Illuminate Hypersomnia

*Shining light on the lived experience of **IH***

ADJUNCT SCIENTIFIC MEETING ON IDIOPATHIC HYPERSOMNIA (IH)

FEBRUARY 13, 2025

Meeting Summary

Organized & Hosted By: Sleep Consortium

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Introduction

On April 11, 2024, Sleep Consortium hosted the Illuminate Hypersomnia Externally Led Patient Focused Drug Development (EL-PFDD) Meeting, which brought members of the global idiopathic hypersomnia (IH) community together to share their challenges living with IH, the burdens of the condition and its current treatment, and priorities for treatment benefits that would make a meaningful difference in their lives. A recording of the EL-PFDD meeting is available for on-demand viewing.

In conjunction with the meeting, Sleep Consortium also conducted an extensive survey about the same topics, attracting 811 responses and making it the largest patient-generated data set on IH collected to date. The learnings from the EL-PFDD meeting and survey were summarized in a comprehensive "Voice of the Patient" report, published in September 2024. This initiative was 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. It is intended to inform staff from the U.S. Food and Drug Administration, life science companies, academic researchers, healthcare professionals, and others affected by IH.

The Illuminate Hypersomnia Adjunct Scientific Meeting (ASM) was organized by Sleep Consortium to provide clinical, research, and life sciences stakeholders with a public venue to reflect and build on the "lived wisdom" shared by people living with IH. The two-hour virtual meeting, held on February 13, 2025, focused on priority topics brought to the forefront in the EL-PFDD meeting. Its objective was to explore key challenges and propose potential collaborative approaches to move the field of IH research and care forward. The ASM meeting recording is available on demand.

Idiopathic Hypersomnia (IH)

Idiopathic hypersomnia (IH) is a central disorder of hypersomnolence (CDoH) 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.

Presentation: Recap of Learnings from the Illuminate Hypersomnia EL-PFDD Initiative

"A really amazing group of people came together for the EL-PFDD meeting to share their stories very openly, honestly, and bravely, and I'm very grateful for it. The full 'Voice of the Patient' report really does reflect the voices of these patients."

– Lynn Marie Trotti, MD, MSc

Lynn Marie Trotti, MD, MSc
Associate Professor of Neurology, Emory University

At the EL-PFDD meeting, Dr. Lynn Marie Trotti presented a clinical overview of IH to set the stage for patient testimony and discussion. She led the Adjunct Scientific Meeting by providing highlights of the EL-PFDD meeting and survey as a foundation for presentations and panel discussions that followed. The executive summary of the "Voice of the Patient" report (pages 4-5) is another helpful resource. Dr. Trotti focused on five key topics in her review.

Diagnostic Delays

"From the onset of first symptoms to the diagnosis, the average delay was 14 years, which clearly contributes to the burden of this disease," she observed, commenting on the clinical challenge of sorting out what's causing a condition marked by sleepiness and fatigue. Participants recalled frequently being told stress, lifestyle, or depression were at the root. Another problem they identified was lack of access to healthcare professionals (HCPs) knowledgeable about IH and appropriate sleep testing. Distinguishing between sleep disorders, particularly IH and narcolepsy type 2 (without cataplexy) was another difficulty that contributed to diagnostic challenges. Dr. Trotti added, "Those are very hard to tell apart and it creates other problems, notably access to medications, depending on what diagnosis you have."

Major Life Impacts

Drawing attention to survey data, Dr. Trotti noted the high proportion of individuals reporting moderate or high impacts to work, education, and their ability to think and concentrate. "These are things we think about pretty commonly as being impacted by IH, but the effects bleed into intimate relationships, social relationships, and even things like self-confidence," she said. Daytime sleepiness, impaired quality of wakefulness, fatigue, and impaired cognition were the most burdensome symptoms. "A common theme was the small number of good hours they have in a day. I can't say it better than patients who said, 'A good day is when I manage to get 3 to 4 hours of wakefulness before my brain starts to shut down,' or 'I struggle to fit life into the 4 to 8 hours of alertness that I may have 3 to 5 days a week.'"

Treatment Burdens

Dr. Trotti reviewed the challenges patients reported managing IH using a combination of prescription medications, lifestyle adjustments, school and work accommodations, and scheduling changes. Making and keeping track of frequent adjustments to medication doses, timing, and formulations compounds burden. "Dealing with HCPs who don't really know what IH is, how to manage it, or aren't comfortable with the medications we use to treat it, along with drug shortages, lack of insurance coverage, and out-of-pocket costs are some of the other barriers that patients reported." She identified two major issues that underscore the large unmet medical needs, "Lack of efficacy of some of these medicines for some people or development of tolerance over time, and the short- and long-term side effects of these medications." She pointed to the survey finding that 60 percent of respondents said their symptoms were not controlled at all or were poorly controlled, but it was better than nothing. "There is a huge, huge need for us to do better than 'better than nothing' in treating IH."

Dr. Trotti pointed to the survey finding that 60 percent of respondents said their symptoms were not controlled at all or were poorly controlled, but it was better than nothing. "There is a huge, huge need for us to do better than 'better than nothing' in treating IH."

Treatment Aspirations and Clinical Trials

Reviewing responses to questions about top priorities for better IH treatments, Dr. Trotti noted, "Pretty robustly, the answer was, 'more good hours in a day,' followed by relief from brain fog." In conducting of research and clinical trials, she stated, "It's a shared belief of many people participating in today's meeting that people with IH are our most important research partners." Yet," citing survey data, "half the people didn't know there were studies they could participate in and half said nobody ever asked me to participate. Those are two problems we can fix." She acknowledged challenges around research participation for people with IH, dedicating their few good hours they have in a day to research, stopping medications, traveling to distant clinical sites, and other burdens – a topic of further discussion later in the program.

Presentation: Brain Fog in IH

"Brain fog is a common complaint in IH. It's described differently by individual patients, so it's not the same thing to everybody. It is regarded as one of the most difficult IH symptoms to treat, and currently we do not have validated scales of brain fog to use in sleep disorders. Further research on brain fog is definitely needed."

– Michael Thorpy, MB, ChB

Michael Thorpy, MB, ChB
Director, Sleep-Wake Disorders Center, Montefiore Medical Center

As Dr. Trotti highlighted, brain fog was one of the most vexing aspects of IH identified by individuals living with IH. (Note: See "Voice of the Patient" report, pages 18-19 and 60-64.) It was also a topic that FDA staff highlighted in a debrief meeting with the Sleep Consortium team following the EL-PFDD meeting. Dr. Michael Thorpy, a leading expert in the study of brain fog, explained that brain fog is reported in many different medical and neurological disorders and received a great deal of attention during the COVID-19 pandemic as a disabling feature of COVID. He noted that brain fog is not reflected in the formal case definition for IH, although it is widely reported by people with IH and has been documented in numerous studies. "The American Academy of Sleep Medicine has been particularly interested in brain fog as an outcome of interest in improving cognitive function for patients with central disorders of hypersomnia (CDoH), of which IH is one," he stated.

Definition and Prevalence in IH

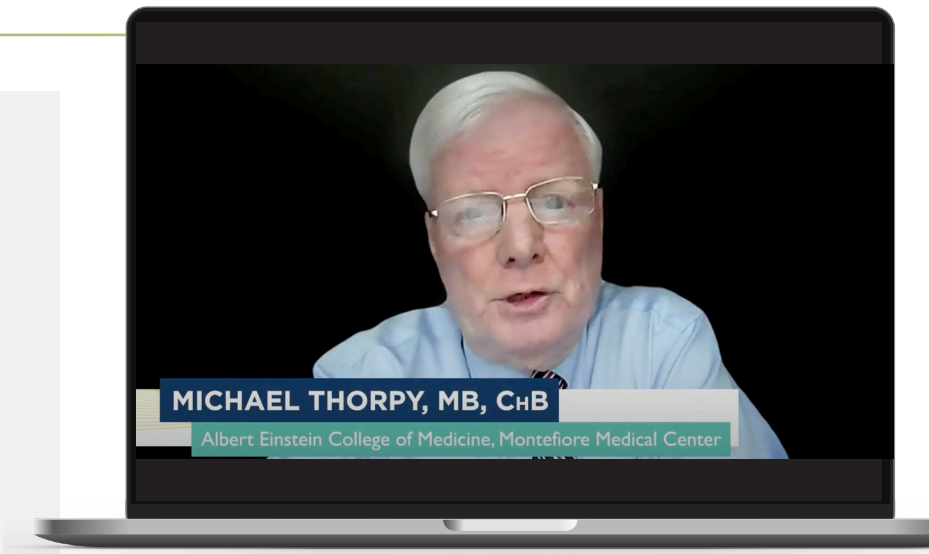
In describing the characteristics of brain fog, Dr. Thorpy reviewed a list of terms and phrases used by patients reporting to the Hypersomnia Foundation's patient registry[1] (see figure on the top of page 6), echoing terms participants used during the EL-PFDD meeting. While several formal definitions of brain fog have been proposed, he contributed to a recent publication that defined brain fog in sleep disorders as, "A cognitive dysfunction that may or may not be linked with excessive sleepiness, related to an underlying neuronal dysfunction, which reduces concentration and impairs information processing, leading to a complaint of lack of clarity of mental thinking and awareness."[2]

[1] *Trotti LM, Ong JC, Plante DT, Friederich Murray C, King R, Bliwise DL. Disease symptomatology and response to treatment in people with idiopathic hypersomnia: initial data from the Hypersomnia Foundation Registry. Sleep Med. 2020;75:343–349.*

[2] *Rosenberg R et al, Brain fog in central disorders of hypersomnolence: A review. J Clin Sleep Med. 2024;20(4):643–651.*

Terms people with IH use to describe brain fog

- "Lack of mental clarity"
- "Groggy," "foggy," or "fuzzy"
- Trouble thinking, focusing, maintaining attention, and functioning
- Feeling "sedated"
- Being "a bit blank," word-finding difficulty, and cognitive slowness when communicating
- Brain being "broken," in a "nebulous state," or "scrambled"
- "Like sleepwalking during the day"
- Forgetfulness, trouble with short-term memory, and difficulty integrating information



Dr. Thorpy described the prevalence of brain fog in IH being similar to narcolepsy, with 87 percent of IH patients with long sleep time and 86 percent of narcolepsy type 1 (with cataplexy) patients reporting brain fog.[3]

He described the prevalence of brain fog in IH being similar to narcolepsy, with 87 percent of IH patients with long sleep time and 86 percent of narcolepsy type 1 (with cataplexy) patients reporting brain fog.[3] Brain fog was reported by 78 percent of IH patients with shorter sleep time and 74 percent of narcolepsy type 2 patients in the same study.

Among the few studies of brain fog in sleep disorders is the Real-World Idiopathic Hypersomnia Outcomes Study (ARISE). The study recruited 75 U.S. adults diagnosed with IH for at least six months. Researchers collected self-reported data using a variety of instruments that captured symptoms, daily functioning, and quality of life. Excessive daytime sleepiness, brain fog, and sleep inertia were identified as the most difficult-to-treat symptoms.[4]

Measuring Brain Fog

"The assessment of brain fog is complicated by our reliance on the patient's interpretation of brain fog, which is complicated by the number of symptoms that patients report as part of brain fog and different ways in which they express those symptoms. Patients realize something is wrong, yet they don't have mental clarity of thought and find it difficult to articulate exactly what's wrong. It's different from patient

[3] *Trotti LM, Ong JC, Plante DT, Friederich Murray C, King R, Bliwise DL. Disease symptomatology and response to treatment in people with idiopathic hypersomnia: initial data from the Hypersomnia Foundation Registry. Sleep Med. 2020;75:343–349*

[4] *Schneider L, et al. Symptom Severity and Treatment Satisfaction in Patients with Idiopathic Hypersomnia: The Real World Idiopathic Hypersomnia Outcomes Study (ARISE). Nat Sci Sleep. 2023 Mar 11;15:89-101.*

to patient, where one may have concentration problems and another might experience word-finding difficulties. A third person might describe more visual symptoms," he stated. Comorbidities common to IH further compound the challenges. "It may be difficult to tease out what's primarily related to the sleep disorder and what's related to a co-existing condition."

Several assessment tools are used to study brain fog in IH and other conditions, shown in the figure below. Dr. Thorpy suggested that ideally, patient-reported surveys would be paired with objective performance-based tests; however, little work has been done yet in sleep disorders. "A visual analogue scale that asks the patient to report the severity of brain fog on a 10-point scale allows us to avoid the challenge of exactly which specific features they have, but it also misses out on understanding the nature of the brain fog the individual experiences," he said.

He highlighted that the validated Brain Fog Scale used for COVID[5] and British Columbia Cognitive Complaints Inventory[6] capture aspects of brain fog described by people with IH, concluding, "So these may be scales that could adopted by the sleep community in the assessment of brain fog. We need to move forward with validating measurement tools for brain fog in IH and other sleep disorders, and with that, I will pass discussion to the panel."

Dr. Thorpy suggested that ideally, patient-reported surveys would be paired with objective performance-based tests; however, little work has been done yet in sleep disorders.

Assessment Tools for Brain Fog

- **IH Symptom Diary** (Hypersomnia Foundation) includes a mental fog scale – not yet validated or published in full
- **IH Severity Scale** – item 11 refers to problems with concentration and memory, which may, at least in part, capture features of brain fog
- **British Columbia Cognitive Complaints Inventory** – established assessment that includes six items common to brain fog
- **Brain Fog Scale** (Polish) – 23-item validated questionnaire used in COVID-19 studies
- **Brain Fog Scale** (Turkish) – used in COVID-19 studies
- **Wood Mental Fatigue Inventory** – used in studies of chronic fatigue syndrome and orthostatic intolerance
- Questionnaire based on the **Nausea Profile** – used to study participants with postural orthostatic tachycardia syndrome (POTS)
- **Thyroid-Specific Patient-Reported Outcome Survey** – used in studies of thyroid disease

[5] *Agata Debowska, et al. Brain Fog Scale (BFS): Scale development and validation. Personality and Individual Differences. Volume 216, 2024, 112427, ISSN 0191-8869.*

[6] *Iverson GL & Lam RW. Rapid screening for perceived cognitive impairment in major depressive disorder. Ann Clin Psychiatry 2013; 25:135.*

Panel Discussion: Approaches to Better Defining and Measuring Brain Fog in IH

PANELISTS

Kiran Maski, MD, MPH, Harvard Medical School and Boston Children's Hospital

Anne Marie Morse, DO, FAASM, Geisinger Commonwealth School of Medicine

David Plante, MD, PhD, University of Wisconsin School of Medicine and Public Health

Lucie Barateau, MD, PhD, of CHU Montpelier and INSERM, was scheduled to participate but was unable to do so due to illness.

> *"No one can say exactly what brain fog is. There are so many different aspects and dimensions to it. …What becomes very important is how the individual patient is experiencing or describing their brain fog, because it's probably going to be very hard to develop a singular scale to capture something that has so many different aspects."*
>
> *– David Plante, MD, PhD*

Moderator Kim McCleary invited panelists Kiran Maski, Anne Marie Morse, and David Plante to discuss the challenges and potential approaches to better defining and measuring brain fog in IH. Dr. Plante kicked off the discussion with a metaphor for defining brain fog: "[Brain fog] is a description of something that everyone experiences. Everyone has been out in the fog in the morning, and you can't see as far as you normally would. You can't be as involved or connected to the world as you normally would be."

Incorporating Patient Experience in Definitions

While there are ongoing formal efforts to define brain fog, in real-world settings, IH patients – and communities representing many other disorders including long COVID – are describing it in their own terms. "In the U.S., we have seen this term become popularized in medicine via its introduction by patients coming to the clinic. Not just sleep clinics; we see a variety of different specialties describing this type of complaint," shared Dr. Morse. Dr. Maski elaborated with this description, "[Brain fog] is a common experience across different groups that they're using to describe a constellation of symptoms that culminate in this feeling of brain fog or mental cloudiness. No one has a clear test or even a survey methodology that fully has been accepted across the fields to capture it."

Dr. Plante began to delve into considerations for efforts to measure brain fog: "It's going to be very hard to develop a singular scale to capture something that has so many different aspects. Hopefully it would capture all the different features that are involved, especially in IH. In medicine, we like to measure things objectively and look for changes, but I think we may need to take a step back and spend some time doing some qualitative research, talking with people about how they experience brain fog and what that means to them."

Fit-for-Purpose Measurement Tools

All three panelists raised additional challenges in developing measurement tools for brain fog. "[Patients are] describing to us that they have a primary cognitive complaint. So sometimes they struggle with word-finding to adequately describe what they're experiencing. We also need to ensure that we're not invalidating the lived experience of what the person is describing because they don't meet a predetermined metric," shared Dr. Morse. Other considerations include how to define the timeframe and timing

"To me, brain fog is characterized by a lack or even an absence of the ability to notice details obvious to others. However, due to my level of alertness - I don't even see it, unless someone draws my attention to it… This lack of alertness makes me appear to be forgetful (since I'm not awake enough to remember) as well as having formed very few memories for my entire life. I first noticed a lack of memories in high school, and I am now 70." – Written comment submitted by S.B., Michigan

of a potential measurement tool and how to differentiate brain fog related to IH from symptoms related to other sleep or neuropsychiatric disorders.

Parsing these elements may be most relevant for a tool that is intended for use in a clinical trial. Dr. Maski commented that a broad scale to measure brain fog might be beneficial to capture the many disparate elements; however, "In a clinical trial, you might be looking at whether sleep duration or sleep inertia could change with a particular compound, so there is a need for a smaller scale that can be used to assess treatments. Does that reflect the full experience of brain fog? Probably not, but at least it may impact a subset of what we think is brain fog."

Dynamic Measurement

The panelists brought ideas and potential solutions to light for approaches to measuring brain fog. Dr. Morse suggested ways to better understand the continuous lived experience and impact of brain fog on someone with IH instead of just one point in time: "Perhaps there are other ways to measure surrogates of brain fog through wearables. They could give us an understanding of your level of activity. Perhaps when a person is experiencing a more severe degree of brain fog, they have slower activity, they may be more reserved, they're less likely to engage. Or we may see the opposite, that because of their brain fog, they're feverishly walking around and doing things, but the activity is misdirected." Dr. Maski agreed that wearables could be helpful and added the potential to augment that data with momentary assessments to get a better sense of how a patient with IH is feeling at that moment: "We don't know if this is autonomic, activity-related, brain-related, etc. To accurately study it, [multi-sensor wearables] could be helpful. But we also need assessments that are available to patients through the day to understand if there are fluctuations that are occurring morning to evening."

Another element to keep in mind is not just understanding brain fog but also tying it to changes in physiology for IH. Dr. Plante commented, "You need a scale or instrument that quantifies the personal experience of brain fog, and you need to map that onto whatever physiologic variable you would be looking at. It's important to keep in mind that we still need to do some of this work on the other important aspects of hypersomnia beyond brain fog." Dr. Morse elaborated by sharing research around potentially related immune responses: "We know that there is significant cytokine involvement in the exaggeration of our homeostatic sleep drive, which will make us more sleepy. Specific interleukins like IL-6 have been attributed to increasing the permeability of the blood-brain barrier, which is an additional component we don't fully understand. There may be an opportunity to understand whether there is an inflammatory component of brain fog."

With any potential measurement tool, keeping the IH patient at the center of development is critical. Dr. Maski and Dr. Plante underscored this. Dr. Maski commented, "I remember hearing a patient say she had an Apple Watch just to find

"I enjoyed the brain fog discussion and hearing Dr. Plante's perspective on qualitative research. Social listening and registries to understand the lexicon is essential. Dr. Morse mentioning impact [on the patient] MUST be considered when discussing brain fog." – Written comment submitted by M.H., Tennessee

her iPhone. So even phone-based [assessments] might not be appropriate. We have to look at things that are easier to access." And Dr. Plante added, "There is general fatigue associated with these types of technologies over time, which you'd imagine in people with brain fog might even be worse… Maybe their disengagement with the app is somewhat a measure of brain fog."

Future Directions

The panel concluded with each expert sharing their vision for the future of brain fog research. Dr. Morse advocated for leveraging existing data and the potential for machine learning and artificial intelligence to analyze polysomnography data in combination with ambulatory EEGs. Dr. Maski emphasized the increased use of tools that are readily available in clinics today and shared excitement for the potential of multi-sensor wearables combined with momentary assessments that might be feasible for an IH patient to complete. Dr. Plante suggested an initial step of validating a self-reported instrument for brain fog specific to IH. He acknowledged that it would not be able to capture every element of this complex symptom; however, he hopes it would capture enough to build on for future research.

Dr. Morse advocated for leveraging existing data and the potential for machine learning and artificial intelligence to analyze polysomnography data in combination with ambulatory EEGs.

Presentation: Barriers to Participation in Research Studies

"Your duty as a doctor is to make sure that this clinical trial [is beneficial]. I want to do clinical trials because I want my patients to benefit from them. So, I have to figure out the patients that are going to benefit. And sometimes, if the protocol is a burden, it's very difficult to justify to myself and to the patients that this is useful for them."

– Emmanuel Mignot, MD, PhD

Emmanuel Mignot, MD, PhD
Craig Reynolds Professor of Sleep Medicine, Stanford University

Meeting host Lindsay Jesteadt invited Dr. Emmanuel Mignot, regarded by many as a leading authority on central disorders of hypersomnolence, to lead off discussion of the second topic of focus, challenges people with IH face participating in research. She referenced the learnings from the EL-PFDD meeting and survey and the hope that bringing attention to these challenges would spur collaborative approaches to mitigating them in future studies to propel better understanding of IH. (Note: See the "Voice of the Patient" report, pages 51-52 and 72-73.)

Inclusive Study Design

Dr. Mignot noted that companies often start with good intentions to make studies accessible for patients to participate, but the inclusionary criteria and exclusion of individuals with comorbidities like depression and sleep apnea can complicate eligibility. The ability to find IH patients who fit a specific medical profile, have certain symptoms, and who can withstand the rigors of a research study can be challenging. Dr. Mignot commented, "In general, I think the inclusion and exclusion criteria are the killers. If it's too strict, of course it's bad because nobody can enter. If it's too loose, that can produce other problems, including bad science and a bad conclusion for the trial." Researchers can amend the protocol if criteria are too broad, but the amendment approval process delays the study and extends the time commitment for patients. Dr. Mignot emphasized

that defining the right eligibility criteria is especially difficult for first trials, as companies develop these without data or prior experience to guide the patient profile and study design.

Protocol Burdens

Dr. Mignot asserted that one of the most significant issues that impacts IH patients' abilities to participate is the requirement to discontinue their current medication regimen. He stated that if their current treatment plan is working, it can be detrimental for IH patients' health and routines to go off medications in favor of participating in a trial. He also noted that, in some cases, study participants don't return to their baseline at the end of the study. This can have a negative impact on the patient and the study. According to Dr. Mignot, the goal should be to shorten the trial to limit the amount of time that participants are off medications, ideally to one month.

Above all, Dr. Mignot believes that the travel, frequent clinic visits, and disruptions to their lives and health that IH patients face should be balanced by the benefits of participating in the trial. He also noted that the physical impacts of participation are often compounded for placebo patients. Dr. Mignot advocates for reducing these burdens and stated, "For studies conducted in my clinic, I insist that the companies pay for transportation and anything that would be an inconvenience for the patient, because I want my patients not to worry about anything." In addition to fair compensation, he proposed that all patients should have access to the medication at the end of the trial regardless of whether an extension study is planned.

Above all, Dr. Mignot believes that the travel, frequent clinic visits, and disruptions to their lives and health that IH patients face should be balanced by the benefits of participating in the trial.

Looking Ahead

One of the aspirations Dr. Mignot has for removing barriers for involving IH patients in clinical trials is at-home measuring devices. He suggested that these could reduce travel burdens and enable more IH patients to participate. Dr. Mignot shared, "I think there is big hope in general for the patient experience to improve a lot through the use of remote technology and at-home measurements."

Panel Discussion: Considerations for Recruiting and Retaining People with IH in Research Studies

PANELISTS

Omavi Bailey, MD, MPH, theSleepMD, El Paso, Texas

Bruce Corser, MD, Sleep Management Institute and Intrepid Research Cincinnati, OH

Yves Dauvilliers, MD, PhD, University of Montpellier and Inserm, France

Anne Marie Morse, DO, FAASM, Geisinger Commonwealth School of Medicine

> *"For those who come from rural or underserved areas who may have IH or narcolepsy, they're living with this condition and they're still working two or three jobs. They're still raising kids, and it's particularly difficult to ask them to step away from all that. They're barely holding it together. To participate in a clinical trial, they should be compensated fairly and supported equally or even more equitably."*
>
> *– Omavi Bailey, MD, MPH*

Moderator Kim McCleary welcomed panelists Omavi Bailey, Bruce Corser, Yves Dauvilliers, and Anne Marie Morse to build on Dr. Mignot's remarks and discuss considerations for recruiting and retaining people with IH in research studies. Each of the panelists conducts IH research studies at their institutions and raised challenges that vary across geographies, demographics, and IH patients' engagement with the medical system.

Study Recruitment and Expanding Awareness

They began with a discussion about how to raise awareness of IH clinical trials – a primary challenge raised by IH community members during the Illuminate Hypersomnia EL-PFDD meeting. Dr. Bailey took a step back to highlight the issue of a lack of awareness of IH in addition to a lack of awareness of research studies. His practice is located in El Paso, Texas, which has a large population but relatively few physicians. He takes a community-based and physician-based approach: "You have to educate the population about 'what is hypersomnia' but also reach out to providers to also let them know that these conditions exist and there are options and treatments. We currently run commercials on local television, and we also do some social media outreach. We have events with providers where we speak and educate on the newest science and recommendations around hypersomnia." Dr. Morse also uses social media to raise awareness around clinical trials, using her platform to alert patients to clinical trial sources such as clinicaltrials.gov and pharmaceutical company websites.

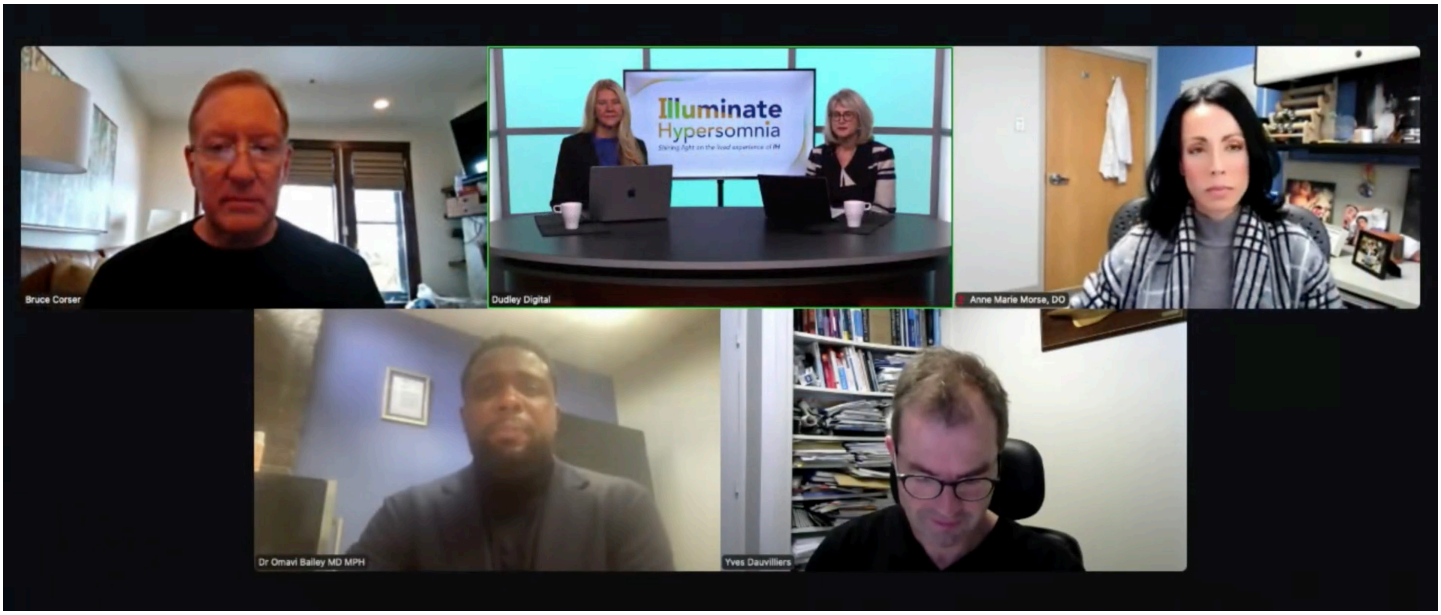
Dr. Corser suggested expanding beyond one's immediate clinic area: "I'm located in Cincinnati, Ohio, but we've been trying to reach out to other geographic areas in close proximity. For example, there are no clinical trial sites in northern Kentucky, so we're targeting outreach to Lexington and Louisville. We're also reaching out to Indianapolis, Indiana, Dayton, Ohio, and Columbus, Ohio." He also highlighted that trusted partners play a vital role in clinical trial awareness: "Advocacy groups are incredibly important. They serve as the intersection between patients and sites and play a very important role in disseminating information about clinical trials. We work together to host regional programs to reach more potential study participants."

"Something to consider is research surveys are generally long and for someone with IH, like me, to start and finish it within a certain timeframe. It's not that we don't want to share our thoughts and feelings, but that we might be too tired to do so." – Written comment submitted by P.B., New York

Inclusion and Exclusion Criteria

Dr. Bailey introduced the importance of raising awareness of IH with patients and providers as a starting point, intended to ease the challenge of receiving an IH diagnosis. This is a global problem, as highlighted by Dr. Dauvilliers: "We need to train and to educate the general public and primary care physicians that being sleepy all day long could be related to a disease such as IH or narcolepsy or other conditions… We need to improve the diagnostic criteria across different countries to ensure we are all addressing the same condition." Dr. Dauvilliers elaborated to highlight the lack of objective measures in IH, which is vital for ensuring those included in IH research studies have IH and not a related condition: "Currently we do not have a very good biomarker for IH… If centers disagree in terms of inclusion criteria, the results will not be replicated. Rather than being due to the wrong results, it could just be due to the heterogeneity of the population being studied."

Restrictive exclusion criteria serve as a major barrier to clinical trial recruitment for those diagnosed with IH. Dr. Corser commented on a challenge raised by Dr. Mignot, requiring patients to stop taking current medications. "Many people with



IH are taking antidepressants or other psychoactive medications, which often causes exclusion of these patients. Alternatively, they have to 'wash out' of these medicines, which is problematic. I would advocate for including a lot of antidepressants or other psychoactive medications in the clinical trials." Dr. Bailey agreed and accentuated this point, "Most of the patients that we end up seeing who've finally been diagnosed with hypersomnia have other health issues as well. They end up on a lot of medications. Coming off these medications could really be scary for them. Particularly for patients in underserved areas, they may not have the support they need to come off their medications. For example, if you're going to take someone off their medication and they don't have support with childcare, that could be a serious problem or even a risk to the family."

Dr. Morse related the consequences of restrictive inclusion and exclusion clinical trial criteria to the clinical setting. "In medicine, we frequently refer to 'lumpers' and 'splitters,' and I live on a constant continuum, depending on the situation. So when talking about research, you want to be as specific as possible about the study population. We've seen how prior narcolepsy studies on oxybate medications have included cataplexy as a primary endpoint. You then see insurers say, 'You don't have cataplexy, so you don't get access to this medication.' Sometimes we develop clinical trials and create tight exclusion criteria in a vacuum to satisfy the FDA, but it is really binding our hands in a clinical setting," she stated.

Dr. Bailey accentuated this point, "Most of the patients that we end up seeing who've finally been diagnosed with hypersomnia have other health issues as well. They end up on a lot of medications. Coming off these medications could really be scary for them."

Patient-Centered Clinical Trial Design

Dr. Morse identified the opportunity for using social media to support the development of clinical trials that address patient-centered unmet needs: "Social media represents an exquisite opportunity, not only for the delivery of information but also to enhance

understanding. By participating in social media conversations, I feel I'm better connected to the lived experience, the knowledge gaps, and locations that people are interested in. My efforts aim to understand where there are care gaps and how we can improve the quality of the clinical trial design so people will be excited to participate because a study is designed to understand the things that they're suffering with."

Dr. Corser commented on opportunities to design trials with IH patients in mind: "Anyone who has participated in or conducted these trials will realize how onerous some of them are. There are multiple different measures, sleep diaries, tests, and questionnaires required. We have to wake up people at a certain time, and they have to complete certain diaries or questionnaires within a short timeframe. It's important to have a longer window of opportunity for some of these patients who have severe sleep inertia or brain fog to complete these tasks. There's an opportunity to minimize the burden on the patient and the staff."

Dr. Bailey highlighted considerations for supports that may be important for an IH patient considering a clinical trial: "Transportation is always an issue that must be considered for a person with IH, not just to and from a clinical trial site. Patients need more support if they're going to be asked to participate in a clinical trial and be off their medications." Dr. Corser also offered potential incentives that may make clinical trial participation more appealing to and less burdensome for IH patients: "Minimizing exposure to placebo is important. Also, offering people the option of an open-label extension study, so that if they do respond well to the medication, they can remain on the medication for a period of time thereafter. That's an important incentive for patients to go through all this."

Dr. Dauvilliers added, "It is very hard for the patient to jump into a trial and be exposed to the placebo. That's very complex, and we must know the patient well to help them decide whether the trial is right for them. But this placebo study design is mandatory to be able to have new drugs on the market. For me, we need to separate what is a randomized control trial backed by pharma or an academic center, and what is the treatment routine for a patient in the clinic. Treating a patient is a completely different story because you want to help them."

"One thing that wasn't addressed for the patient is their ability to safely drive anywhere if they are no longer taking their medication." – Written comment submitted by S.B., Michigan

Future Directions

To close the session, panelists were asked to share one change the scientific community could make to IH clinical trials so that they're less burdensome for participants without compromising scientific rigor. Dr. Morse encouraged clinical trial sponsors to design trials with the full person in mind: "Think comprehensively about what that person's day-to-day looks like. Consider transportation, groceries, support. Do we need to make sure that there's a home health aide available to ensure the safety of the patient and those they're a caregiver for? Take a step back to understand that we are purposely inducing a tremendous disability by asking people to be off their usual medication and potentially randomizing them to weeks or months without medication."

Dr. Bailey urged clinical trial sponsors to take an equitable approach to support patients' participation in research studies. "Put more emphasis and resources into reaching out to underserved communities and diversity, equity, and inclusion in clinical trials."

Dr. Corser summarized his suggestions about reaching out to patients to meet them where they are, minimizing exposure to placebos, being mindful of trial timelines, and offering open-label extension studies. He added, "Consider emphasizing enriched trials so participants who don't benefit from medication are not forced to continue to take the medication for the duration of the trial."

Dr. Bailey urged clinical trial sponsors to take an equitable approach to support patients' participation in research studies. "Put more emphasis and resources into reaching out to underserved communities and diversity, equity, and inclusion in clinical trials. Approach this with both diverse patients and diverse providers. Providers in underserved areas have access to patients because the patients trust them. But the resources in those areas are not the same as the academic centers or big city multi-specialty groups, and they may need more support to be a clinical trial site. There is also a lack of equity in how much patients get reimbursed based on where they live – an underserved area versus a major city, or if they are being seen in an academic institution versus a small clinical trial site in the rural area. There needs to be more equity in that."

Dr. Dauvilliers closed by encouraging spending time to educate an individual patient on the elements of clinical trial protocols and the benefits of the information the participant and the scientific community may receive from it: "We need to explain why clinical trial assessments are mandatory. It's an opportunity to engage them in addressing the problem – the burden of the disease – and how that may disappear or decrease with the drug being studied. Take time to engage their help to gain a better understanding of the disease. It will help with disease recognition and also to potentially get a new drug on the market."

The diverse topics – and opinions – raised across this panel highlighted the many opportunities to make IH research studies more patient-centered.

"I love the attention on diversity and equity in trials. Dr. Corser mentioned decreasing exclusionary criteria, which is imperative considering comorbidities and weight issues are prevalent in CDoH. Dr. Dauvilliers made a great statement about using trials as an educational tool for patients. This approach resonates strongly."
-Written comment submitted by M.H., Tennessee

Industry Roundtable: Discussion of Unmet Needs for IH Identified by the Illuminate Hypersomnia Initiative

INDUSTRY ROUNDTABLE PARTICIPANTS

ASM 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

"Dr. Trotti discussed the multi-year gap between symptom onset, seeking medical attention, and diagnosis earlier today. A number of ways to help shorten this diagnostic delay emerged during our Roundtable discussions. For example, we know there are challenges and limitations with current screening and diagnostic tools. Further enhancing the clinical utility of existing tools like actigraphy, which is in the diagnostic criteria, may help support and add confidence in making an IH diagnosis. Developing newer sleep testing protocols that can aid in the differential diagnosis of IH, particularly from narcolepsy type two, would be incredibly productive. Many of us agree the big pie-in-the-sky goal is ultimately to identify a biomarker that could be truly diagnostic of IH and aid in research."

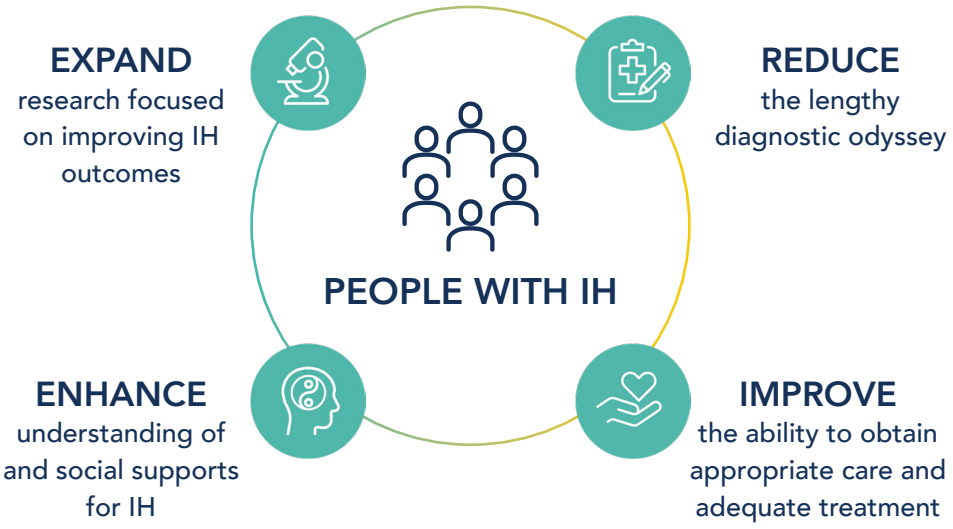
– Jessica Sacks, PhD

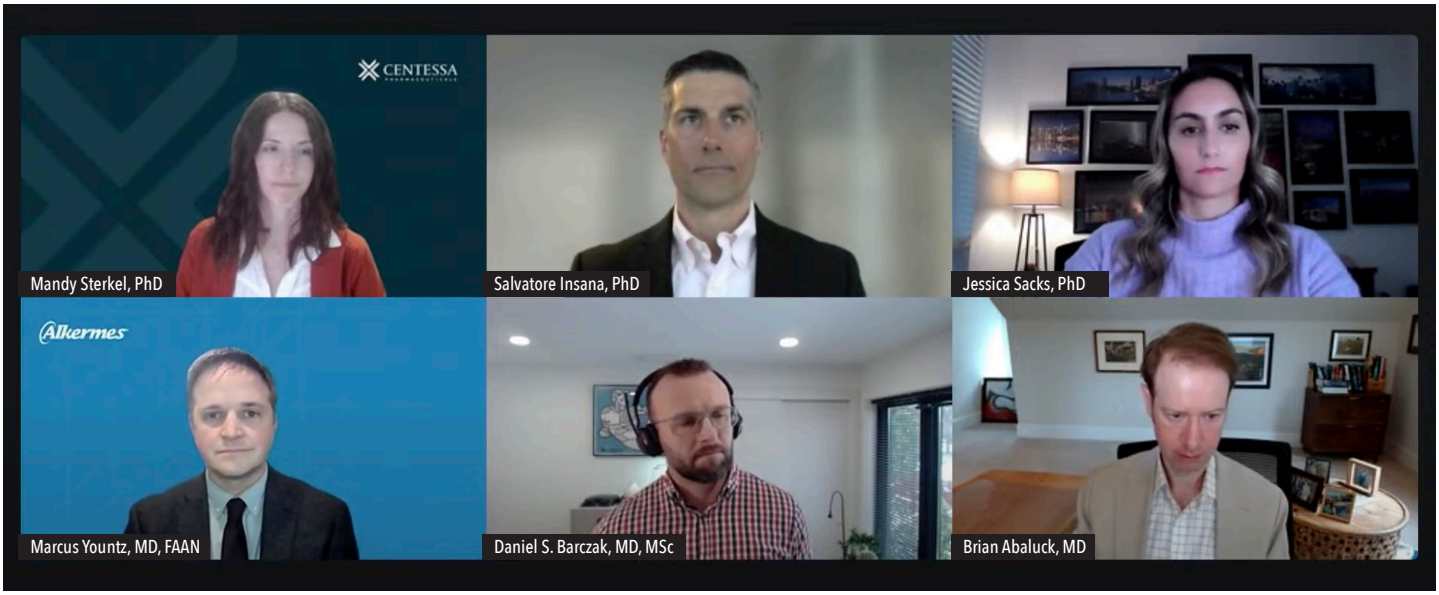
Following the Illuminate Hypersomnia EL-PFDD initiative, Sleep Consortium heard from biopharmaceutical industry stakeholders interested in discussing potential ways to tackle unmet needs that were identified by patients and caregivers. This led to the creation of the Illuminate Hypersomnia Industry Roundtable – an opportunity for industry representatives to participate in a precompetitive, non-product-specific discussion to generate an aspirational list of opportunities to advance patient-centered medical product development in IH. Two participants from each of six biopharmaceutical companies – Alkermes, Avadel Pharmaceuticals, Centessa Pharmaceuticals, Harmony Biosciences, Jazz Pharmaceuticals, and Takeda Pharmaceuticals – participated in two roundtable meetings in December 2024. A single representative from each of the six participating companies joined the Adjunct Scientific Meeting to report on those discussions.

Dr. Sterkel started with an overview of the work the roundtable participants conducted in advance of the Adjunct Scientific Meeting: "In preparation for the two sessions that occurred in December, we reviewed the Illuminate Hypersomnia Voice of the Patient report, and we gave thought to the key challenges and unmet needs expressed by the IH community. As a group, we then collectively reflected on the unmet needs and discussed potential ways to address them, whether that be through new or enhanced endeavors, practices, programs, or policies. We truly took a blue-sky approach to these discussions that was unbound by any budgetary or other restrictions."

Dr. Insana introduced the way the Roundtable organized their thinking, acknowledging that the unmet needs expressed by the IH community and the ideas generated by this group fell into four broad categories that are closely interrelated. He described the categories the group used to organize their discussion: reducing the lengthy diagnostic odyssey, improving the ability to obtain appropriate care and adequate treatment, enhancing understanding of and social supports for IH, and expanding research focused on improving IH outcomes.

"...As a group, we then collectively reflected on the unmet needs and discussed potential ways to address them, whether that be through new or enhanced endeavors, practices, programs, or policies. We truly took a blue-sky approach to these discussions that was unbound by any budgetary or other restrictions." – Mandy Sterkel, PhD





In discussing the priority of **reducing the lengthy diagnostic odyssey**, Dr. Sacks highlighted key ideas the group generated, including enhancing the clinical utility of existing screening and diagnostic tools like actigraphy, which may add confidence in the diagnosis of IH, developing new sleep testing protocols to aid in differentiating IH from other disorders, and ultimately developing a biomarker that is specific to IH. She also raised the need for communication resources to help patients describe IH and raise awareness about the condition among health care professionals and payers, and dedicating resources to the development of self-assessment tools to help inform and empower patients.

Dr. Yountz shared thoughts generated by the group on the topic of **improving the ability to obtain appropriate care and adequate treatment**, starting with how to address the shortage and geographic imbalance of physicians that may be comfortable caring for and treating a person with IH, which could be supported by using telehealth. The group also discussed the potential benefits of developing centers of excellence for IH to improve access to physicians, research studies, and support services. Access to treatments, increasing education around the long-term health effects of IH, and encouraging additional support from trusted family or friends at care visits were also points of discussion.

Dr. Barczak shared the following thoughts generated by the Roundtable on the topic of **enhancing understanding of and social supports for IH**. The group discussed the need to increase public understanding and awareness of IH and generate resources for patients to share with others in their community. Similarly, the development of messaging to counter myths about and dismissive attitudes towards IH and work to better understand IH in different cultural contexts could help support IH community members. Lastly, the group discussed the generation of resources to aid in the coordination of care, especially for young adults new to navigating the health care system.

The group discussed the need to increase public understanding and awareness of IH and generate resources for patients to share with others in their community.

Dr. Abaluck closed the report out session by sharing the Roundtable's thoughts on the topic of **expanding research focused on improving IH outcomes**. The group discussed the potential of better leveraging technology, such as EEGs and actigraphy, and real-world data sources, such as testing and claims data, to inform and conduct research studies. The group also discussed the need to meet patients where they are during a research study, given the burdens of research participation and the importance of measuring symptoms beyond sleepiness to better understand the full impact of IH on a patient's life and how to best improve their quality of life. They also talked about strengthening epidemiology around IH and the opportunity for pre-competitive consortia to spur research-related advancements.

This report and the complete list compiled by the Industry Roundtable (below) complemented the earlier presentations and panels and it provides IH community stakeholders with a comprehensive set of possibilities to prioritize and work towards potential solutions collectively.

Full List of Unmet Needs Generated by the Sponsor Roundtable

REDUCE the lengthy diagnostic odyssey

- Enhance clinical assessment tools
  - Consider additional existing tools, such as actigraphy, that may add confidence to IH diagnoses
  - Define polysomnography protocols to better distinguish between IH and NT2 (in particular)
- Revisit IH definition and descriptions of key symptoms
  - Seek sentinel set of findings to differentiate IH from NT2 and other conditions
  - Reflect on ways symptoms are described by patients vs. HCPs/researchers and cultural contexts
  - Consider barriers imposed by name "IH" & symptom nomenclature
- Expand search for biomarker to aid diagnosis & research
- Enhance awareness of IH and training for HCPs (including sleep specialists) to diagnose and/or make appropriate referrals
  - Launch a sleep-related campaign to help increase awareness of sleep disorders
  - Develop short, digestible medical trainings for HCPs
- Address shortages of/limited access to formal sleep testing
  - Support increased reimbursement of sleep testing
- Explore development of self-assessment tools to help inform and empower patients who may be seeking to connect dots between disparate IH symptoms

Continued

Full List of Unmet Needs Generated by the Sponsor Roundtable *Continued*

IMPROVE the ability to obtain appropriate care and adequate treatment

- Facilitate access to sleep specialists & informed HCPs
  - Expand availability of telehealth as an option for IH patients
- Increase awareness of long-term health effects related to IH and its treatments
  - Build monitoring of these health impacts into routine IH care practices
- Expand treatment options indicated for IH
- Support better access to available medications
  - Look at impact of diagnostic codes on coverage of services & medications
  - Collect & provide compelling evidence to support coverage
  - Educate payers about burdens and total costs of IH ("humanize IH")
- Establish hypersomnia Centers of Excellence linking care, research, clinical trials, patient navigation, advocacy
- Encourage patients to involve trusted family/friend in care visits to share observations and help with follow-up

ENHANCE understanding of and social supports for IH

- Increase public understanding and awareness of IH
  - Develop resources for patients to share with family, peers, employers, school staff, etc.
  - Validate need for family and other supports
  - Develop messaging to enlighten those making dismissive statements
- Seek a better understanding of cultural differences in how patients may experience and articulate symptoms
  - For example: depression, "brain fog," and lack of translation of some terms in other languages
- Develop resources/supports to aid with coordination of care (especially for young adults, given common age of onset/symptom worsening and lack of familiarity navigating healthcare system)

EXPAND research focused on improving IH outcomes

- Develop more patient-centered outcome measures
  - Leverage advances in EEG & actigraphy technologies
  - Develop and validate ways to measure fatigue, brain fog, sleep inertia, etc.
- Increase access to real-world data sources, such as testing and claims data, to inform IH research
- Enable remote monitoring in clinical trials to reduce participant burden
- Explore new ways of defining and quantifying functional improvements
  - "More quality wakefulness"
  - How quality wakefulness translates to quality of life, "extending" life, fulfilling life potential, fewer injuries, etc.
- Strengthen epidemiology to clarify IH determinants, phenotypes, natural history, and progression
- Initiate industry-led consortia to spearhead precompetitive research-related advancements

Closing Remarks

Moderator Kim McCleary noted the density of information delivered by presenters and panelists in the brief two-hour session. "They brought additional light – and some heat – to just a subset of the topics that came up in the EL-PFDD meeting and survey. There was great interest in the discussion, judging by the nearly 400 people who registered for the meeting, representing people living with IH, caregivers, researchers, health care professionals, life science companies, and federal agencies."

Host Lindsay Jesteadt remarked on the scale of interest in this initiative. "When Sleep Consortium co-founder Claire Wylds-Wright and I first began discussing an IH initiative two years ago, we could not have predicted the generous response from all corners of the IH community to be part of this effort to move IH out of the shadows, bring the lived experience of IH into the light, and then focus attention on how to address research and other unmet needs on what we have all learned from the community." Kim agreed, adding, "We've heard from so many people with IH about how validating this initiative has been and the hope it has inspired."

Lindsay closed the program by thanking presenters, panelists, partners, and sponsors for their contributions to the Illuminate Hypersomnia initiative. "This is an exciting time for the IH community, and speaking on behalf of Claire and myself, we could not be more proud of the work you have all done to illuminate hypersomnia."

"This was truly excellent. Thank you so much!" – Written comment submitted by R.H., Pennsylvania

Sleep Consortium and Kith Collective Team: left to right: Lauren Kenney, Lindsay Jesteadt, Samantha Mayberry, Kim McCleary, and Claire Wylds-Wright.

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.

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).

PRESENTATION: RECAP OF THE ILLUMINATE HYPERSOMNIA EL-PFDD MEETING AND SURVEY

Lynne Marie Trotti, MD, MSc

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.

PRESENTATION: BRAIN FOG IN IH

Michael Thorpy, MB, ChB

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.

PANEL: APPROACHES TO BETTER DEFINING AND MEASURING BRAIN FOG IN IH

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.

PRESENTATION: BARRIERS TO PARTICIPATION IN RESEARCH STUDIES

Emmanuel Mignot, MD, PhD

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.

PANEL: 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.

Acknowledgements

CORPORATE SPONSORS

Thank you to these generous sponsors for their unrestricted educational grants in support of the Illuminate Hypersomnia initiative.

ILLUMINATE HYPERSOMNIA INITIATIVE PARTNERS

Sleep Consortium thanks these partners of the Illuminate Hypersomnia initiative for their enthusiastic and active support with community outreach for the EL-PFDD meeting, survey, and Adjunct Scientific Meeting.

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 the Adjunct Scientific Meeting and make it available for later on-demand viewing.

Lauren Kenney of the Kith Collective for support with the Adjunct Scientific Meeting and summary.

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 of the EL-PFDD meeting, Sponsor Roundtable sessions, and Adjunct Scientific Meeting.

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

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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