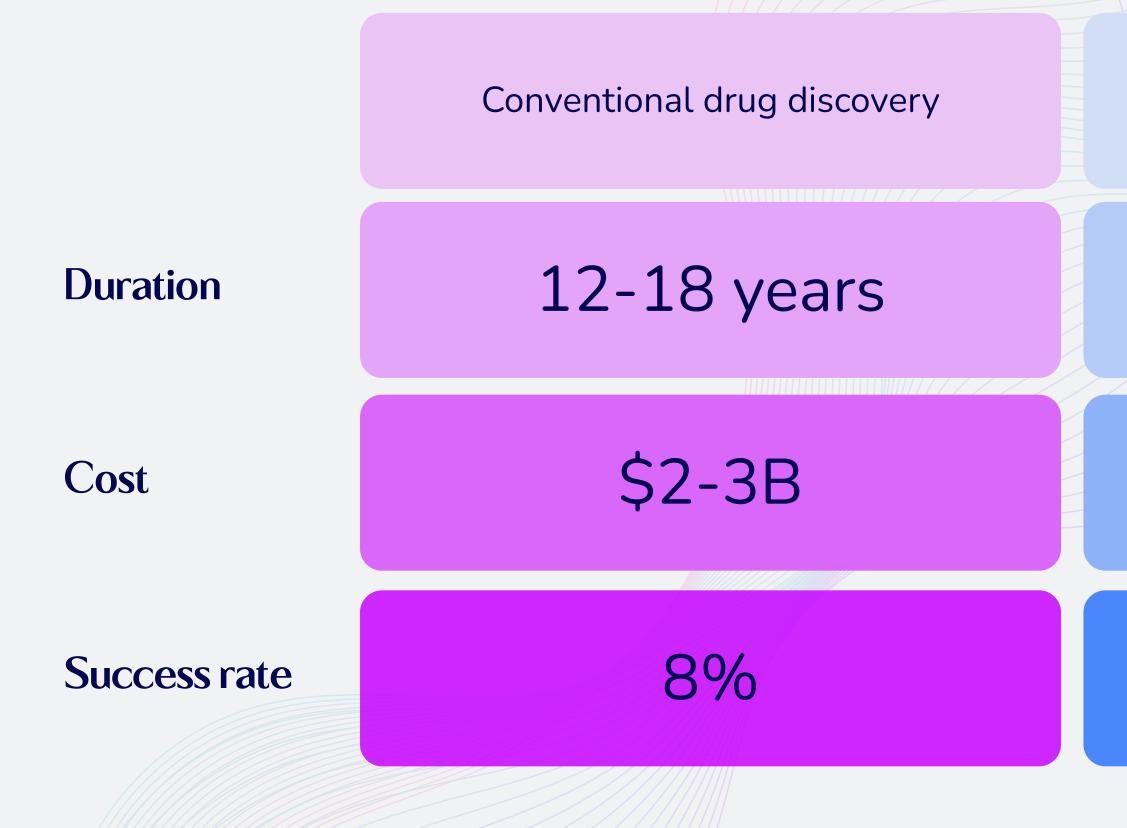
### Sama's precision platform can help:

### Guide clinical discovery & development strategy

Lead optimization: bridge animal models and human trials Benchmark therapy effects and safety/adverse events Demonstrate brain penetration, molecular target engagement Visualize brain network effects and extract biomarkers Establish dose-response relationship, PK/PD profiling

Disease progression, severity, and placebo responsiveness Digital twins, baseline likelihood of response to treatment Realtime, state-based response and relapse predictors during

## Sama redefines and de-risks treatment discovery



AI-powered drug development

## 5-10 years

\$1B

40%

### **Case Study**

## **Closing the** translational gap for new pharma asset classes







#### **Projected Revenue**



2024 ARR \$1.1M

• A customer needed efficacy signal (GABAA- $\alpha$ 5 receptor) • Undiscoverable via conventional hypothesis-driven techniques • Quick \$15K pilot: our data-driven AI/ML platform discovered dose-responsive EEG/EMG signals missed by major CROs • Won ~\$50K/month platform deal to license our multimodal precision analytics (\$10M Phase 1 from Q1 2024)

2024 O Phase 1: \$50K/month platform licensing + \$500K success milestones

2025-2027 O Phase 2/3: \$200K/month platform, digital twins + \$1M milestone payment per phase

**FDA Approval:** \$2M milestone payment

2028-2030 O Phase 4: \$300K/month companion diagnostics, post-market surveillance

> Royalties 5-10% Depending on total sales

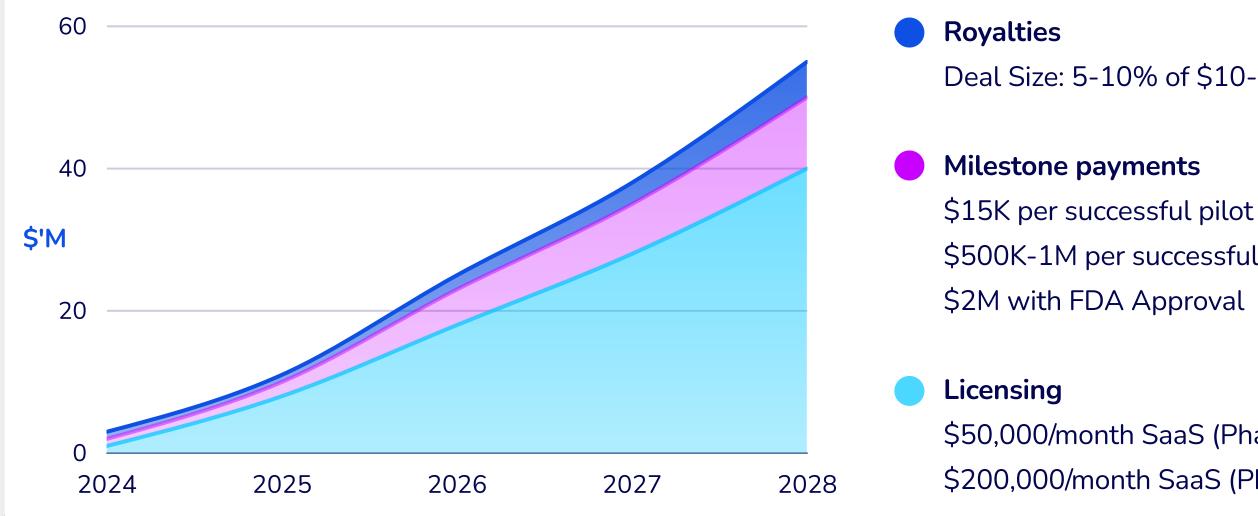
LTV of customer \$18.5M Before royalties

## **Precision brain health** is a growing market

Sama's revenue projections

TAM **\$123B** 

**Global CNS Therapeutics** Market (\$205B by 2030)



### SAM **\$2.91B**

**Global Mental Health Clinical** Trials Market (\$5.1B by 2030)

Deal Size: 5-10% of \$10-50M, 4x/year

- \$500K-1M per successful phase

\$50,000/month SaaS (Phase 1) \$200,000/month SaaS (Phase 2/3)

## Roadmap

### Go-to-market & phased regulatory entry

	2022	<b>2023</b> Q1	Q2		Q3	Q4	
Funding	Pre-seed \$500,000 Friends & Family (SSA Capital, LLC)	Open \$1.25M Pre-Seed round to angels/VCs		Mystic Ventures leads with \$500k	Y)	stic Ventures ds \$200k	
Growth Strategy & Partnerships	Zeto EEG hardware and cloud platform license for exclusive plug-in	Exploratory studies for veteran PTSD/TBI, MDE device partnerships with Emotiv & IDUN		Damona Pharma paid \$15k preclinical pilot; Reconnect Labs Phase 1 trial development	partn	l and Evidation herships for data ction; Bottneuro device hership	
Legal & Regulatory	Incorporation & public benefit mission via 10% founder shares' charity	Publish AI/ML white papers & precision biomarker clinical protocols		Earn ISO certification, establish Quality Management Systems	filing trade	isional patent gs; defensive emarks, trade et protection	
Product R&D	Begin data collection across transdiagnostic drug/device indications	EEG/ECG/psychometrics Al model development > 10,000 patients		Cross-validation, data harmonization, and augmentation of predictive AI/ML stack	inter psyc	ned #1 team in mational precision hiatry biomarker lenge <sup>1</sup>	L t r



SSA Capital finishes Pre-Seed with \$500k

Damona Pharma trial partnership \$50k/month; deploy Zeto plug-in and data flywheel B2B2C

FDA "Software as Medical Device" 510(k) application

LLM/VR multimodal tech stack expansion, datasets +5000 pts partner Brainclinics

Launch \$5M Seed round

Acquire 30-40 pharma customers, KPI: revenue ~\$1M/quarter

FDA "Software as Medical Device" 510(k) Approval; randomized clinical trials & real world studies

Prove drug & device development ROI; increase proprietary & partnered datasets

Fundamental neuroscientific discovery GTM

Launch ~\$25M Series A for enterprise scaling

2025

Partner with large companies, expand web of subsidiaries

biotech/pharma

FDA "de novo" biomarkers for diagnostics & prognostics

## Competitive landscape: clinical trial optimization

	Samo	UNLEARN.ai	Beacon Biosignals Cumulus Neuroscience	DeepPsy & iMedSync	Firefly Neuroscience ANT-NeuroGuide	Alto Neuroscience Neumora Therapeutics
Generative AI (digital twins, chatbot, etc)	✓	~				
Preclinical Platform	✓		~			~
Traditional RCTs (Ketamine, TMS)	✓	~	~	~	~	Proprietary compounds
Schedule 1 Trials (LSD, DMT, etc)	✓			~		
Biosensing (ECG, EMG, Oculometrics, etc)	✓		~	~		~
Neural Recording (EEG, fMRI, etc)	✓		~	~	~	~
Cognitive Assessment		~	~		✓	✓
Omics (RNAseq, etc)	<ul> <li></li> </ul>	✓				✓

## **Executive and computational team**

Academic/industry hybrid: clinical, regulatory, Al/ML & psychedelics expertise



Shobi Ahmed, MD PhD\* **Chief Executive Officer** Founder



**Kristel Carrington, MD Chief Medical Officer Co-Founder** 



Adam Teed, PhD\* **Chief Operating Officer Co-Founder** 



Elias Mouchlianitis, PhD

**Chief Scientific Officer** 



**Russell Hanson, PhD** 





**Mollie Fleury** Chief of Staff



**Tyler Moore, PhD** Chief Development Advisor



Alan Tucholka, PhD\* **Chief Technology Officer** 



Franz Hell, PhD **Chief Al Officer** 



Karim El Kanbi, PhD\* Head of AI/ML

\*4 full-time employees, remainder fractional

## **Consulting and operational team**

Academic/industry hybrid: clinical, regulatory, Al/ML & psychedelics expertise



Mario de la Fuente Revenga, PharmD PhD Clinical Pharmacology, GONOGO



Andrew Cutler, PhD Generative AI Engineering, **Psychometrics & Cognition** 



Eric Lin, MD

Natural Language Processing Psychiatrist, Stanford / VA



Sivan Kinreich, PhD

Asst. Professor of Psychiatry, SUNY Downstate Medical Center



Koene van Dijk, PhD

**Digital Sciences & Translational** Imaging, KVD (ex-Pfizer)



**Prival Sheth, MSc VP** Business Development



Marijn "Ryan" Lijffijt, PhD Translational Biomarker Medicine, Digital Twins (ex-Sage, Baylor)



Kelly Kennedy **Psychometrics & Business** 

Development



Brock Pluimer, PhD (c)

Neuroimaging AI/ML & Scientific Operations



Derek Hill, PhD

**Regulatory** Affairs, Panoramic Digital Health

## Team's track record

### More than 200 combined years of industry achievements & 45 PhD/MD/JDs



~1000s of high impact papers: 100,000+ cited, with patents & licensing across our tech stack

**10 FDA 510k / de novo device technology approvals:** Class 2/3, ISO, IEC, CE mark Raised over \$1.6B at previous companies: pre-seed to acquisition / IPO





#1 in precision psychiatry challenge: top 4 places on the Brainclinics leaderboard & hackathons Al/ML key contributions: "gold standard" toolboxes, high dimensional modeling, open science pioneers

#### Clinical / Academia



## Scientific advisory board

Extraordinarily interdisciplinary platform oversight



Diego Pizzagalli, PhD Professor, Psychiatry Harvard Medical School



Laura Bevilacqua, MD PhD Psychiatrist & Professor, Mt. Sinai School of Medicine



Martijn Arns, PhD Professor, Cognitive Neuroscience, Maastricht; Director, Brainclinics



Stephen Morse, JD PhD Professor of Law in Psychiatry, Penn



Konrad Kording, PhD Professor, PIK, University of Pennsylvania



Adam Safron, PhD Founding Chief Scientific Officer, Postdoc, JHU



#### John Allen, PhD

Distinguished Professor, Psychology, University of Arizona



#### **Rex Jung, PhD**

Professor of Neurosurgery, University of New Mexico

# Sonno Therapeutics

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Samā' (שמים سَمَاَءَ) , Proto-Semitic šamāy) Of the heavens, divinity, ascension, ego-dissolution

> Śāma (सम, Sanskrit) Tranquility of mind, equanimity, season

Therapeutikós (θεραπευτικός, Ancient Greek) Obliging, curative; to attend, do service

