



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

2:30 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

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 2nd 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.