



Curriculum Vitae

Thomas Merrill Shiovitz, M.D.

CTSdatabase, LLC

9777 Wilshire Blvd. Suite 1011
Beverly Hills, CA 90212
Tel 855.827.2873
Fax 818.986.9716

California Neuroscience Research
4835 Van Nuys Blvd., Ste. 104
Sherman Oaks, CA 91403
Tel 818.990.2671
Fax 818.986.9716

Positions Held, Certifications and Education

Professional Experience

- 2011 to Present President, CTSdatabase, LLC
Founder of and overall responsibility for a clinical trial subject registry designed to provide sponsors and sites with information about potential subjects' current and previous study participation.
- 2002 to Present: Director, California Neuroscience Research Medical Group, Inc.
Ultimate responsibility for all operations of CNS clinical trial site in Sherman Oaks, CA. President, Principal Investigator and research psychiatrist. Research consultation to pharmaceutical sponsors in CNS trial design and execution
- 2000 to 2002 President, Investigative Sites, Ingenix Pharmaceutical Services.
Beverly Hills, California
Ultimate responsibility for all operations of California Clinical Trials in Beverly Hills, CA and International Clinical Trials in London. Report directly to President and CEO.
- 1995 to 2002 Medical Director
California Clinical Trials Medical Group
Beverly Hills, California
- 1995 to 2000 Medical Director
International Clinical Trials
London, England
- 1993 to 2002 Research Psychiatrist
California Clinical Trials Medical Group
Beverly Hills, California
- 1988 to Present Assistant Clinical Professor in Psychiatry
University of California, Los Angeles
School of Medicine
Los Angeles, California
- 1987 to Present Psychiatrist
Private Practice in Adult Psychiatry,
Psychotherapy and Psychopharmacology
Beverly Hills, California

- 1987 to 1994 Group Leader
Housestaff Assistance Program
Cedars-Sinai Medical Center
Los Angeles, California
- 1987 to 1993 Consulting Psychiatrist
Hillview Mental Health Center
Lakeview Terrace, California

Licensure Licensed Physician and Surgeon
State of California, License # G53155

Certifications American Board of Psychiatry and Neurology
Diplomate in Psychiatry, June, 1989

American Board of Psychiatry and Neurology
Added Qualifications in Geriatric Psychiatry, November, 1996
Recertified, March, 2006

Hospital Affiliations Cedars-Sinai Medical Center
Los Angeles, California
Psychiatric Attending Physician (Emeritus)

Sherman Oaks Hospital and Health Center
Sherman Oaks, California
Psychiatric Attending Physician

Memberships/Awards:

American Psychiatric Association, Member

Southern California Psychiatric Society, Member

American Society of Clinical Psychopharmacology, Member

American Association of Geriatric Psychiatry, Member

International Society for CNS Clinical Trials and Methodology, Member

Accreditation in Continuing Medical Education, California Medical Association 1996- 2002
(Director of Medical Education, California Clinical Trials)

Leo Rigler Award, Outstanding Psychiatric Resident
Cedars-Sinai Medical Center
Los Angeles, California, 1987

Education

- 1986 to 1987 Chief Resident
Cedars-Sinai Medical Center
Department of Psychiatry
Los Angeles, California
- 1984 to 1986 Psychiatric Resident
Cedars-Sinai Medical Center
Los Angeles, California
- 1983 to 1984 Psychiatric Intern
UCLA/Sepulveda V.A. Medical Center
North Hills, California
- 1983 Doctor of Medicine
University of Michigan Medical School
Ann Arbor, Michigan
- 1978 Bachelor of Science, Biology
University of Michigan
College of Literature, Science and the Arts
Ann Arbor, Michigan

Research

- 2002 to Present Director, Principal Investigator
California Neuroscience Research
Sherman Oaks, California

Founder and Director of a leading CNS clinical trial site specializing in studies of Alzheimer's Disease, Anxiety, Depression, Migraine & Insomnia
- 1995 to 2002 Medical Director
California Clinical Trials Medical Group
Beverly Hills, California

Assure the safe, ethical and cost-efficient completion of more than one hundred clinical trials through direct supervision of all research physicians and pharmacologists. Oversight of inpatient, outpatient, regulatory and quality assurance departments. Assist pharmaceutical sponsors in protocol design and clinical trial program development
- 1995 to 2000 Medical Director
International Clinical Trials
London, England

Responsible for the conduct of all research (Phase I, Bridging, Phase II and Phase III) through the supervision of the Director and Medical Affairs Director of International Clinical Trials.

- 1993 to 2002 Principal Investigator and Sub-Investigator
California Clinical Trials Medical Group
Beverly Hills, California

Investigator on well over 100 Phase I, II and III clinical trials of medications for most psychiatric and neurologic disorders. Specialty in studies in depression, anxiety, migraine, Alzheimer's Disease, Schizophrenia and other indications
(See Addendum for Principal Investigator Experience)

- 1978 to 1979 Research Assistant
University of Michigan Hospital
Department of Anesthesiology
Ann Arbor, Michigan

In vivo research on platelet function.

Scholarly Publications/Presentations:

1. **Shiovitz TM**, Greenberg W, Chen W, et al. A Randomized, Double-Blind, Placebo-Controlled Trial of the Efficacy and Safety of Levomilacipran ER 40-120 mg/day for Prevention of Relapse in Patients with Major Depressive Disorder. *Innov Clin Neurosci*. 2014; 11 (1-2): 10-22.
2. **Shiovitz TM**, Zarrow ME, Mangano TC. How Duplicate Subjects Impact Clinical Trial Data: Under-compliant, Over-responding and Statistically Overlooked. Poster. ISCTM Annual Meeting, Feb 2014, Washington, DC
3. **Shiovitz TM**, Gevorgyan L, Shiovitz ZW, Zarrow, ME. How Far Are Duplicate Subjects Willing to Go? Changing Indications and Identifiers in Order to Participate in Studies at Distant Sites. Poster. ACNP Annual Meeting, Dec 2013, Hollywood, FL.
4. **Shiovitz TM**, Wilcox CS, Gevorgyan L, Mehra V, Mangano TC. Using a Subject Registry to Create a Duplicate-Free Corridor for Conducting Clinical Trials. Poster, CNS Summit, Nov 2013, Boca Raton, FL.
5. **Shiovitz TM**, Gevorgyan I, Mangano T. Subject Registries Reduce Duplicate Subjects Entering CNS Studies. Poster, NCDEU Annual Meeting, Hollywood, FL, May, 2013
6. **Shiovitz TM**, Manlosa NB, Gevorgyan I, Zarrow ME, Wilcox CS. Characteristics of Duplicate Subjects in a Clinical Trial Subject Registry. Poster, NCDEU Annual Meeting, Hollywood, FL, May, 2013
7. **Shiovitz TM**, Wilcox CS, Gevorgyan I, Shawkat A. CNS Sites Cooperate to Detect Duplicate Subjects with a Clinical Trial Subject Registry *Innov Clin Neurosci* 2013;10(2):17-21
8. Coric V, van Dyck CH, et al. (**Shiovitz, TM co-author**). Safety and Tolerability of the Gamma Secretase Inhibitor Avagacestat in a Phase 2 Study in Mild-to-Moderate Alzheimer's Disease. *Arch Neurol*, 2012; 69(11):1430-1440
9. **Shiovitz TM**, Bose A, Greenberg W, et al. The Efficacy and Safety of Levomilacipran SR in the Prevention of Relapse in Major Depressive Disorder; Results from a Phase III Clinical Trial. Poster. 2012 Psych and Mental Health Congress, San Diego, Nov 2012

10. **Shiovitz TM**, Wilcox CS, Gevorgyan L, et al. CNS Sites Cooperate to Detect Duplicate Subjects with a Clinical Trial Subject Registry. Poster. CNS Summit, Boca Raton, Nov 2012
11. **Shiovitz TM**, Zarrow ME, Shiovitz AM, Bystritsky A. Failure rates and “Professional Subjects” in Clinical Trials of Major Depressive Disorder. Letter. J Clin Psychiatry 72:9 Sept 2011
12. Rickels K, **Shiovitz T**, Ramey TS, et. al. Adjunctive Therapy with Pregabalin in Generalized Anxiety Disorder Patients with Partial Response to SSRI or SNRI treatment. Accepted, Inter Clin Psychopharmacol, Jan, 2012
13. **Shiovitz TM**, Zarrow ME, Sambunaris A, Gevorgyan, L. Subjects in CNS Clinical Trials Poorly Reflect Patient Population. Poster. CNS Summit, Nov 2011
14. Miceli JJ, Tensfeldt TG, **Shiovitz T**, et. al. Effects of Oral Ziprasidone and Oral Haloperidol on QTc interval in patients with Schizophrenia or Schizoaffective disorder. Pharmacotherapy 2010 Feb; 30(2):127-35
15. Mohs RC, **Shiovitz T**, et al. Atomoxetine Augmentation of Cholinesterase Inhibitor Therapy in Patients with Alzheimer’s Disease. Am J Geriatr Psychiatry 2009; 17(9): 752-759
16. **Shiovitz TM**, Song JL, et al. Extreme Creatine Phosphokinase Elevation in a 20 Yr-Old Man Participating in a Clinical Trial of Major Depressive Disorder. Letter. J Clin Psychiatry 69:11,1832-34, 2008
17. Scharre DW, **Shiovitz, T**, Zhu Y, Amantriek J. One-week Dose Titration Schedule of Extended-Release Galantamine in Patients with Alzheimer’s Disease. Alzheimer’s & Dementia 4:1, 30-37, 2008
18. Harrigan EP et al (**Shiovitz, TM co-author**). A Randomized Evaluation of the Effects of Six Antipsychotic Agents on QTc, in the Absence and Presence of Metabolic Inhibition. J Clin Psychopharmacol 24:1, 62-69, 2004
19. Potkin SG, **Shiovitz TM**, Wolfgang CD. Safety and Efficacy of 2 loperidone Dose Titration Schedules for the Treatment of Schizophrenia: A Haloperidol-Controlled Study. Submitted, 2007
20. Jhee SS et al (**Shiovitz, TM co-author**). First Clinical Evaluation of Ganstigmine in Patients with Probable Alzheimer’s Disease. Clin Neuropharmacol. 2003; 26(3) 164-169
21. Schneider LS et al (**Shiovitz TM co-author**) An Eight-Week, Multicenter, Parallel-group, Double-Blind, Placebo-controlled Study of Sertraline in Elderly Outpatients with Major Depression. Am J Psychiatry 160:7, 1277-1285, July 2003
22. Sramek JJ, Cutler NR, **Shiovitz, TM**. Short-term The Effect of Antipsychotics on Plasma Lipids. Letter. J Clin Psychopharmacol 23(6):679-680, 2003
23. Jhee SS, Kim E, **Shiovitz T** et al. Single dose escalation study of PPI-1019, a β -Amyloid Aggregation Inhibitor. Poster. NCDEU, Boca Raton, FL May 2003
24. Miceli JJ, **Shiovitz TM**, Swift RH, Anziano RJ. Effects of Oral Ziprasidone and Haloperidol on QTc at Clinical and High Doses. Poster. Presented International Conference on Schizophrenia Research, April, 2003
25. Jhee SS (**Shiovitz TM co-author**). Multiple-dose Safety and Tolerability of LY 450108 and LY451395 in Patient’s with Probable Alzheimer’s Disease. Presented (Dr Jhee), Society for Neuroscience, Orlando, November, 2002

26. Frackiewicz EJ, **Shiovitz TM**, Jhee SS. Ethnicity in Drug Development and Therapeutics. London, Greenwich Medical Media, 2002. **Book**
27. Jhee, SS et al (**Shiovitz TM** co-author). LY 451395 Cerebrospinal Fluid Pharmacokinetics in Healthy Human Subjects. *J Clin Pharmacol* 2002; 42 (9), 1067
28. **Shiovitz T**, Monici P, Pietra C, Fabbri L, Piccinno A, Jhee SS, Zarotsky V, Tan E. A Double-Blind, Placebo-Controlled Evaluation of the Safety and Tolerability of Increasing Doses of CHF 2819.01 (Ganstigmine) in Patients With Probable Alzheimer's Disease. 7th International Geneva/Springfield Symposium on Advances in Alzheimer Therapy. Geneva, April, 2002.
29. Hossain M, Jhee SS, **Shiovitz TM**, et al. Estimation of the Absolute Bioavailability of Rivastigmine in Patients with Mild to Moderate Dementia of the Alzheimer's Type. *Clin Pharmacokinet* 2002; 41(3) 225-234
30. **Shiovitz, TM**, et al. Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of BAY 36-1677 (IL-4 Selective Agonist) in Patients with Multiple Sclerosis. poster, CINP 2002 Congress, Montreal, Canada, June, 2002.
31. Jhee SS, **Shiovitz TM**, et al. Safety and Tolerability of Serial Cerebrospinal Fluid (CSF) Collections During PK/PD Studies: 5 Years Experience – Abstract, presented 2002.
32. Frackiewicz EJ, Jhee SS, **Shiovitz T**, Webster J, Topham C, Dockens RC, Whigan D, Salazar DE, Cutler, NR. Rasagiline Treatment for Parkinson's Disease in Combination with Levodopa/Carbidopa. *Ann Pharmacother* 2002 February, Volume 36.
33. Jhee SS, **Shiovitz, T**, Hartman RD, Messina J, Cutler NR, Anand, R, Sramek J. Centrally Acting Antiemetics Mitigate Nausea And Vomiting in AD Patients Receiving Rivastigmine. Letter. *Clinical Neuropharmacology*, March/April 2002, Vol 25, Issue 2.
34. Miceli, JJ, Anziano RJ, Swift RH, **Shiovitz, TM**. IM Ziprasidone and IM Haloperidol have comparable effects on QT_c at Cmax. Poster. American Psychiatric Association, Philadelphia, May 2002
35. Jhee SS, **Shiovitz TM**, et al. A Double-Blind, Placebo-Controlled Pharmacokinetic (PK), Pharmacodynamic (PD) and Safety of Celecoxib Treatment for Four Weeks in Patients with Alzheimer's Disease (AD) – Abstract
36. Salazar DE et al (**Shiovitz TM** co-author). Pharmacokinetics and Tolerability of Buspirone during oral Administration in Children and Adolescents with Anxiety Disorder and Normal Healthy Adults. *J Clin Pharmacol* December, 2001;41:1351-1358.
37. Jhee, SS, **Shiovitz, TM**, Crawford, AW, Cutler, NR. Clinical Pharmacokinetics of the Triptan Anti-Migraine Agents: A Comparative Review. *Clin Pharmacokin.* February 2001.
38. Jhee, SS, **Shiovitz, TM**, Crawford, A, Cutler, NR, "β-Amyloid Therapies in Alzheimer's Disease." *Exp. Opin. Invest. Drugs* (2001)10(4):593-605.
39. Frackiewicz, E, **Shiovitz, TM**, "Evaluation and Management of Premenstrual Syndrome and Premenstrual Dysphoric Disorder," *J Am Pharm Assoc* 2001 May-Jun; 41(3):437-47.
40. Jhee, SS, PharmD, **Shiovitz, TM, MD**, et al. GV196771 in the CSF of Healthy Subjects Following 300 mg Oral Dose Administered Once Daily for 7 Days. Poster, American Society for Clinical Pharmacology and Therapeutics, March 2001.
41. Pande, AC et al (**Shiovitz, TM** co-author). Placebo-Controlled Study of Gabapentin Treatment of Panic Disorder. *J Clin Psychopharmacol* 2000 Aug; 20(4):467-71.

42. Ascher J, et al (**Shiovitz TM co-author**). A Meta Analysis of Clinical Safety Data from Controlled Monotherapy Trials of Lamotrigine in Depression. Presented at American College of Neuropsychopharmacology, December 1999.
43. Sramek JJ, Anand R, et al (**Shiovitz, TM co-author**). A Bioequivalence Study of Brand and Generic Clozapine in Patients with Schizophrenia: Pharmacokinetic and Safety Findings. ClinDrugInvest 17(1): 51-58, 1999.
44. Cutler NR, Friday G, Haskell L, Jhee SS, Knuttsson M, Martin T, Ohlman S, **Shiovitz TM**, Sramek JJ, NXX-066 in Alzheimer Patients: A Bridging Study. Abstract. American Association of Geriatric Psychiatry New Orleans, Louisiana, March 16, 1999.
45. Apter J, et al (**Shiovitz, TM co-author**) Lamotrigine: Evidence for Antidepressant Activity in Bipolar Disorder: Abstract. Presented at American College of Neuropsychopharmacology, December 1998.
46. **Shiovitz, TM**, et al: "The Safety and Tolerability of Sertindole in Elderly Patients with Dementia," Poster, American Association of Geriatric Psychiatry, Orlando, Florida, February .1997.
47. Cutler, NR et al, (**Shiovitz TM. co-author**). A Bridging Study of Once-Daily Iloperidone in Schizophrenic Patients – Poster 1996
48. **Shiovitz TM**, Welke TL, Tigel PD, Anand R, Hartman RD, Sramek JJ, Kurtz NM, Cutler NR. Cholinergic rebound and rapid onset psychosis following abrupt Clozapine withdrawal. Schizophr Bull. 1996; 22(4):591-5.