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#### Newsletter

Where Life-changing Therapies Turn First®



## Sleep Disorders and New Ways to Treat Them

Getting a good night's sleep can be very difficult for many individuals. Studies show that insomnia costs the US workforce \$63.2 billion in lost productivity per year. Poorer workplace performance, increased health care utilization and increased accidents at work can all be reduced by treating insomnia. In fact, insomnia treatment has been shown to be cost-effective.

For more than 20 years <u>CTI's Clinical Research Center</u> has conducted numerous Phase I-IV clinical trials to support development of novel treatments for sleep disorders. This body of work includes providing data for 11 FDA approved medications and devices for the treatment of various sleep problems. The CTI CRC is considered a top-tier site for conducting sleep research studies.

#### **About Common Sleep Disorders**

Those patients with insomnia and those with narcolepsy are two good examples of individuals who have trouble getting a good night's sleep. New therapies, both on the market and in development offer hope to both of these groups of individuals.

**Insomnia** - Insomnia is a common sleep disorder that can make it hard to fall asleep, hard to stay asleep, or cause you to wake up too early and not be able to get back to sleep. Insomnia affects about 30% of the adult population.

**Narcolepsy** - Narcolepsy is a chronic neurodegenerative disease caused by a deficiency of orexin-producing neurons. It is characterized by excessive daytime sleepiness and by intrusions into wakefulness of the physiological aspects of rapid eye movement sleep (REM sleep) such as cataplexy, sleep paralysis and hallucinations on arising called hypnagogic hallucinations.

**Orexin** - Orexin, also known as hypocretin, was first discovered in 1998 and is a neuropeptide. It orchestrates and modulates the control of arousal and vigilance levels in response to external cues. Orexin A and Orexin B are endogenous ligands derived from a common precursor peptide, which exert their effects on orexin receptors type 1 and 2 in the brain. Some of the new compounds, both in research as well as in use today, are what are called Dual Orexin Receptor Antagonists.

#### **Treating Insomnia and Narcolepsy**

Research in sleep medicine is always trying to find safer and more effective ways to treat sleep disorders. Many of the effective treatments have been shown to have negative side effects like being addictive or overly sedating to the patient.

It was the identification of the deficiency of orexin as the cause for the symptoms surrounding those with narcolepsy, which has allowed for the discovery of dual orexin receptor antagonists and current research helping those with both narcolepsy and insomnia.

#### **CTI Cares Spotlight:**



The Gift of Life Donor Program is the leading Organ Procurement Organization in the Nation, exceeding more than 540 donors in 2016, and transplanting more than 1,412 organs. The Gift of Life also procures tissue donors from 2,575 donors resulting in more than 100,000 tissue grafts. Howard Nathan has lead this organization since 1974 and is instrumental in collaborating and training programs in the United States and the Rest of the Worlds.

Recognizing the critical need for affordable accommodations and supportive services for transplant families, Gift of Life Donor Program opened a unique lodging facility for transplant candidates, recipients, family members and living donors. Gift of Life Family House serves as a "home away from home" for transplant patients and their families by providing temporary, affordable lodging and supportive services to those who travel to Philadelphia, Pennsylvania for transplant-related care. Since opening its doors in 2011, the Family House has provided more than 37,000 lodging nights of care, over 143,000 home-cooked meals, and 7,500 trips to and from the region's transplant centers.

Nominated by: Lynn Fallon

neurons of the arousal system, allowing for the natural transition from wakefulness to sleep, thus eliminating the subject's insomnia. This new class of drugs is noted to be non-addictive and show a favorable tolerability and limited side-effect profile.

More recently, another new compound that mimics orexin, and can enter the brain (YNT-185), was demonstrated to significantly promote wakefulness in mice. This may offer hope in the future to those with narcolepsy, by replacing the orexin which has been lost.

CTI has a long history of working in neurology including rare/orphan diseases, central nervous system (CNS) disorders, psychiatry, and sleep research. We have conducted hundreds of studies in neurology indications with more than half of these being sleep research studies. Over decades of working in sleep research, we have developed a network of research trained, registered polysomnographic technicians. Our facilities and our personnel are more than equipped to efficiently and expertly execute these types of trials. In addition to our sleep trials, we have experience in the execution of studies evaluating neurological rare and orphan diseases, psychiatric indications, as well as indications specific to pain perception. Our medical affairs team includes a board certified neurologist with experience as an investigator and medical monitor across diverse indications within this area.

Interesting in having CTI/CRC help with for your sleep study related needs? Let our experience and expertise assist your team with whatever needs that you have.

For more information, contact us!

### New Additions & Promotions at CTI

Elizabeth Burger joins as Senior Clinical Data Manager

Amanda Coleman promoted to Assistant Research Scientist, HECOR

Angel Fetters promoted to Project Accounts Coordinator

Debbie Huey joins as Travel Coordinator

Ryan Imhoff promoted to Assistant Research Scientist, HECOR

Megan Kamm promoted to Senior Study Manager

Brett Marshall promoted to Senior Study Coordinator

Natalie Nortman promoted to Study Manager II

Sherry Plantholt promoted to Project and Laboratory Manager

Susan Roettgers joins as Administrative Assistant, Medical Affairs

## Upcoming Meetings We Will Be Attending

ASGCT Washington, DC May 10-13

Bio Connect Cork, Ireland May 11

Cell & Gene Exchange Washington, DC May 22-23

Outsourcing Conference King of Prussia, PA May 23-24

2017 Life Science Innovation Northwest Seattle, WA May 23-24

PCMG Conference Copenhagen, Denmark June 2-6

**54th ERA-EDTA Congress** Madrid, Spain June 3-6

DIA 2017

To schedule a meeting with us at one of these, please <u>click here</u>

# Join our Team! We're looking for individuals to fill these positions:

Administrative Assistant (Ulm, Germany)

Clinical Research Associate (US, UK, Germany, France, Spain, Australia, Brazil, Korea, Taiwan, Japan, Argentina)

Clinical Research Associate Manager (Greater Cincinnati, OH Area)

Clinical Quality Assurance Auditor (Greater Cincinnati, OH Area)

Clinical Safety Scientist (Raleigh, NC)

Clinical Trial Assistant (Ulm, Germany)

Director, Business Development -HECOR/Consulting (Greater Cincinnati, OH Area)

Director, Business Development -Regulatory and Drug Development (Greater Cincinnati, OH Area)

Director, Executive Level HECOR (Greater Cincinnati, OH Area)

Manager, HECOR (Greater Cincinnati, OH Area)

