

# DIGITAL BIOMARKERS & ENDPOINTS SUMMIT

August 26, 2024 @ 7:30am



EVERYTHING ALS  
CARE TO CURE

## “Accelerating the Path from Validated Endpoints to Biomarkers and Beyond”

### AGENDA

Time	Presentation	Topic, Speaker, Activity
07:30 – 08:30	Breakfast networking	Check-in at the J&J lobby
08:30 – 08:50	J&J Welcome and Opening Remarks	Gayle Wittenberg, J&J; Indu Navar, EverythingALS
08:50 – 09:20	Accomplished – Ongoing - Next Inspirational Commentary	Dr. James Berry + Dr. Lyle Ostrow
09:20 – 10:00	Overcoming Challenges: Adding Digital Outcome Measures to Clinical Trials (Panel + open discussion)	<b>Moderator:</b> Dr. Lyle Ostrow; <b>Panelists:</b> Dr. Merit Cudkowicz, Dr. James Berry, Dr. Terry Heiman-Patterson, Dr. Eduardo Locatelli, and Steve Kowalski;
10:00 – 10:10	History and Path Forward of Endpoints in ALS Trials (AI tool presentation)	EverythingALS Research Fellow & Team
10:10 – 10:40	Data that matters: Evolving Regulatory Strategies and Opinions on Clinical Trial Endpoints (Open discussion)	Brendon O’ Leary, Henk Schuring (Prilenia), Collin Hovinga (C-Path)
10:40 – 10:50	Break	
10:50 – 11:30	BMS + EALS: Preliminary findings from the ongoing Radcliff Study (Presentation + Q&A)	Joel Schwartz, BMS; Esteban Roitberg, Julian Peller, Silviya Bastola, Stephanie Henze (EALS);
11:30 – 12:00	pALS (+): What would it take to leverage DHTs used in clinical trials for ongoing care to increase compliance?	<b>Moderator:</b> Dr. Lyle Ostrow Temple Health

		<b>Panel:</b> Brooke Eby, John Hudacek, Dave Shulman, McFinn Lovere, and Janie Gobeli
12:00 – 13:00	Lunch	Lunch together while we turn the room over to prepare for afternoon work stream setting and breakouts
13:00 – 13:30	Platform Considerations: Needs + Ongoing Development (Presentation)	EALS App + Avatar; Sensor Lab (EALS team + Terry/App nutrition) Vision 2030 (Dr. Merit Cudkowicz & Dr. Ernest Fraenkel)
13:30 – 13:45	Introduction to overall goal, work streams and session methodology	EALS Product & Research Team with Support from Consortia Leads
13:45 – 15:15	Individual Workstream Sessions	Discussion by Consortia to Define 3-5 Priority Work Streams Co-Leads will present core areas of focus, propose key milestones/ deliverables & set on next steps
15:15 – 15:30	Coffee Break	
15:30 – 16:30	Individual workstream presentations to larger group	Group prioritization of 1-2 achievements to focus per work stream
16:30 – 17:00	Agreement on rough draft for the next 12 months & cadence for work streams & Close-out	Looking ahead to rest of year
17:00	Reception	

<b>Individual Workstream Sessions</b> <b>13:45 – 15:15</b>				
Workstream 1:  SENSOR LAB:  Solving sensor related	Workstream 2:  Which Clinical Endpoint(s) /'deep' measures should we	Workstream 3:  Standardization of data collection within	Workstream 4:  Clinical Endpoints /  Regulatory Angle	Workstream 5 (Option B)  New standardization in

ecosystem problems via consortia platform development	prioritize?	platform + in general:		patient engagement and retention in clinical trials
<p>Developing a consortia roadmap for the next 12 months:</p> <p>Multimodal studies: review / prioritize and ideate mitigation on pain points in sensor selection from bus angle?</p> <p>Kapner Study: selection path for 25 sensors to be evaluated by superusers in an EALS feasibility study</p> <p>Ideation on scaling: E.g. extending to care / remote care from clinics with the same sensors as used in clinical trial; overview of all consortia trials</p>	<p>Looking at the prioritization of neurological and other features from an academia / neurologist + pharma angle, e.g. understanding pathology for other than speech</p>	<p>Point of data collection: Standardized approach for POC with smaller sizing</p> <p>Standardization of population description: describe it in a same way (e.g, as done in HD from the biology perspective)</p> <p>Standardization of data collection to support other studies within consortia</p> <p>Standardization on constant data analysis during trial</p> <p>Leveraging frequent data to define outliers</p>	<p>From exploratory to secondary endpoints: What is the path forward?</p> <p>What data and evidence do we need to make this happen... going backwards</p> <p>Define / standardize intermediate endpoints?</p> <p>Prioritization of different options to help companies to take this on</p>	

with potential multi-modal needs				
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