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

3:30 PM - 8:30 PM

Mixology Social & Tuscan Jeffersonian Dinner

Tuscan Kitchen, Salem, NH

MON

7:30 AM - 6:00 PM **Full Day Summit at** Johnson & Johnson

© 320 Bent St, Cambridge, MA 02141

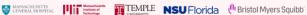
ATTENDEES





















REGENERON



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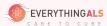
HOSTED BY



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

O 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





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

MASSACHUSETTS
GENERAL HOSPITAL

8:45 AM - 9:05 AM

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

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



Brian Radecki, CEO



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'Learv



Henk Schuring

9:20 AM - 9:30 AM

NETWORKING BREAK



8:45 AM - 10:30 AM

SESSION 1: KEY AREAS OF GROWTH

Session Chair





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



Fernando Vieira



Fiona Elwood
Johnson&Johnson



Eduardo Locatelli **NSU**



10:30 AM - 11:50 AM

SESSION 2: IMPACT AND OUTCOME

Session Chair



Lyle Ostrow
TEMPLE
UNIVERSITY*

10:30 AM - 11:00 AM

Defining the Next Wave of Clinical Outcome Measures

Insights and Priorities from Consortium Members and Collaborators







Matthew Wipperman REGENERON







Jason Osik ullı Bristol Myers Squibb







Oren Levy *REGENERON*

11:00 AM - 11:10 AM

Healey Platform Trial: Speech Outcome Analysis

Listener's Effort: Retrospective Insights from Speech Data







Dr. James Berry

MASSACHUSETTS
GENERAL HOSPITAL



10:30 AM - 11:50 AM

SESSION 2: IMPACT AND OUTCOME

Session Chair





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

EVERYTHINGALS

CARE TO CURE



Ivonne Vaughn
EverythingALS Pathfinder



John Furey
TEMPLE

11:50AM - 12:35 PM

LUNCH BREAK



12:35 PM - 1:50 PM

SESSION 3: STRATEGIC PARTNERSHIPS FUELING INNOVATION

Session Chair



Susan Catalano

EVERYTHINGALS
CARE TO CURE

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

EVERYTHINGALS
CARE TO CURE



Swapnil Harkanth

EVERYTHINGALS

CARE TO CURE

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
ALLEN



12:35 PM - 1:50 PM

SESSION 3: STRATEGIC PARTNERSHIPS FUELING INNOVATION

Session Chair





1:15 PM - 1:35 PM

Amazon AWS: Al-Driven Trial Enablement

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





















1:35 PM - 1:50 PM

Precision Recruiting and Screening via Baselining

Empowering Clinical Sites through AI and Human in the loop













	SESSION 4:
1:50 PM - 5:45 PM	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 nd 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.