

Tentative Outline: Full Hot Topic: Sleep Therapeutics
Special Issue Proposal for Reviews on Recent Clinical Trials

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Sleep is a biological imperative for all mammals. Sleep deprivation and disorders pose an expanding public health hazard and lead to impaired health, general functioning, and quality of life. Sleep medicine has emerged as a unified discipline over the last two decades, and sleep disorders and insufficient sleep have significant bearing on a variety of co-morbid medical, neurological, and psychiatric disorders. Several recent randomized controlled trials have shown benefit for a variety of new sleep therapeutics for sleep disordered breathing, restless leg syndrome, narcolepsy, and insomnia. A Full Hot Topic issue devoted to sleep therapeutics is therefore timely and of potential wide ranging interest. **AIMS:** (1) To produce a comprehensive yet imminently readable review of the current clinical practice of sleep therapeutics, grounded in relevant basic science and pharmacology. (2) To review emerging preclinical therapies on the immediate and mid-range horizon likely to gain future approval through progression in clinical trials in the field of sleep medicine; (3) To identify and discuss current unmet needs in sleep therapeutics that may spur further drug development in the field of sleep medicine. **SCOPE:** This single Full Hot Topic Issue should be of wide ranging potential appeal to practitioners, trainees, and allied health professionals in the fields of sleep medicine, neurology, psychiatry, pulmonary medicine, general internal medicine, pediatrics, and family medicine, as well as scientific and industry stakeholders in drug and device development.

Key Words: Sleep, therapies, narcolepsy, hypersomnia, insomnia, parasomnia, epilepsy, restless leg syndrome, periodic leg movements, pain, fibromyalgia, circadian, sleep apnea

Subjects with Titles and Authors/Institutions:

1. **A Hot Topics Special: Overview of Sleep Therapeutics:** Erik K. St. Louis, M.D., Mayo Clinic

Narcolepsy and Hypersomnia:

2. **Neurostimulant Therapies for Hypersomnia:** Satish Rao, M.D., University of Louisville, and Erik K. St. Louis, M.D., Mayo Clinic

3. **Anticatataplectic Therapy:** Michel Cramer-Bornemann, M.D., Ph.D., University of Minnesota, and Erik K. St. Louis, M.D., Mayo Clinic

Restless Legs Syndrome:

4. **Restless Leg Syndrome and Periodic Limb Movement Disorder: Treatments and Complications:** Jason Cornelius, Minneapolis Clinic of Neurology/University of Minnesota, and Erik K. St. Louis, M.D., Mayo Clinic

Insomnia Treatment:

8. Behavioral and Hypnotic Therapies for Insomnia: Piyush Das, M.D., and Erik K. St. Louis, M.D., Mayo Clinic

Circadian Sleep Disorders:

9 Diagnosis and Treatment of Circadian Sleep Disorders: Afshin Shirani, M.D., Dartmouth University, and Erik K. St. Louis, M.D., Mayo Clinic

10. Circadian Periodicity of Medical and Neuropsychiatric Disorders: Chronopharmacologic Influences on Current Treatment, Future Clinical Trial Design, and Drug Development: Fellow to be Named, and Erik K. St. Louis, M.D., Mayo Clinic

Parasomnias:

11. Behavioral and Pharmacotherapies for the Parasomnias and Nocturnal Epilepsies: Mithri Junna, M.D., and Erik K. St. Louis, M.D., Mayo Clinic

Sleep Apnea/Sleep Disordered Breathing:

12. Sleep Disordered Breathing: Positive Airway Pressure, Pharmacologic Approaches, and Neuromodulatory Therapies: Kannan Ramar, M.D., Sean Caples, D.O, Timothy Morgenthaler, M.D., and Erik K. St. Louis, M.D., Mayo Clinic

13. Treatment of Co-morbid Sleep Apnea in Cardiac, Medical, and Neuropsychiatric Disorders: Andrew Calvin, M.D., Virend Somers, M.D., and Erik K. St. Louis, M.D., Mayo Clinic

General Article Format/Content

Introduction

Disease/Disorder State Background Review

Review of Basic Background Clinical Pharmacology/Basic Science Germane to Drug(s)/Therapies in this Specific Disorder/Disease State

Including Relevant Summary Tables/Figures

Clinical Pharmacology and Evidence Basis (including SORT Rating) of Currently Marketed Therapies

Summary Table Required: Basic Format

Agent (Generic/ Trade Name)	Dosage	T1/2	Adv. Effects	Precautions/ Monitoring	Interactions
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The Horizon: Drugs In Preclinical Development in the Area

The Future: Expanding the Pipeline; Developing Therapies and Unmet Needs in Sleep Medicine (Identification of Unmet Needs in Therapeutic Area and Potential for Further Pharma Drug Development)

Conclusions

Issues: ?