

# ASX ANNOUNCEMENT



30 July 2024

## TechKnow Invest Roadshow presentation

**Perth, Australia, and Minneapolis, USA: TrivarX Limited** ('the **Company**') (ASX: TRI) is pleased to advise that Chief Operating Officer, Mr Kai Sun will be presenting at the TechKnow Invest Roadshow event in Sydney and Melbourne on 30 July 2024 and 31 July respectively. For investors that cannot attend in-person, livestream links are available below.

**Sydney (presentation commencing at 10:15am AEST):**

<https://www.youtube.com/live/N3p-ElbxNjc>

**Melbourne (presentation commencing at 1:45pm AEST):**

<https://www.youtube.com/live/MEp9AI72Rdc>

A copy of the Company's presentation is attached to this announcement.

**This announcement is authorised for release by the Board of Directors of TrivarX Limited.**

**ENDS**

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**About TrivarX Limited:**

TrivarX (ASX: TRI) (OTCPINK: MDBIF) is a mental health technology company pioneering the use of objective measures to aid in the early detection and screening of mental health conditions. The Company was founded in Australia, with offices located in Perth (WA) and Minneapolis (MN, USA). TrivarX is listed on the Australian Securities Exchange Ltd and trades on the OTCQB Venture Market. Investors can find additional information on [www.otcmart.com](http://www.otcmart.com) and [www.asx.com.au](http://www.asx.com.au)

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## AI-driven solutions to objectively screen for mental health conditions

TECHKNOW INVEST ROADSHOW – JULY 2024

(ASX: TRI)

This presentation has been authorised for release by the Board of TrivarX Limited

## Forward looking statements

The purpose of the presentation is to provide an update of the business of TrivarX Limited (ASX: TRI). These slides have been prepared as a presentation aid only and the information they contain may require further explanation and/or clarification.

Accordingly, these slides and the information they contain should be read in conjunction with past and future announcements made by TrivarX Limited and should not be relied upon as an independent source of information. Please contact TrivarX Limited and/or refer to the Company's website for further information. The views expressed in this presentation contain information derived from publicly available sources that have not been independently verified.

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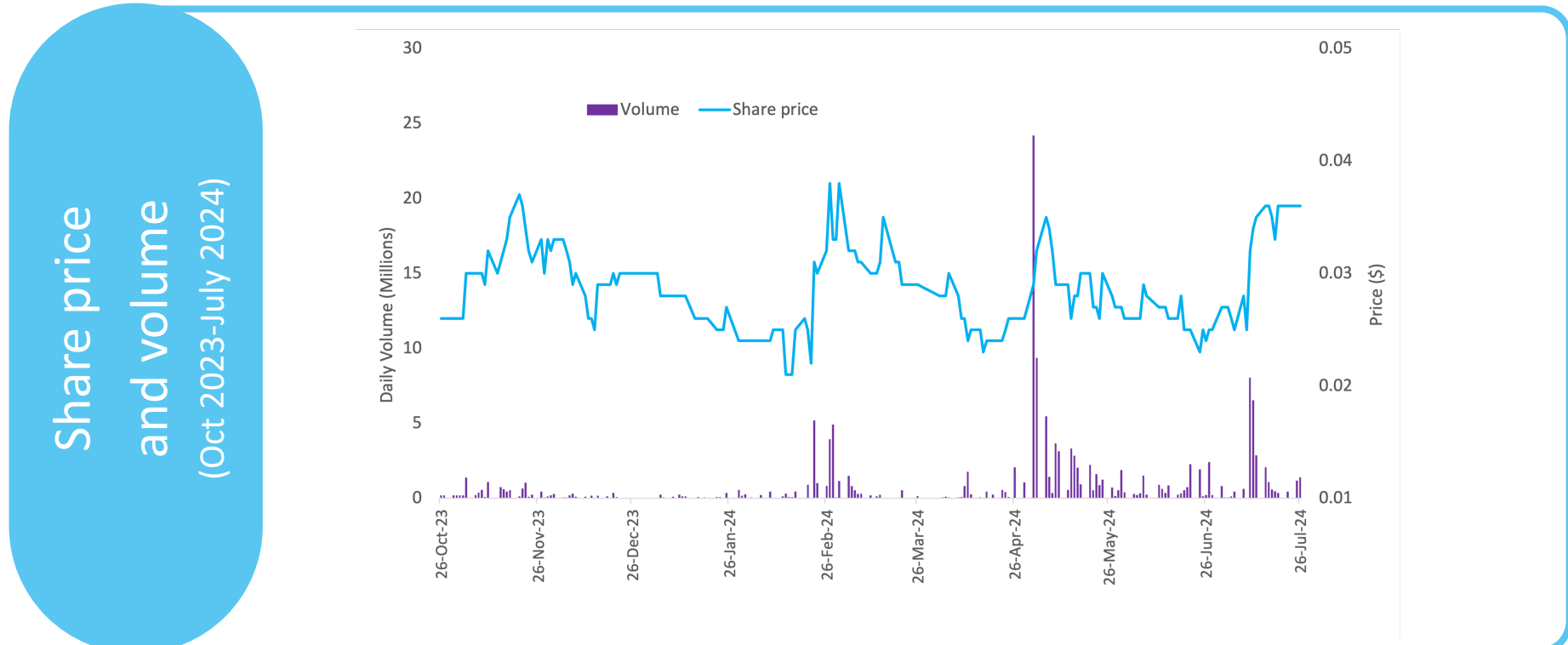
# Corporate overview

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| Corporate Snapshot   |           |
|--|-----------|
| ASX code:  | TRI       |
| Shares on issue:   | ~457m     |
| Market capitalisation (at \$0.036 per share):<br><small>(as at 29 July 2024)</small> | ~A\$16.5m |
| Options on issue:  | ~172.8m   |
| Debt:  | Nil       |

| Major shareholders                            |        |
|---|--------|
| FIL Investment Management (Hong Kong) Limited | 9.30%  |
| Top 20:                                       | 45.72% |

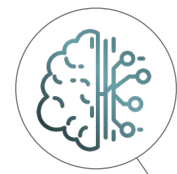
| Board and management            |                         |
|---------------------------------|-------------------------|
| Non-Executive Chairman          | Mr David Trimboli       |
| Chief Operating Officer         | Mr Kai Sun              |
| Executive Director              | Dr Tony Keating         |
| Non-Executive Director          | Mr Chris Ntoumenopoulos |
| Chief Medical Officer           | Dr Archie Defillo       |
| Head of Artificial Intelligence | Mr Massimiliano Grassi  |



# Company overview

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## Pioneering the use of AI to aid in the early detection of mental health conditions



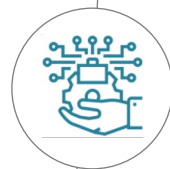
AI-driven, scientifically-backed software tools to objectively screen mental health conditions



Lead program, MEB-001 uses biometric data, EEG and ECG recordings collected during sleep studies to screen for current Major Depressive Episode



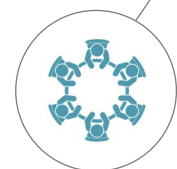
Phase 2 Study successfully completed across 15 US-based sleep centres. Final analysis reported sensitivity of 87% and specificity of 72%



Defined pathway to US FDA regulatory approval via De Novo submission – Company has held multiple pre-submission meetings with the US FDA and gained positive feedback to date



The world's largest database of sleep study data labelled with patient's mental health status – a strong foundation for algorithm development in other mental health conditions



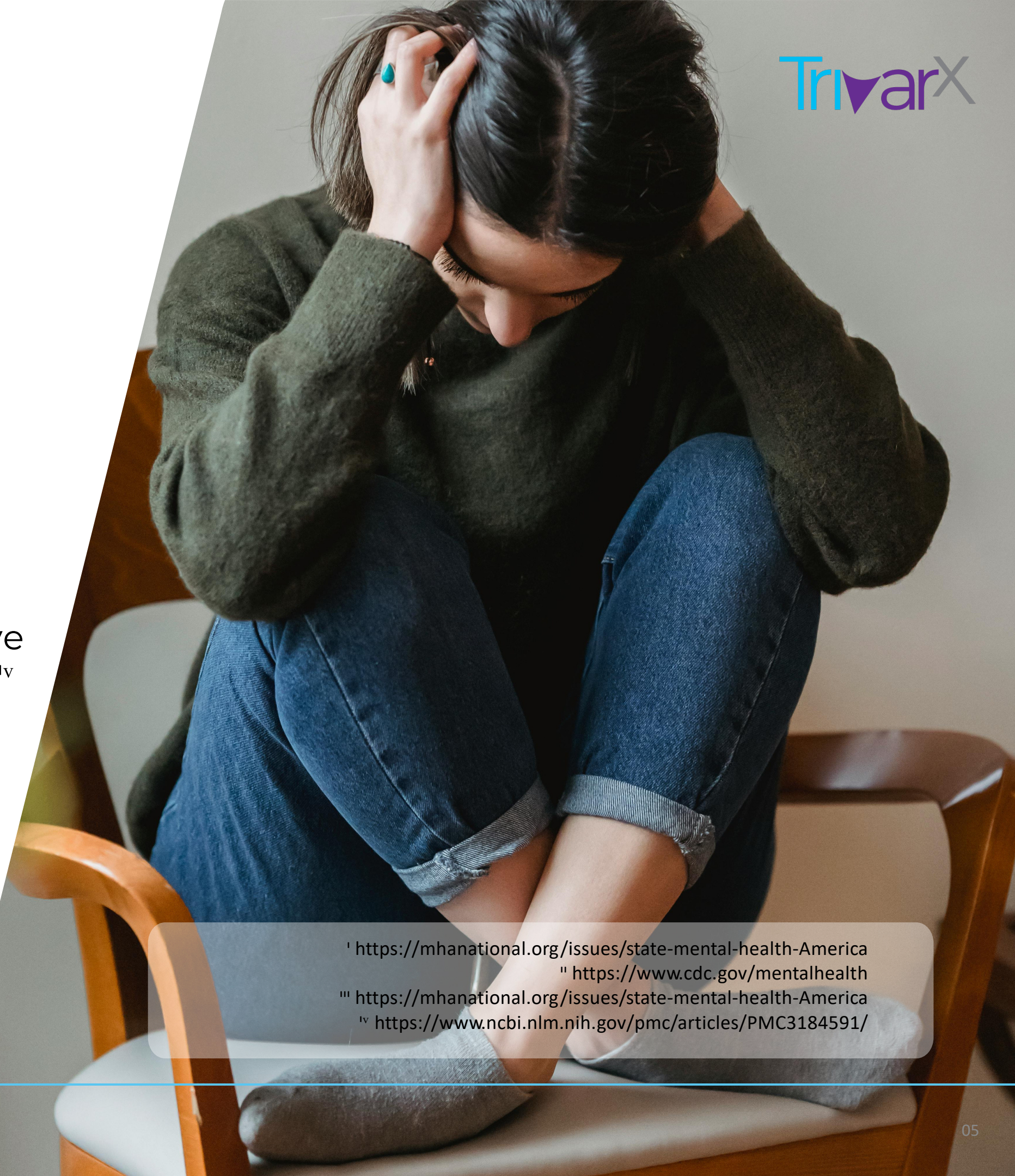
Unique opportunity to deploy into solution sleep centres, where there is a high prevalence of undiagnosed depression – but no screening currently performed

# The US mental health epidemic

- ▶ 21% of US adults experience mental illness – the equivalent to over 50m Americans<sup>i</sup>
- ▶ 1 in 25 US adults live with a serious mental health condition such as major depression, bipolar and schizophrenia<sup>ii</sup>
- ▶ 55% of US adults with a mental health condition receive no treatment<sup>iii</sup>
- ▶ Mental health misdiagnosis is rife – Major Depressive Disorder: 65.9%, Social anxiety: 97.8%, Bipolar: 92.7%<sup>iv</sup>



Prevalent mental health illnesses



<sup>i</sup> <https://mhanational.org/issues/state-mental-health-America>  
<sup>ii</sup> <https://www.cdc.gov/mentalhealth>  
<sup>iii</sup> <https://mhanational.org/issues/state-mental-health-America>  
<sup>iv</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3184591/>

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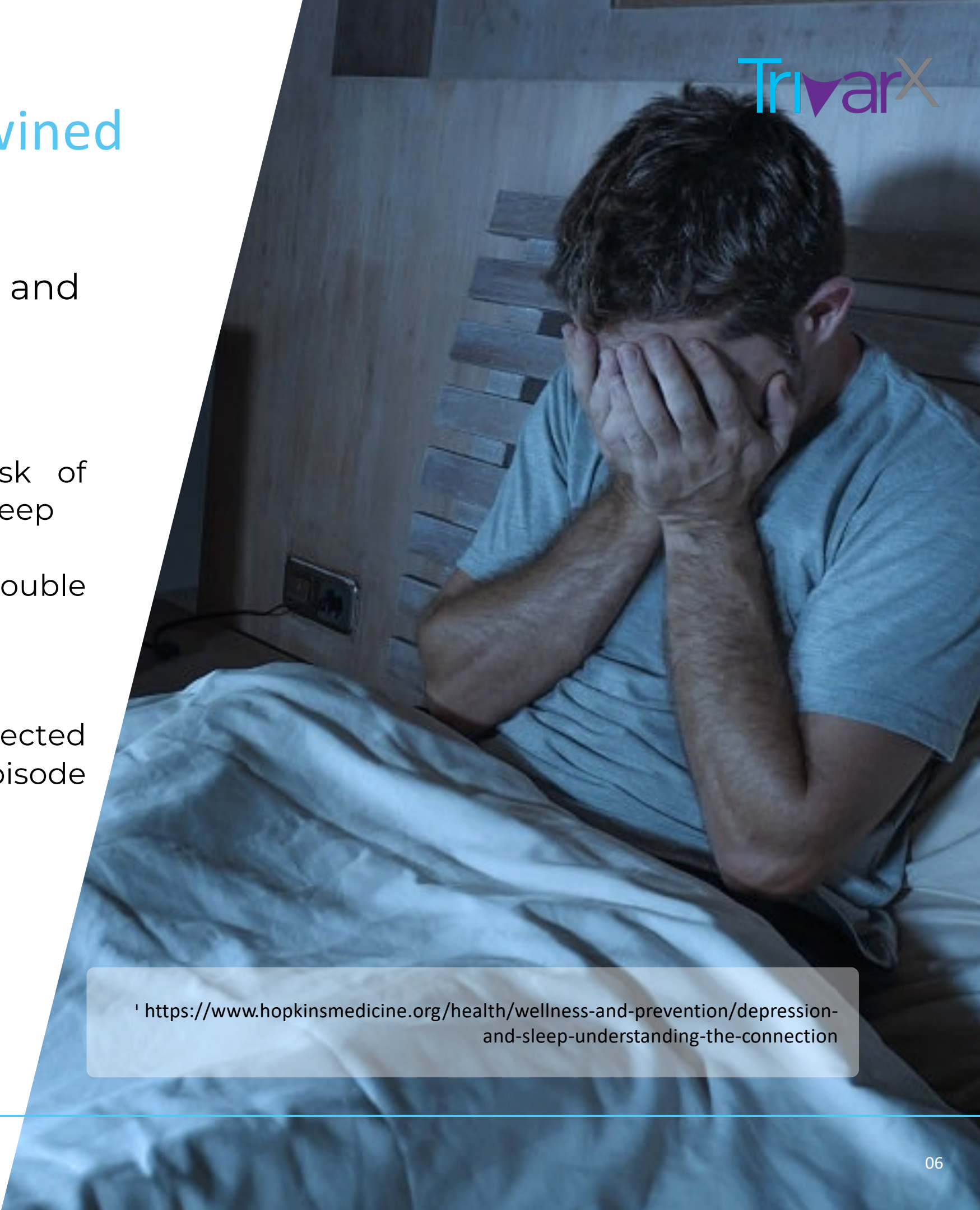
# Sleep and mental health are deeply intertwined

TrivarX is exploring the robust relationship between sleep and mental health using AI

- ▶ Depression and sleep problems are closely linked:
  - People with insomnia may have a tenfold higher risk of developing depression than people who get a good night sleep
  - Among people with depression, '75% of people have trouble falling or staying asleep'
  
- ▶ MEB-001 uses biometric data, EEG, and ECG recordings collected during sleep studies to screen for current Major Depressive Episode (cMDE)



<sup>1</sup> <https://www.hopkinsmedicine.org/health/wellness-and-prevention/depression-and-sleep-understanding-the-connection>



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# A scientifically backed approach

Underpinned by leading management, extensive experience and industry validation

## Extensive industry validation

- ▶ Since the early 2000s, TRI's dedicated scientific personnel have built evidence to support that EEG and ECG data collected during sleep can be used to assist with the screening of mental health conditions via AI
- ▶ Three peer reviewed publications and top congress scientific presentations
- ▶ Four clinical trials completed including a Phase 2 clinical trial for current Major Depressive Episode (cMDE)

## Leading scientific expertise



### Archie Defillo M.D. – Chief Medical Officer

- ▶ 25 years clinical experience with neurological diseases and a trained neurosurgeon
- ▶ 70+ publications on topics predominantly based on heart rate studies
- ▶ Dedicated to advancing TRI's knowledge of heart rate variability and autonomic modulation



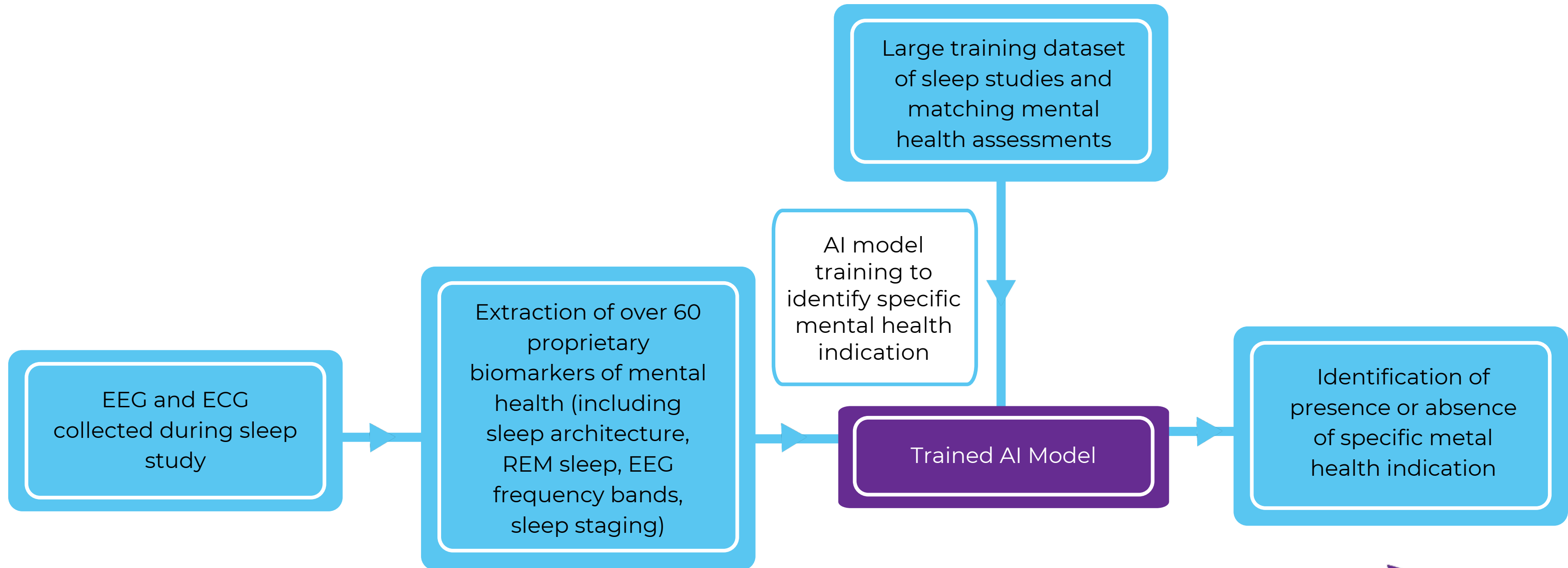
### Massimiliano Grassi PhD – Head of AI

- ▶ 15 years experience as a data scientist in mental health field with an extensive background in psychology
- ▶ Ph. D in Supervised Machine Learning for Clinical Psychiatry
- ▶ Focused on the development of machine learning algorithms using sleep as the window into mental health

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# AI used to connect proprietary sleep biomarkers with mental health



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## An enviable global database

Leveraging the world's largest repositories of EEG and ECG data combined with neuropsychiatric evaluations

**Over 1,000 unique patient cases collected**

1,000+ PHQ9s completed by patients

Over 400 MINIs

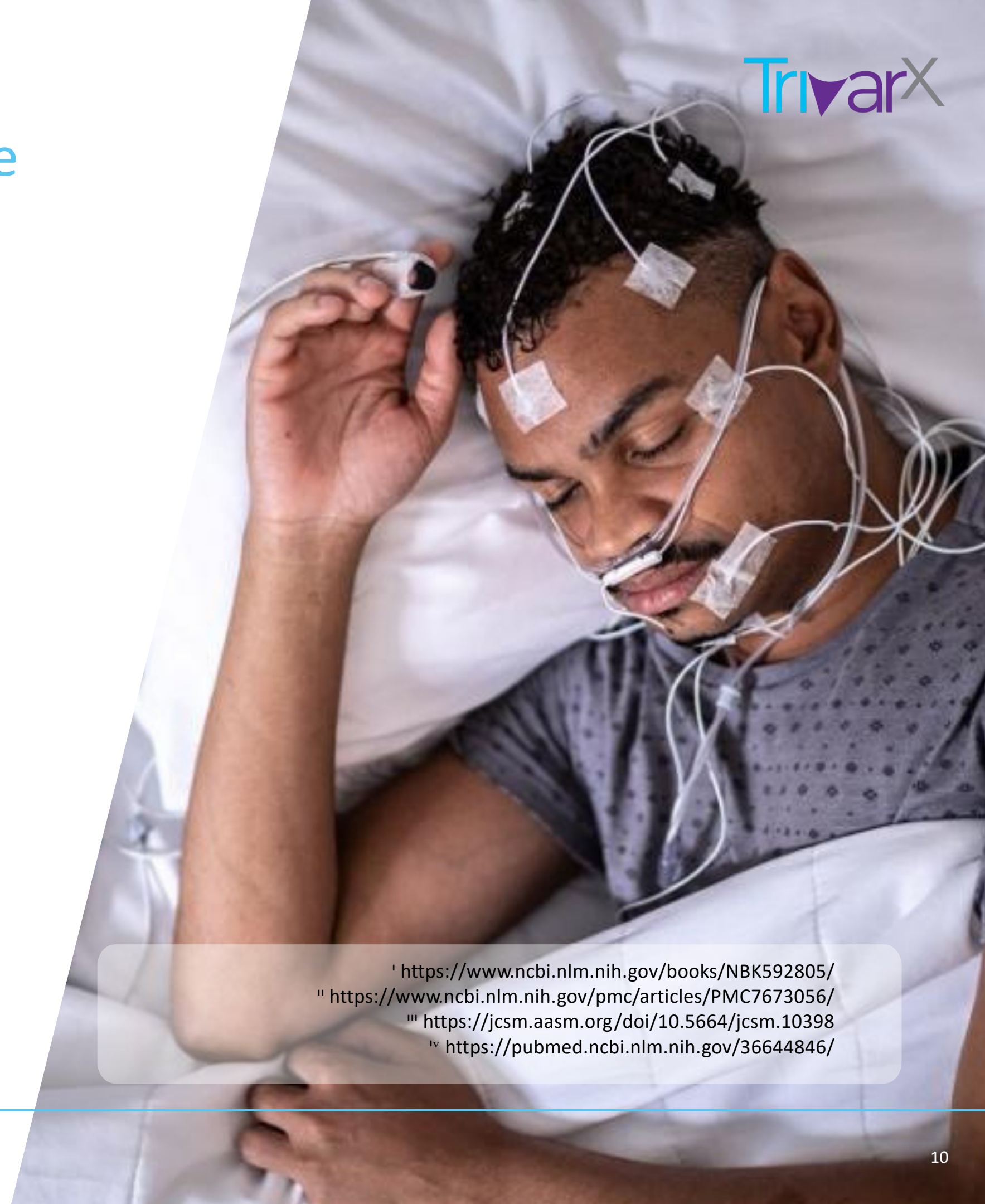
Used by clinicians in structured interviews to find cases of MDE, Manic and Hypomanic episodes (Bipolar Disorder), Panic Disorder, OCD, PTSD, psychotic and mood disorders, General anxiety Disorder and medically related associated disorders



## MEB-001, TrivarX's lead product targets the major market of depression

- ▶ Kaiser Permanente estimates that doctors miss 50% of depression cases in the US<sup>i</sup>
- ▶ Only 1.4% of US outpatients are screened for depression at the primary care level<sup>ii</sup>
- ▶ Depression screening is not part of clinical practice in sleep clinics in the US or globally<sup>iii</sup>
- ▶ 21% of people undergoing a sleep study have depression<sup>iv</sup>

<sup>i</sup> <https://www.ncbi.nlm.nih.gov/books/NBK592805/>  
<sup>ii</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7673056/>  
<sup>iii</sup> <https://jcsn.aasm.org/doi/10.5664/jcsn.10398>  
<sup>iv</sup> <https://pubmed.ncbi.nlm.nih.gov/36644846/>



# MEB-001 is the only objective depression screening tool for sleep centres

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MEB-001 is TRI's AI-driven algorithm which assists in the screening of depression

MEB-001 uses AI to identify depression from EEG and ECG data collected during a sleep study

## Clinical and regulatory development well progressed

- ▶ TrivarX's first proprietary algorithm, MEB-001, is being developed as a tool to be used to screen and aid in the diagnosis of current Major Depressive Episode (cMDE)
- ▶ Regulatory approval is well advanced – Phase 2 clinical study completed and multiple pre-submission meetings with US FDA
- ▶ Pivotal study set to commence December 2024 with De Novo submission to FDA anticipated [early H2 CY2025]

# Positive outcome in MEB-001 Phase 2 trial

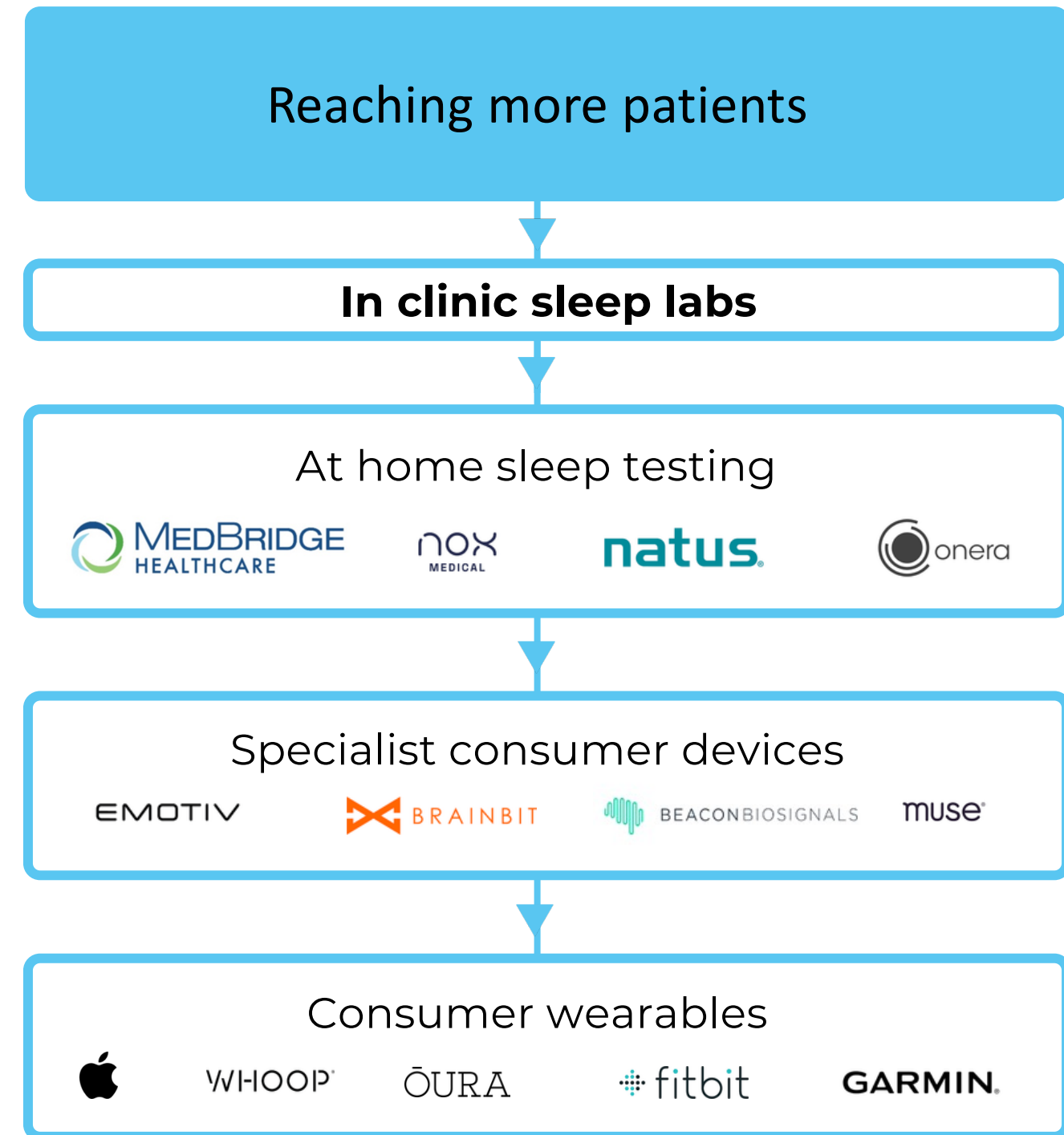
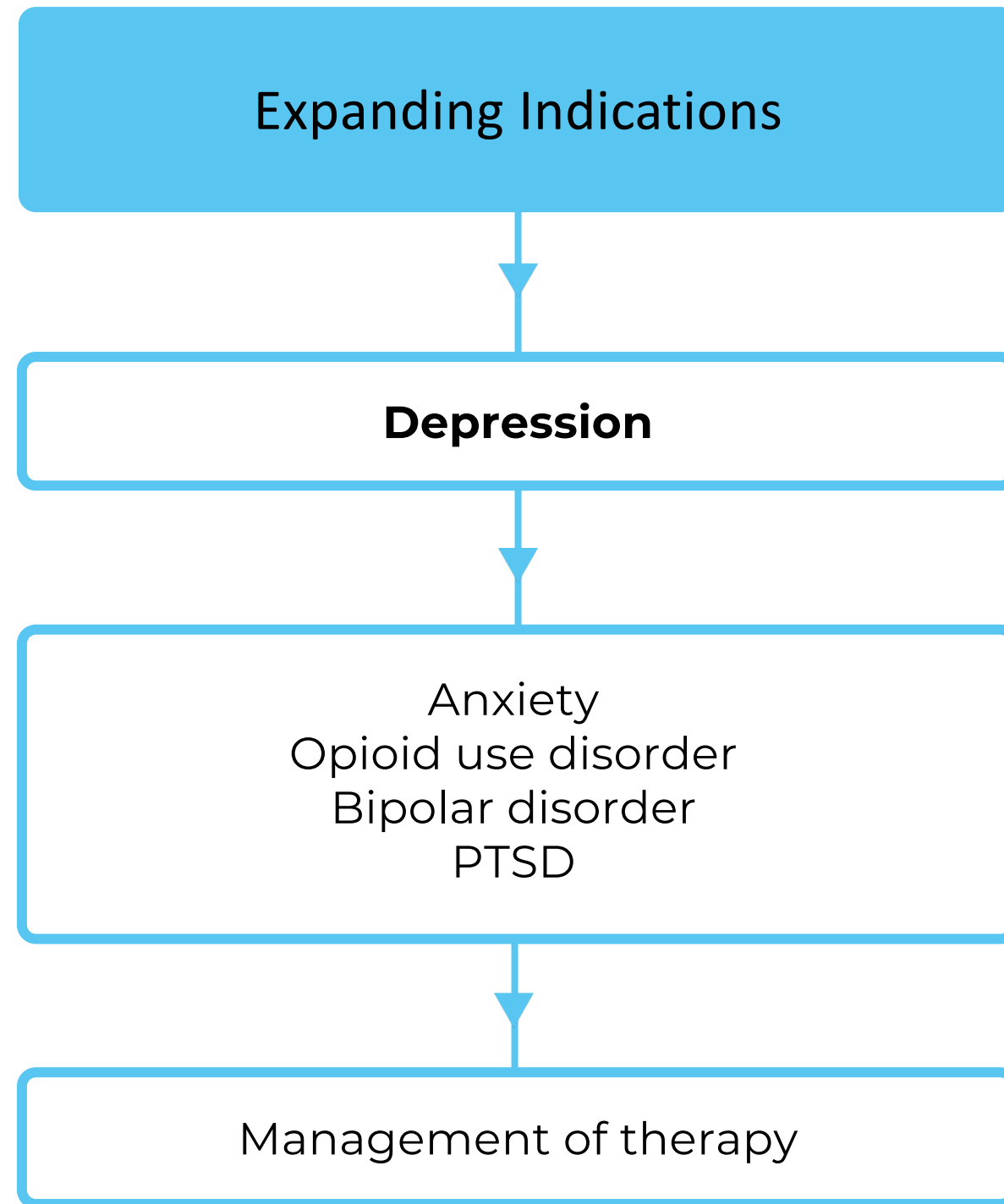
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| Summary            |   |
|--------------------|---|
| Study              | Sleep Signal Analysis for Current Major Depressive Episode (SAMDE) – NCT0570822   |
| Objective          | Use MEB-001 to detect likelihood of a current Major Depressive Episode (cMDE) using Clinician Reporting Outcomes (CRO) assessment in individuals referred to a sleep clinic |
| Sites              | 15 sleep centres across Florida, Minnesota, North Carolina, South Carolina, Ohio and Texas  |
| Subjects           | 400 patients aged between 22 and 75 years old who have been referred to a sleep clinic  |
| Reference standard | Current Major Depressive Episode (cMDE) identified by MINI administered by clinician  |

| Results  |  |  |  |
|--|--|--|--|
| Sensitivity  | Specificity  | Positive Predictive Value (PPV)  | Negative Predictive Value (NPV)  |
| <b>87% (95% CI 73-95%)</b>   | <b>72% (95% CI 66-77%)</b>   | <b>35% (95% CI 27-45%)</b>   | <b>97% (95% CI 93-99%)</b>   |
| The ability for the test to correctly identify patients with the disease | The ability of the test to correctly identify patients without the disease | The likelihood that an individual with a positive test truly has the disease | The likelihood that an individual with a negative test truly does not have the disease |

# The start of a large global opportunity in mental health

Trivarx is positioned to be the world leader in AI-based assessment of mental health



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# Multiple near-term value catalysts

| Catalyst   | Timeframe (CY) | Status |
|--|----------------|--------|
| Second FDA Pre-Submission Meeting                                  | H1 2024        | ✓      |
| Completion of MEB-001 SAMDE Phase 2 Trial                          | H1 2024        | ✓      |
| Final data from MEB-001 SAMDE Phase 2 Trial                        | H2 2024        | ✓      |
| Appointments to strengthen Board of Directors                      | H2 2024        | ✓      |
| Commencement and completion of pivotal study design                | H2 2024        |        |
| Third FDA Pre-Submission Meeting to confirm MEB-001 Pivotal design | H2 2024        |        |
| CRO appointment for MEB-001 Pivotal study                          | H2 2024        |        |
| IRB approval for MEB-001 Pivotal study                             | H2 2024        |        |
| Establish Scientific Advisory Board ahead of US FDA submission     | H2 2024        |        |
| Additional Board appointments to strengthen US presence            | H2 2024        |        |
| Commencement of FDA registration MEB-001 Pivotal Trial             | H2 2024        |        |
| Completion of MEB-001 cMDE Pivotal Trial and interim results       | H1 2025        |        |
| Submission of MEB-001 De Novo application to US FDA                | H2 2025        |        |

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# Appendix 1: Intellectual Property and patents

Four patents granted and currently active

1

US Pat. No. 10,912,508  
Issued 09 Feb 2021

Method and system for assessing  
mental state

2

US Pat. No. 10,638,965  
Issued 05 May 2020

Method and system for monitoring  
stress conditions

3

US Pat. No. 10,039,485  
Issued 07 Aug 2018

Method and system for assessing  
mental state

4

US Pat. No. 9,861,308  
Issued 09 Jan 2018

Method and system for monitoring  
stress conditions

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# Appendix 2: Clinical research and technology

## Supervised Artificial Intelligence

Data has been taken from 400+ subjects to date:

- ▶ Prospective data collection – remains ongoing
- ▶ Combining EEG and ECG enables the technology to map the connectivity between brain and heart activity throughout sleep stages
- ▶ TRI has identified novel sleep biomarkers that map a person's mood disorder

| Clinical Study     | SLEEP                          | SADB                              | SAMDE PI  | SAMDE PII                                  | Clinical Validation                     |
|--------------------|--------------------------------|-----------------------------------|---|--|---|
| Status             | Complete                       | Complete                          | Complete  | Complete                                   | Planned                                 |
| Software Module(s) | SEEG SHRV                      | SEEG SHRV                         | SEEG SHRV DMI                                       | SEEG SHRV DMI                              | SEEG SHRV DMI                           |
| Location           | USA                            | USA                               | USA   | USA  | USA                                     |
| Study Size         | 40                             | 329                               | 313   | Up to 400                                  | TBD                                     |
| Study Dates        | 2019                           | 2019                              | 2021  | 2023                                       | 2024 (Planned Study Start)              |
| Subjective Data    | None                           | BDI PHQ-9                         | MINI (PRO) PHQ-9                                    | MINI (CRO) PHQ-9                           | MINI (CRO) PHQ-9                        |
| Value Delivered    | Internal POC for Supervised AI | Early AI performance data vs. PRO | Enhanced PRO w/reduced noise and broadened symptoms | Use of MINI (CRO) as proposed ground truth | US FDA clearance                        |
| Objective Data     | EEG ECG                        | EEG ECG                           | EEG ECG Socio-demographics                          | EEG ECG Socio-demographics                 | EEG ECG Socio-demographics Risk Factors |
| Hardware           | In-Lab Polysomnography         |                                   |   |  |   |
| Focus              | Autonomic Function             | Depressive Symptoms/Severity      |   |  | Depressive Symptoms/Severity            |

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# Appendix 3: MEB-001 Hypnogram outputs

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cMDE Negative

cMDE Positive

