



# FUTURE OF DIGITAL BIOMARKERS SUMMIT 2025

Co-hosted by

**Johnson & Johnson**

*We are excited to host our third annual  
Digital Biomarkers and Endpoints Summit*

**August 10th & 11th, 2025**

**10**  
SUN

3:30 PM - 8:30 PM

**Mixology Social & Tuscan  
Jeffersonian Dinner**

📍 *Tuscan Kitchen, Salem, NH*

**11**  
MON

7:30 AM - 6:00 PM

**Full Day Summit at  
Johnson & Johnson**

📍 *320 Bent St, Cambridge, MA 02141*

## ATTENDEES



HOSTED BY



FOUNDER, CEO

**Indu Navar**

EverythingALS.org  
EverythingAD.org  
Peter Cohen Foundation



CO-HOST

**Fiona Elwood**

Vice-President, Disease Area  
Lead, Neurodegeneration

**Johnson & Johnson**

SESSION CHAIRS AND  
LEAD COLLABORATORS



**James Berry**

Chief of the Division of ALS and MND,  
Director of the Massachusetts  
General Hospital ALS clinic.



**Lyle Ostrow**

Associate Professor of Neurology,  
Lewis Katz School of Medicine  
Neurologist, MDA/ALS Center of Hope



**Susan Catalano**

Chief Scientific Officer,  
Biotechnology Industry Leader  
EverythingALS Boardmember



**Ernest Fraenkel**

Department of Biological Engineering



# AGENDA:

## FUTURE OF DIGITAL BIOMARKERS SUMMIT 2025

### SUNDAY, AUGUST 10TH

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2:30 PM - 8:30 PM

#### MIXOLOGY, NETWORKING, TUSCAN DINNER

📍 **TUSCAN KITCHEN, SALEM, NH**

We'll kick off Sunday afternoon with a casual and informative mixology session and networking event, followed by a Tuscan dinner in the Jeffersonian style—small-group conversations centered on a unifying theme to foster meaningful connections. It's a chance to get to know your fellow attendees in an engaging, conversational setting.

*We will be arranging a private shuttle, and all address and transportation details will be shared via email*

#### CO-SPONSOR





**MONDAY,  
AUGUST 11TH**

**JOHNSON & JOHNSON  
320 BENT ST, CAMBRIDGE, MA 02141**

7:30 AM - 8:00 AM

## **BREAKFAST & NETWORKING**

8:00 AM - 8:20 AM

## **WELCOME AND OPENING REMARKS**



**Fiona Elwood**  
**Johnson&Johnson**



**Indu Navar**  
EVERYTHINGALS  
CARE TO CURE

8:20 AM - 8:45 AM

## **QUICK INTRODUCTIONS (20 SECONDS EACH)**

To help us get to know each other and set the tone for collaboration, we'll begin with brief introductions. Please share:

1. Your name
2. Your company and role
3. What you're hoping to take away from today's conversation

We kindly ask that you keep it to around **20 seconds**. **Shorter introductions help everyone stay engaged and ensure we have time to hear from everyone.**

Studies have shown that keeping it brief often leads to more memorable and effective communication. Appreciate your help to make the most of our time together.

8:45 AM - 10:30 AM

## SESSION 1:

### KEY AREAS OF GROWTH

#### Session Chair



**James Berry**



8:45 AM - 9:05 AM

#### Advancing Multi-modal Monitoring in Rapa Therapeutics's Expanded Access Program

*Implementation of the Multi-Modal Radcliff Protocol in a Real-World Setting*



**Brian Radecki, CEO**  
RAPAtherapeutics



**Dan Fowler, CSO**  
RAPAtherapeutics

9:05 AM - 9:20 AM

#### FDA Perspective: Speech LOI & Regulatory Pathway

*Listener's Effort: The First Wave of Digital Clinical Outcome Assessments & Implications for Redefining Indication Strategies*



**Brendan O'Leary**



**Henk Schuring**  
prilenia

9:20 AM - 9:30 AM

### NETWORKING BREAK

**8:45 AM - 10:30 AM****SESSION 1:****KEY AREAS OF GROWTH****Session Chair****James Berry** MASSACHUSETTS  
GENERAL HOSPITAL**9:30 AM - 9:50 AM****Featured Keynote**

*Eric Dane shares his personal journey with ALS, resilience, and raising awareness through storytelling*

**Eric Dane**  
**Award-Winning Actor**  
**Television & Film**  
**Performer****9:50 AM - 10:30 AM****Scaling Remote Assessments: Operationalizing Digital Measures**

*Panel Discussion on the Economics and Infrastructure of Remote Monitoring*

**Brian Winger**  
*Lilly***Fiona Elwood**  
**Johnson&Johnson****Fernando Vieira****Eduardo Locatelli**  
**NSU**  
Florida

10:30 AM - 11:50 AM

**SESSION 2:**  
**IMPACT AND OUTCOME****Session Chair****Lyle Ostrow**

10:30 AM - 11:00 AM

**Defining the Next Wave of Clinical Outcome Measures***Insights and Priorities from Consortium Members and Collaborators***Ernest Fraenkel****Matthew Wiperman****REGENERON****Julian Peller****Jason Osik****Marcos Trevisan****Oren Levy****REGENERON**

11:00 AM - 11:10 AM

**Healey Platform Trial: Speech Outcome Analysis***Listener's Effort: Retrospective Insights from Speech Data***Alan Taitz****Dr. James Berry**

10:30 AM - 11:50 AM

## SESSION 2: IMPACT AND OUTCOME

**Session Chair**



**Lyle Ostrow**



11:10 AM - 11:50 AM

## Participant Burden: Perspectives from People with ALS and Caregivers

*Panel discussion - In Their Own Words: Engagement & Adherence Challenges in Clinical Trials shared by EverythingALS Pathfinders*



**Steve Kowalski**



**John Hudacek**

EverythingALS Pathfinder



**Willard Blackwell**

EverythingALS Pathfinder



**Mcfinn Lovere**



**Ivonne Vaughn**

EverythingALS Pathfinder



**John Furey**



11:50AM - 12:35 PM

**LUNCH BREAK**

12:35 PM - 1:50 PM

**SESSION 3:****STRATEGIC PARTNERSHIPS FUELING INNOVATION****Session Chair****Susan Catalano**

12:35 PM - 12:55 PM

**Expanding to Alzheimer's Disease: Precision Trial Matching**

*Launched EverythingAD.org. Remote cognitive assessments to support Alzheimer's research*

**Joel Schwartz****Stephanie Henze****Silviya Bastola****Swapnil Harkanth**

12:55 PM - 1:15 PM

**Allen Institute Collaboration: Mapping the ALS Brain**

*A partnership driving speed and innovation — from discovery to medicine*

**Ed Lein**



12:35 PM - 1:50 PM

**SESSION 3:****STRATEGIC PARTNERSHIPS FUELING INNOVATION****Session Chair****Susan Catalano**

1:15 PM - 1:35 PM

**Amazon AWS: AI-Driven Trial Enablement**

*The Sava AI platform supports informed patient choices and fast-tracks trial enrollment*

**Lou Warnett**  
**aws****Natalia Luchkina****Julian Peller**  
 **EVERYTHINGALS**  
CARE TO CURE**David Master**  
**aws****Anusha Rao**  
 **EVERYTHINGALS**  
CARE TO CURE

1:35 PM - 1:50 PM

**Precision Recruiting and Screening via Baseline**

*Empowering Clinical Sites through AI and Human in the loop*

**Christian Rubio****Merit Cudkowicz****Philip Reilly**

**1:50 PM - 5:45 PM****SESSION 4:****AFTERNOON WORKSHOPS**

1:50 PM - 2:00 PM

**Workshop Introduction: Overview and Group Assignment**

2:00 PM - 2:10 PM

**GROUP PHOTO & STRETCH BREAK**

2:10 PM - 4:10 PM

**From Ideas to Action: OKR Creation and Brainstorming Workshops**

*The workshop focus is to develop high-level objective for 2<sup>nd</sup> half 2025 and 2026 deliverables. Your participation will help prioritize key activities and achievable outcomes.*

*Deliverables: Create actionable Key Goals & Objectives (OKRs)*

4:10 PM - 4:30 PM

**ICECREAM PICKUP**

4:30 PM - 5:30 PM

**Workshop Presentations (20 mins each)**

5:30 PM - 5:45 PM

**Closing remarks and Group Photo**

5:45 PM - 6:30 PM

**CLOSING RECEPTION****ICE CREAM SOCIAL**

We'll close the day with a casual reception to thank everyone for their contributions.