

Illuminate Hypersomnia

Shining light on the lived experience of IH

ADJUNCT SCIENTIFIC MEETING ON IDIOPATHIC HYPERMOMNIA (IH)

February 13, 2025
12:00 p.m. – 2:00 p.m.
Eastern Time

(((●))) Streamed live at sleepconsortium.org/ih-asm



Available for on-demand viewing on sleepconsortium.org



Social Media Hashtags: #IlluminateIH #idiopathichypersomnia
#livingwithIH #idiopathichypersomnolence #PFDD #patientfocused
#sleepconsortium #thisisIH

Organized & Hosted By:  Sleep Consortium

MEETING AGENDA (all times are Eastern Time)

In this virtual scientific session, IH experts will address critical challenges in drug development for idiopathic hypersomnia (IH), identified during the groundbreaking [Illuminate Hypersomnia Externally-Led Patient-Focused Drug Development \(EL-PFDD\) meeting](#) held on April 11, 2024 and the companion survey.

- 12:00 pm Welcome & Introductions**
Lindsay Jesteadt, PhD, Sleep Consortium
Kim McCleary, Kith Collective
- 12:05 pm Recap of Key Learnings from the Illuminate Hypersomnia EL-PFDD Initiative**
Lynn Marie Trotti, MD, MSc
- 12:15 pm Focused Topic #1: Brain Fog in IH**
Michael Thorpy, MB, ChB
- 12:25 pm Topic #1 Panel Discussion: Approaches to Better Defining and Measuring Brain Fog in IH**
Kim McCleary (Moderator)
Lucie Barateau, MD, PhD
Kiran Maski, MD, MPH
Anne Marie Morse, DO
David Plante, MD, PhD
- 1:00 pm Focused Topic #2: Barriers to Participation in Research Studies**
Emmanuel Mignot, MD, PhD
- 1:10 pm Topic #2 Panel Discussion: Considerations for Recruiting and Retaining People with IH in Research Studies**
Kim McCleary (Moderator)
Omavi Bailey, MD, MPH
Bruce Corser, MD
Yves Dauvilliers, MD, PhD
Anne Marie Morse, DO
- 1:40 pm Industry Roundtable: Discussion of Unmet Needs for IH Identified by the Illuminate Hypersomnia Initiative**
Brian Abaluck, MD, Avadel Pharmaceuticals
Daniel S. Barczak, MD, MSc, Takeda Pharmaceuticals
Salvatore Insana, PhD, Harmony Biosciences
Jessica Sacks, PhD, Jazz Pharmaceuticals
Mandy Sterkel, PhD, Centessa Pharmaceuticals
Marcus Yountz, MD, FAAN, Alkermes
- 1:55 pm Recap, Next Steps, and Closing Remarks**
Lindsay Jesteadt, PhD and Kim McCleary

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Idiopathic Hypersomnia (IH)

Idiopathic hypersomnia (IH) is a sleep disorder in which the affected individual has prolonged sleep or daytime sleepiness. About half of people with IH have sleep inertia, during which they have difficulty waking up, frequently return to sleep, are quite irritable, and have automatic behaviors and confusion. Many people with IH have headaches, orthostatic hypotension, difficulty regulating their temperature, and Raynaud syndrome (all symptoms of a disturbance in the autonomic nervous system). Some people may have sleep paralysis or hypnagogic hallucinations.

The Illuminate Hypersomnia Initiative

The Illuminate Hypersomnia externally-led patient-focused drug development (EL-PFDD) meeting was conducted on April 11, 2024 as a parallel effort to the U.S. Food and Drug Administration's PFDD initiative to more systematically gather patients' perspectives on their conditions and available therapies. The [meeting recording](#) is available for on-demand viewing. The initiative also included a PFDD survey, attracting responses from 811 people affected by IH. The ["Voice of the Patient" report](#) summarizes the Illuminate Hypersomnia meeting and survey as an enduring resource for researchers, drug development sponsors, regulators, healthcare professionals, and others.

The Illuminate Hypersomnia Adjunct Scientific Meeting

Under the FDA's EL-PFDD meeting guidelines, people living with the condition are the experts and researchers, sponsors, healthcare professionals, and other interested parties participate in listen-only mode. The Adjunct Scientific Meeting provides a public venue for researchers and sponsors to reflect on what they heard from people living with IH to inform key research and drug development issues. A meeting summary will be published this spring.

BIOS Leaders of Sleep Consortium

Lindsay Jesteadt, PhD (also serving as Co-Moderator for the meeting)

Co-founder and CEO, Sleep Consortium

Lindsay began her career in education, focusing on Compliance, Special Education Policies and Procedures in the State of Florida—work that challenged the current provisions of State Education for disadvantaged and under-represented children. In 2014, following the abrupt onset of Type 1 Narcolepsy in her 4-year-old son Noah, Lindsay's life took on a new trajectory—one that merged her professional expertise and personal passion to help Noah and children like him. Following Noah's diagnosis, she served as director of development for Wake Up Narcolepsy for four years, playing a pivotal role in creating and implementing educational programs, events, and support services. In 2021, she and Claire Wylds-Wright founded the Sleep Consortium, having identified the critical need to accelerate sleep research through a global patient-centric database.

Lindsay holds a PhD and two M.Eds from Florida Atlantic University. She has published research in peer-reviewed journals in education and central disorders of hypersomnolence and is the recipient of academic prizes. Lindsay also serves as chief operating officer of the Hypersomnia Foundation and as program coordinator for the World Sleep Society.



Claire Wylds-Wright, Grad Phys, SRP, MCSP, MFA

Co-Founder and CXO, Sleep Consortium

Born, raised, and educated in England, Claire trained as a physical therapist and specialized in chronic pain management, community care, trauma, and medico-legal representation. In 2011, she moved her family from England to the United States to secure expert care and treatment after her youngest daughter contracted Type 1 narcolepsy at the age of three. Once daughter Mathilda's health stabilized, Claire began writing on narcolepsy and the impact of a pediatric diagnosis on the family unit, giving voice to children and their caregivers and exposing the under-recognized aspects of a pediatric sleep disorder diagnosis. She served as executive director of Wake Up Narcolepsy from 2017 until 2021, when she and Lindsay founded the Sleep Consortium. Co-creating Sleep Consortium directly responds to her desire to reduce diagnostic delays and accelerate life-changing therapies for people with sleep disorders across all ages and demographics. Claire also serves as chief executive officer of the Hypersomnia Foundation.



In 2017, Claire published her first book, *Waking Mathilda – A Memoir of Childhood Narcolepsy*. She built a large global audience for the Narcolepsy 360 podcast, is regularly called upon as a key opinion leader and speaker, and, in 2022, received the Citizen Scientist award by TREND.

BIOS Moderator

K. Kimberly McCleary

Founder & CEO, The Kith Collective

Kim McCleary has been at the forefront of patient engagement for more than 30 years. She is a nationally regarded subject matter expert on patient-focused medical product development, patient-centered benefit-risk assessment, and organizational change. Her passion for this work is rooted in personal experience, lived and as a family caregiver.

In 2018, Kim founded the Kith Collective to speed adoption of patient-centricity by life science companies, not-for-profit organizations, and academic research teams. She has been involved in numerous PFDD meetings, including sessions led by the FDA and patient advocacy organizations, including narcolepsy (2014), sleep apnea (2018), and IH (2024).



BIOS Presenters *(in order of meeting topics)*

Lynne Marie Trotti, MD, MSc

Recap of the Illuminate Hypersomnia EL-PFDD Meeting and Survey

Associate Professor of Neurology, Emory University

Dr. Trotti is an Associate Professor of Neurology at Emory University, where she also serves as the Associate Program Director for the sleep medicine fellowship. Her clinical practice is focused on treatment-refractory hypersomnolence disorders and the multidisciplinary care of people with Parkinson's disease. Her research focuses on the pathophysiology and treatment of the central disorders of hypersomnolence through investigator-initiated, randomized, controlled trials and functional neuroimaging.

Dr. Trotti earned her medical degree from Baylor College of Medicine and completed her training at Emory University with a neurology residency and a sleep medicine fellowship. She is a member of the Board of Directors of the American Academy of Sleep Medicine (AASM) Foundation and the American Academy of Neurology (AAN); she is board-certified by both AASM and AAN.



BIOS Presenters Continued *(in order of meeting topics)*

Michael Thorpy, MB, ChB

Brain Fog in IH

Professor of Neurology, Albert Einstein College of Medicine, and Director, Sleep-Wake Disorders Center

Montefiore Medical Center, New York

Dr. Thorpy is a Professor of Neurology at Albert Einstein College of Medicine and Director of the Sleep-Wake Disorders Center at Montefiore Medical Center. He specializes in treating sleep disorders and conducts research on narcolepsy, insomnia, and sleep apnea.

He is President of the New York State Society of Sleep Medicine and has held leadership roles in various sleep medicine organizations. Dr. Thorpy has authored over 250 peer-reviewed articles and numerous books, including *The Encyclopedia of Sleep and Sleep Disorders*. He chaired the first International Classification of Sleep Disorders.

A recipient of the Nathaniel Kleitman Award and the Lifetime Achievement Award, Dr. Thorpy is board-certified in sleep medicine and has given over 100 media interviews on sleep disorders.



Emmanuel Mignot, MD, PhD

Barriers to Participation in Research Studies

Craig Reynolds Professor of Sleep Medicine

Stanford University

Dr. Mignot, a leading researcher in sleep and neuroscience, discovered that human narcolepsy is caused by the autoimmune loss of hypothalamic neurons producing the wake-promoting peptide hypocretin. He identified HLA-DQB1*06:02 and T-cell receptor genes as key factors in a T-cell-mediated autoimmune process, often triggered by influenza.

A Breakthrough Prize recipient and member of the National Academies of Sciences and Medicine, his work spans sleep disorders and autoimmune brain diseases. His lab conducts clinical and basic research, including a large-scale machine-learning analysis of over 200,000 polysomnographic (PSG) sleep recordings to predict cardiovascular, neurological, and psychiatric diseases.



PANELISTS Topic #1: Approaches to Better Defining and Measuring Brain Fog in IH

Lucie Barateau, MD, PhD

Gui-de-Chauliac Hospital, CHU Montpellier, and INSERM, France
National Reference Centre for Narcolepsy and Rare Hypersomnia
Institute of Neuroscience of Montpellier, University of Montpellier, INSERM,
Montpellier, France

Dr. Barateau is a neurologist specializing in rare sleep disorders, particularly narcolepsy in children. As an investigator in multiple clinical trials and studies, she focuses on understanding pathophysiological mechanisms, biomarkers, and optimizing treatment for these disorders. She also has a significant clinical role in diagnosing and managing central hypersomnolence disorders. Dr. Barateau is part of the scientific committees of SFRMS and EU-NN, and has authored over 85 publications in international peer-reviewed journals on hypersomnolence and narcolepsy.



Kiran Maski, MD, MPH

Harvard Medical School and Boston Children's Hospital

Dr. Maski is an Associate Professor at Harvard Medical School and a child neurologist and sleep specialist at Boston Children's Hospital. Her work focuses on CNS hypersomnolence disorders, and she has led key task forces for the American Academy of Sleep Medicine and the International Classification of Sleep Disorders. A member of several medical advisory boards, Dr. Maski's research on sleep biomarkers is NIH-funded, and she received the 2024 Research Pioneers Award for her work in pediatric narcolepsy.



Anne Marie Morse, DO, FAASM

Geisinger Commonwealth School of Medicine

Dr. Morse is a board-certified child neurologist and sleep medicine specialist. She is the chair of child neurology and pediatric sleep medicine, and director of the child neurology residency program. Beyond her leadership roles, she is an advocate, researcher, educator, and patient ally. Dr. Morse is committed to improving healthcare by focusing on holistic care and communication. She envisions a world where sleep is recognized as a vital sign of health and where people with hypersomnolence live fully.



David Plante, MD, PhD

University of Wisconsin School of Medicine and Public Health

Dr. Plante is an Associate Professor of Psychiatry and Sleep Medicine at the University of Wisconsin-Madison, where he also serves as the Medical Director of the Wisconsin Institute for Sleep and Consciousness/Wisconsin Sleep and as the Program Director of the clinical sleep medicine fellowship. He is a clinician-scientist whose research focuses on central nervous system disorders of hypersomnolence and the interface of sleep and neuropsychiatric disorders.



PANELISTS Topic #2: Considerations for Recruiting and Retaining People with IH in Research Studies

Omavi Bailey, MD, MPH

theSleepMD

Dr. Bailey is a somnologist, epidemiologist, and physician whose depth of knowledge and enthusiasm about natural and novel treatments for chronic disease prevention influences his use of sleep as an intervention to prevent chronic illnesses. His unique and holistic approach to sleep medicine integrates traditional non-invasive ventilation therapy with cutting-edge solutions such as oral appliance therapy, sleep apnea medication, hypoglossal nerve stimulators, natural weight loss, and cognitive behavioral therapy for insomnia.



Bruce Corser, MD

Medical Director, Sleep Management Institute and Intrepid Research
Cincinnati, OH

Dr. Corser received his medical degree from SUNY Upstate Medical Center in 1980 and completed postgraduate training at the University of Cincinnati. Board-certified in Internal Medicine, Pulmonary, and Sleep Medicine, he has extensive clinical research experience, focusing on sleep-related conditions like sleep apnea, insomnia, and narcolepsy. He has co-authored over 30 publications in journals such as *Sleep* and *Journal of Clinical Sleep Medicine*. Voted Ohio's top sleep medicine physician (2020–2024), he is a member of numerous professional organizations.



Yves Dauvilliers, MD, PhD

University of Montpellier and Inserm, France

Professor of Neurology and Physiology at the University of Montpellier, Dr. Dauvilliers heads the sleep lab's clinical and research activities. He coordinates the French National Reference Network for Orphan Diseases (Narcolepsy, Hypersomnia, Kleine-Levin Syndrome) and directs a research group at INSERM. He is President of the European Narcolepsy Network and Vice-President of the French Sleep Medical and Research Society. Dr. Dauvilliers has authored over 550 peer-reviewed papers and several books on sleep medicine.



Anne Marie Morse, DO, FAASM

Geisinger Commonwealth School of Medicine

Dr. Morse is a board-certified child neurologist and sleep medicine specialist. She is the chair of child neurology and pediatric sleep medicine, and director of the child neurology residency program. Beyond her leadership roles, she is an advocate, researcher, educator, and patient ally. Dr. Morse is committed to improving healthcare by focusing on holistic care and communication. She envisions a world where sleep is recognized as a vital sign of health and where people with hypersomnolence live fully.



INDUSTRY ROUNDTABLE PARTICIPANTS

presenters are indicated by an asterisk ()*

Brian Abaluck, MD,* Senior Medical Director, Avadel Pharmaceuticals

Daniel S. Barczak, MD, MSc,* Senior Medical Affairs Director,
Neuroscience, Takeda Pharmaceuticals

Michael Doane, PhD, Senior Director of Health Economics and Outcomes
Research, Alkermes

Jennifer Gudeman, PharmD, Senior Vice President, Medical and Clinical
Affairs, Avadel Pharmaceuticals

Deborah Hartman, PhD, Global Scientific Head, Orexin Program, Centessa
Pharmaceuticals

Salvatore Insana, PhD,* Senior Director, Clinical Development & Strategy,
Harmony Biosciences

Jessica Sacks, PhD,* Associate Medical Director, Jazz Pharmaceuticals

Mandy Sterkel, PhD,* Senior Director, Clinical Development, Centessa
Pharmaceuticals

Marissa Whalen, PharmD, Senior Medical Director, Jazz Pharmaceuticals

Melody Wu, MPH, Associate Director, Global Evidence and Outcomes,
Takeda Pharmaceuticals

Marcus Yountz, MD, FAAN,* Vice President of Clinical Development,
Alkermes

CORPORATE SPONSORS

Thank you to these generous sponsors for their unrestricted educational grants in support of the Illuminate Hypersomnia initiative, including the Adjunct Scientific Meeting:



INITIATIVE PARTNERS

Sleep Consortium thanks these partners of the Illuminate Hypersomnia initiative for their enthusiastic and active support with community outreach.



ACKNOWLEDGEMENTS

Sleep Consortium expresses gratitude to all who have enhanced the Illuminate Hypersomnia initiative, with particular thanks to hundreds of IH community members who participated in the EL-PFDD meeting, by responding to the survey, and/or by submitting written comments. In addition to the presenters, panelists, Roundtable participants, sponsors and partners named above, we wish to recognize:

John Dudley and his team at Dudley Digital Works for creative and technical services to broadcast today's meeting and to preserve it for later on-demand viewing.

Samantha Mayberry of the Kith Collective for support with program management, content development, preparation, and communications for the Illuminate Hypersomnia initiative.

Kim McCleary of the Kith Collective for strategic counsel, survey and content development, writing and communications for the initiative, and meeting moderation.

Julie Rathjens of Hello Brand for the design of the Illuminate Hypersomnia logo and production of other creative materials, including this meeting program.

Elizabeth Windom of Windhaven Productions for coordinating social media for this initiative.

Sleep Consortium

Sleep Consortium is a registered not-for-profit (501(c)(3)) organization created to accelerate next-generation research, disease understanding, and therapy development for those living with Central Disorders of Hypersomnolence (CDoH), including IH and related diseases. Sleep Consortium works to advance sleep health through innovation and patient empowerment.

Our Mission

Through ethical data sharing practices, leveraging artificial intelligence and machine learning, Sleep Consortium is re-imagining data collection by creating a global comprehensive, federated database of CDoH omics and clinical data. The DREAMS (Data Repository for Evaluating and Analyzing Metrics in Sleep) Portal aims to:

- Reduce diagnostic delays in all communities across the world by identifying new patients with sleep-related phenotypes
- Improve therapeutic options and access for all patients experiencing symptoms of disordered sleep and sleep/wake instability
- Identify the relationship of symptoms of CDoH across other rare and non-rare disease spaces
- Increase the understanding of CDoH in under-represented populations
- Power patient progress by leveraging break-through technology
- Elevate the patient voice by providing a platform for people living with CDoH and their caregivers to engage with community members, partnering patient advocacy organizations, industry, and government agencies.

Stay In Touch


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