



PACIFIC RESEARCH NETWORK

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RENATA SHAFOR, M.D.

EDUCATION

1958 – 1964 Kishinev State Medical Institute, Kishinev, U.S.S.R.
Degree: M.D. with Honors
1957 – 1958 Kishinev State University, School of Physics, Kishinev, U.S.S.R.

POST GRADUATE EDUCATION

1975 Diagnosis and Treatment of Blood Diseases, Kishinev Institute of Advanced Training, Kishinev, U.S.S.R.
1973 Advanced Training in Internal Medicine, Graduated in Physician First Class Category, State Institute of Advanced Training, Donzek, U.S.S.R.
1971 – 1972 Advanced Training in Rheumatology and Cardiology, Odessa Medical Institute, U.S.S.R.
1968 Specialization Program in Internal Medicine, State Medical School Kishinev, U.S.S.R.

TRAINING

1984 – 1985 Fellowship: Clinical Fellow in Sleep Disorders, Division of Chest and Critical Care Medicine, Scripps Clinic and Research Foundation, La Jolla, California
1983 – 1984 Residency: Chief Resident in Neurology, Department of Neurology University of Missouri Hospital and Clinic, Columbia, Missouri
1981 – 1983 Residency: Neurology, Department of Neurology, University of Missouri Hospital and Clinic, Columbia, Missouri

MEDICAL EXPERIENCE

1992 – Present Investigator, Pacific Research Network, San Diego, California
1990 – Present Medical Director, San Diego Sleep Disorder Center, San Diego, California
1986 – 1996 Scripps Clinic Medical Group, Scripps Clinic and Research Foundation La Jolla, California
1986 – 1990 Medical Director, San Diego Sleep Disorder Center, Harborview Medical Center and Hospital, La Jolla, California
1986 – 1988 Physician, Sleep Disorders Center, Scripps Clinic and Research Foundation La Jolla, California
1975 – 1978 City Supervisor, Hematological Service in Outpatient Clinic, Odessa, U.S.S.R.
1975 Diagnosis and Treatment of Blood Diseases, Kishinev Institute of Advanced Training, Kishinev, U.S.S.R.
1971 – 1978 District Internist, City Hospital #6, Odessa, U.S.S.R.
1966 – 1971 District Internist, City Hospital #4, Kishinev, U.S.S.R.
1964 – 1966 General Physician, Rural Area, U.S.S.R.

CERTIFICATION AND LICENSURE

1984 American Board of Psychiatry and Neurology – Board Eligible

1985 American Board of Sleep Medicine, Board Certified, Accredited Clinical Polysomnographer

LICENSURE:

State of California

License Number: A41108

Expiration Date: April 30, 2008

1980 E.C.F.M.G.

PROFESSIONAL AND ACADEMIC APPOINTMENTS

1993 – 1996 Appointed Member of the Accreditation Committee, American Sleep Disorders Association

1992 – 1995 Chairperson, Quality Improvement Committee, Harborview Medical Center San Diego, California

1990 – 1991 Chairperson, Ancillary Committee, Harborview Medical Center San Diego, California

PRESENTATIONS

1. *Excessive Somnolence: Differential Diagnosis and Treatment*, Course of Sleep Disorders in Internal Medicine, Scripps Clinic and Research Foundation, La Jolla, California, November 1984.
2. *Sleep Apnea – Diagnosis and Management*, Grand Rounds, Mercy Hospital and Medical Center, San Diego, California, December 1987.
3. *Sleep Disorders Medicine*, Conference of the Family. Coronado Hotel, Coronado, California, February 1987.
4. *Polysomnography and Common Sleep Disorders*, CME Presentation, Costa Rica, October 1988.
5. *Insomnia Diagnosis and More News In Sleep Disorders*, CME Presentation, Costa Rica, October 1989.
6. *Update on Sleep Disorders*, CME Presentation, Costa Rica, October 1992.

PUBLICATIONS

1. *Changes in Caolase Activity in Brain and Liver After Exposure to Radiation*, Biochemical Research M.S.S.R. (Abstract)
2. Timms R, **Shaforenko R**, Hajdukovic R, Mitler M. *Sleep Apnea Syndrome: Quantitative Studied of Nighttime Measures and Daytime Alertness*, Sleep Research, 14, 222, 1985.
3. Mitler M, Hajdukovic R, **Shaforenko R**, Han P, Kripke D. *When People Die: Cause of Death vs. Time of Death*, Journal of the American Medical Association (Submitted) 1987.
4. **Shaforenko R**, Times R, Mitler M. *Maintenance of Wakefulness Test: What Parameters are Most Useful?*, (In preparation).
5. Mitler M, **Shafor R**, Sobers M, Hajdukovich RM, Rubin RL, *Human Leukocyte Antigen (HLA)*

- Studies in Excessive Somnolence: Narcolepsy Versus Sleep Apnea*, Sleep Res. 15:148, 1986.
6. **Shafor R**, Ancoli-Israel S, Mitler M. *The Architecture of PLMS: Fragmented vs. Solid Leg Jerk Episodes*, Sleep Research, 1988.
 7. Barrera H, Gutierrez F, **Shafor R**, *Standardization of Optimal CPAP Pressure According to Percent of Excessive Weight in Patients with Obstructive Sleep Apnea*, Sleep Research Abstract, 1988.
 8. **Shafor R**, *Lumbosacral Spine Abnormalities and Periodic Leg Movements in Sleep*, Sleep Research Abstract, 1989.
 9. **Shafor R**, *Prevalence of Abnormal Lumbosacral Spine Imaging in Patients with Insomnia – Restless Legs, Periodic Leg Movements in Sleep*, Sleep Research Abstract, 1992.
 10. **Shafor R**, *Prevalence of Restless Legs Symptoms in Patients with Documented Abnormal Spine Imaging*, Sleep Research Abstract, 1995.

AWARDS AND PRIZES

1984 O.R.T. Woman of the Year, San Diego, California

PROFESSIONAL ORGANIZATIONS

American Medical Association
 American Academy of Neurology
 American Sleep Disorders Association
 California Medical Society
 Clinical Sleep Society
 National Sleep Foundation
 San Diego County Medical Society

CLINICAL RESEARCH EXPERIENCE

1. A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Safety and Efficacy of 12 Weeks of 2 Oral Doses (200 mg and 400 mg Once Daily) of XXXXX as Treatment for Adults with Excessive Daytime Sleepiness Associated with Obstructive Sleep Apnea/Hypopnea Syndrome Followed by a 9-Month Open-Label Extension. (2581)
2. A Randomized, Double-Blind, Placebo-Controlled, Dose-Response Study to Assess the Efficacy and Safety of XXXXXX in Patients with Chronic Insomnia. (2973)
3. A Randomized, Double-Blind, Placebo-Controlled, Single-Dose Study to Assess Dose Response of XXXXXX in Subjects Transient Insomnia. (2580)
4. A Randomized, Double-Blind, Placebo-Controlled, Dose-Response Study to Assess the Efficacy and Safety of XXXXXX in Elderly Patients with Chronic Insomnia. (3927)
5. A Randomized, Double-Blind, Placebo-Controlled, Dose-Response Study to Assess the Efficacy and Safety of Modified Release Formulation of XXXXXX in Elderly Patients with Chronic Sleep Maintenance Insomnia. (4097)
6. A Phase II, Randomized, Double-Blind, 5-Way Cross-Over Study to Evaluate the Efficacy and Safety of XXXXXX (5,10 and 15 mg) and XXXXXX (10 mg) Versus Placebo in a Model of Transient Insomnia. A sleep Laboratory Study in Healthy Subjects. (4485)

7. A Phase III, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Multicenter Study To Assess the Efficacy and Safety of XXXXXX in Adults with Primary Insomnia. (4310)
8. A Phase III, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Assess the Efficacy and Safety of XXXXXX for the Treatment of Transient Insomnia in Adult Subjects. (4311)
9. XXXXXX 30 mg and 60 mg Once Daily Versus Placebo in Generalized Anxiety Disorder. A Randomized, Double-Blind, Placebo- and XXXXXX-Controlled, Fixed-Dose, Parallel-Group, Multicenter Study of 10 Weeks (Including a 2-Week Single-Blind Placebo Period). (4128)
10. An Open-Label Extension Trial to Assess the Long-Term Safety of a Controlled Release Formulation of XXXXXX HBr in the Treatment of Alzheimer's Dementia. (2918x1)
11. A Randomized, Double-Blind, Placebo-Controlled Evaluation of the Safety and Efficacy of XXXXXX in Patients with Mild to Moderate Dementia of the Alzheimer's Type. (4441)
12. A Randomized, 26-Week, Double-Blind, Placebo-Controlled Trial To Evaluate the Safety and Efficacy of XXXXXX in the Treatment of Dementia Secondary to Cerebrovascular Disease. (3666)
13. A Well-Controlled Safety and Efficacy Study of XXXXXX In Subjects with Mild to Moderate Alzheimer's Disease. (3261)
14. XXXXXX 60 mg (or 30 mg) Once Daily in the Treatment of Generalized Anxiety Disorder. An Open Multicenter Safety Study of 5 Months, Including a 1-Month Drug-Free Follow-Up Period. Follow-Up to Studies. (4458)
15. An Open-Label Extension Trial to Assess the Safety of XXXXXX HBr in the Treatment of Vascular Dementia. (4556)
16. Efficacy and Safety of a Flexible Dose of XXXXXX Versus Placebo in the Treatment of Psychosis of Alzheimer's Disease. (2956)
17. A Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Efficacy and Safety of XXXXXX in Subjects with Mild Cognitive Impairment (MCI) Clinically at Risk for Development of Clinically Probable Alzheimer's Disease. (2920)
18. A Long-Term Open-Label Study of XXXXXX in Subjects with Mild to Moderate Alzheimer's Disease. (3261x1)
19. A Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Efficacy and Safety of XXXXXX in Subjects with Mild Cognitive Impairment (MCI) Clinically at Risk for Development of Clinically Probable Alzheimer's Disease. (2919)
20. A Randomized, Double-Blind, Single-Dose, Double-Dummy Evaluation of the Efficacy, Safety and Pharmacokinetics of the Adenosine A1 Agonist, XXXXXX 100 mg, and XXXXXX 50 mg Versus Placebo in the Acute Treatment of Migraine. (4452)

21. A Randomized, Double-Blind, Placebo-Controlled Evaluation of the Safety and Efficacy of XXXXXX in Patients with Mild to Moderate Dementia of the Alzheimer's Type. (3811)
22. A Long-Term Extension Study Evaluating the Safety and Tolerability of BID and QD Administration of XXXXXX in Patients with Mild to Moderate Dementia of the Alzheimer's Type. (3811x1)
23. Assessment of Variance in FDG-PET Measurement of CNS Effects in Healthy Volunteers. (4082)
24. An Eight-Week, Double-Blind, Placebo-Controlled Multicenter Study to Evaluate the Safety and Efficacy of 2 Doses of XXXXXX (1.5 mg and 3.0 mg) and XXXXXX in Subjects with Major Depressive Disorder. (3495)
25. A Phase III, Randomized, Double-Blind, Placebo-Controlled, Outpatient Study to Assess the Long-Term Safety and Efficacy of Two Dose Levels of XXXXXX in Adult Patients with Primary Insomnia. (3934)
26. A Phase III, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter Study to Assess the Efficacy and Safety of a Modified Release Formulation of XXXXXX in Elderly Primary Insomnia Patients with Sleep Maintenance Difficulties. (4315)
27. A Double-Blind, Placebo-Controlled Dose-Finding Study Evaluating the Safety and Efficacy of XXXXXX, 80 mg bid, and 20 and 80 mg QD in the Treatment of Mild to Moderate Alzheimer's Disease. (4807)
28. A Phase III, Randomized, Double-Blind, Placebo-Controlled, Outpatient Study to Assess the Efficacy and Safety of Two Dose Levels of XXXX in Elderly Patients with Primary Insomnia. (3931)
29. A Phase III, Double-Blind, Outpatient, Extension Study to Assess the Long-Term Safety of Two Dose Levels of XXXX in Elderly Patients with Primary Insomnia. (3931x1)
30. A Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Safety and Efficacy of XXXX 25 mg in Slowing the Progression of Alzheimer's Disease. (202531)
31. A Long-Term Safety and Efficacy of Open-Label XXXX, 80 mg b.i.d. in the Treatment of Probable Alzheimer's Disease: A 18-Month Follow-up After Completion of Study XXXX. (202859)
32. A Long-Term, Open-Label, Flexible-Dose Study of the Efficacy and Safety of XXXX in Patients with Idiopathic Restless Legs Syndrome. (4382)
33. A Randomized, Double-Blind, Placebo-Controlled Evaluation of the Safety and Efficacy of XXXX in Patients with Moderate to Severe Dementia of the Alzheimer's Type. (4887)
34. A Randomized, Double-Blind, Placebo-Controlled Evaluation of the Safety and Efficacy of XXXX in Patients with Moderate to Severe Dementia of the Alzheimer's Type. (4988)
35. Pharmacogenomics Blood Sampling Protocol to Obtain DNA in a Reference Population of Patients Diagnosed with Restless Legs Syndrome. (5152)

36. An 8-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Flexible-Dosage Study to Evaluate the Efficacy and Safety of XXXX, at Dosages up to 16mg/day, in the Treatment of Generalized Anxiety Disorder in Adults. (202359)
37. A 12-Month, Open-Label, Flexible-Dosage Study to Evaluate the Safety of XXXX, at Dosages up to 16 mg/day in Adults with Generalized Anxiety Disorder. (202976)
38. An Evaluation of the Long-Term Safety and Efficacy of XXXX in Patients with Moderate to Severe Dementia of the Alzheimer's Type. (202891)
39. A Multicenter, Randomized, Double-Blind, Active and Placebo Controlled 5-Way Crossover Study of the Safety and Efficacy of XXXX, Zolpidem, and Placebo in Primary Insomnia. (5076)
40. A Randomized, Double-Blind, Placebo-Controlled, 4-Period-Cross-Over Pilot Study of the Safety and Efficacy of Multiple Doses of XXXX in Subjects with Alzheimer's Disease. (202856)
41. An Open-Label Extension Study to Assess the Long-Term Safety and Tolerability of XXXX in the Treatment of Mild Cognitive Impairment. (5075)
42. A Phase III, Randomized, Double-Blind, Placebo-Controlled, Outpatient Study to Assess the Long-Term Safety and Efficacy of Two Dose Levels of XXXX in Adult Patients with Primary Insomnia. (3934)
43. A 12-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of Obstructive Sleep Apnea/Hypopnea Syndrome. (203233)
43. A 12-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of XXXX (150 and 250 mg/day) as Treatment for Adults with Excessive Sleepiness Associated with Narcolepsy. (203231)
44. A One year, Multicenter, Randomized, Double-Blind, Placebo-Controlled Evaluation of the Efficacy and Safety of XXXX in Subjects with Mild Cognitive Impairment. (202493)
45. A Randomized, Multicenter, Double-Blind, Placebo-Controlled, 18-Month Study of the Efficacy of XXXX in Patients with Mild-To-Moderate Dementia of the Alzheimer's Type. (202793)
46. A Randomized, Double-blind, Placebo-Controlled Trial of XXXX to Attenuate the Progression of Alzheimer's Disease. (202530)
47. A Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multicenter, Fixed-Dose, Polysomnographic Study of XXXX in Patients with Primary Insomnia. (202700)
48. A Multicenter, Randomized, Open-Label Study Evaluating the Effects of XXXX, 80 mg b.i.d., vs. XXXX, 5 or 10 mg, on Adrenal Function in Patients with Mild Alzheimer's Disease. (202538)
49. A Double-Blind, Phase II, Safety and Efficacy Evaluation of XXXX in Patients with Mild to Moderate Alzheimer's Disease. (203096PRN)
50. A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase II Study of Efficacy and Safety of XXXX in Subjects with Mild to Moderate Alzheimer's Disease. (00012)

51. A Study to Define the Non-Restorative Sleep Population. (00010)
52. A Randomized, Double-Blind, Placebo-Controlled Trial of XXXX to Attenuate the Progression of Alzheimer's Disease. (00026)
53. A Phase III Study of the Efficacy and Safety of XXXX in Patients with Mild to Moderate Alzheimer's Disease. (203077PRN)
54. A 12-Month, Open-Label, Flexible-Dosage (100-250 mg/day) Extension Study of the Safety and Efficacy of XXXX in the Treatment of Patients with Excessive Sleepiness Associated with Narcolepsy, Obstructive Sleep Apnea/Hypopnea Syndrome, or Chronic Shift Work Sleep Disorder. (203903)
55. A Phase III, Randomized, Double-Blind, Placebo-Controlled, Polysomnographic Study to Assess the Efficacy and Safety of a Modified Release Formulation of XXXX in Primary Insomnia Patients with Sleep Maintenance Difficulties. (00047)
56. A Randomized, Double-Blind, Placebo-Controlled, Cross-Over Study to Evaluate the Effects of XXXX (2.5, 10, and 30 mg) on Polysomnographic Sleep Recordings, Subjective Sleep Assessment and Daytime Cognitive Function in Elderly and Non-Elderly Subjects with Primary Insomnia. (00088)
57. A Randomized, Double-Blind, Placebo Controlled, Cross-Over Study to Evaluate Effects of the XXXX in Patients with Insomnia. (00077)
58. A Randomized, Double-Blind Comparison of 5 mg of XXXX, 15 mg of XXXX, and Placebo in the Treatment of Patients with Primary Insomnia. (00076)
59. A Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study to Demonstrate the Subjective Treatment Effects of XXXX on Sleep Using a Post Sleep Questionnaire-Interactive Voice Response System (PSQ-IVRS) in at "At-Home Setting" in an Adult Population with Chronic Insomnia. (00145)
60. A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Study to Investigate the Efficacy and Safety of a Single Oral Dose of XXXX (20, 50, and 100 mg) and Matching Placebo in Healthy Male and Female Subjects with Induced Transient Insomnia. (00107)
61. Efficacy and Safety of XXXX 5mg/day on Sleep Maintenance Insomnia: A 6-Week, Multi-Center, Randomized, Double-Blind, Placebo-Controlled Study. (00103)
62. A Randomized, Double-Blind, Placebo and Active-Controlled, Multicenter, Proof of Concept Trial of XXXX in Subjects with NonRestorative Sleep. (00095)
63. A Double-Blind, Randomized, Placebo-Controlled Study of The Efficacy, Safety and Tolerability of 8 Week Treatment of XXXX 8 mg (QHS) in Sleep Disturbed, Mild to Moderately Severe Alzheimer's Disease Subjects. (00090)
64. A Six-Week, Double-Blind, Randomized, Placebo-Controlled, Parallel Group, Efficacy and Safety, Sleep Lab Trial with XXXX in Patients with Chronic Primary Insomnia. (00118)

65. A Randomized, Double-Blind, Placebo-Controlled, Parallel, Proof of Concept Study to Evaluate the Effectiveness of XXXX to Advance the Timing of Sleep in Individuals with Delayed Sleep Phase Syndrome (DSPS). (00198)
66. A Randomized, Double-Blind, Placebo-Controlled, Phase IIa Study to Assess the Short-Term Effects of XXXX Alone and in Combination with Donepezil in Subjects with Mild Alzheimer's Disease. (00144)
67. Efficacy and Safety of 2mg/Day XXXX on Sleep Maintenance Insomnia: a 6-Week, Multicenter, Randomized, Double-Blind, Placebo-Controlled Polysomnographic Study. (00192)
68. A Phase II, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group, Dose-Ranging Study Assessing the Efficacy and Safety of XXXX Tablets Twice Daily in Adults with Mild to Moderate Alzheimer's Disease. (00214)
69. Fifty-Two Weeks, Open-Label Extension Trial to Evaluate Safety and Efficacy of XXXX in Outpatients with Chronic Primary Insomnia Who Completed Clinical Trial Protocol 176001 or 176002. (00217)
70. A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Study to Investigate the Efficacy and Safety of XXXX (20mg/Day and 50mg/Day) in the Treatment of Primary Insomnia. (00273)
71. XXXX Dose-Ranging Trial: A Randomized, Double-Blind, Placebo-Controlled, 5-Way Crossover, Multicenter Polysomnography Trial of XXXX in Adults with Primary Insomnia. (00284)