ROBERT CLIFTON ALEXANDER, M.D.

robert.alexander@bannerhealth.com

Brief Bio:

I have extensive experience in both early- and late-stage drug development and medical governance and have led clinical groups since 2006. Prior to my appointment at Banner, I was the Vice President and Head, Clinical Science, Neuroscience Therapeutic Area Unit at Takeda, where my group was responsible for all clinical trials in Neuroscience from Phase I-III. At Pfizer, I was the CMO for BioTherapeutics, which included Neuroscience, Rare Disease, and the Centers for Therapeutic Innovation, and was also the leader of the clinical pharmacology and statistics groups within BioTherapeutics. At GSK, I was co-chair of the Peer Review Forum, which reviewed Phase I and II protocols across all therapeutic areas. I am an expert in psychopharmacology and have conducted or supervised clinical studies in a broad range of neurologic and psychiatric indications, including Alzheimer's disease (AD), Parkinson's disease (PD), Huntington's disease, pain (neuroinflammatory and neuropathic), Multiple Sclerosis, Friedreich's Ataxia, Tourette's syndrome, epilepsy, sleep disorders (including insomnia, narcolepsy, obstructive sleep apnea and idiopathic hypersomnia), tinnitus, major depression, bipolar disorder, anxiety disorders (in particular, social phobia and GAD), schizophrenia (both full spectrum antipsychotics and drugs targeted for cognitive impairment or negative symptoms in schizophrenia), and sexual dysfunction.

In recent years, I have focused on neurodegeneration, both AD and PD, as well rare neurologic disorders. At Takeda, I guided the clinical development of multiple treatments in neuroscience, including small molecules, antibodies, antisense oligomers and gene therapies and my group successfully completed 4 regional filings in Japan and China as well as 3 sNDAs in the US in two years.

I am currently the Chief Scientific Officer for the Alzheimer's Prevention Initiative (API), based at the Banner Alzheimer's Institute in Phoenix, Arizona, where my focus is on galvanizing API's efforts to conceive, fund and implement new cutting-edge programs; establish new collaborations in the pharmaceutical, biotechnology and contract research arenas; and serve as API's lead representative in regulatory interactions and as a clinical scientific expert in other internal and external academic collaborations.

Current:

Chief Scientific Officer, Alzheimer's Prevention Initiative, Banner Alzheimer's Institute, Phoenix, Arizona (January 2021 – Present)

Research Professor, Department of Psychiatry, University of Arizona College of Medicine – Phoenix (September 2021 – Present)

Member, FDA Peripheral and Central Nervous System Advisory Committee (December 2021 - 2026)

Consultant for CNS Drug Development (Jan 2021 - Present)

Prior:

Takeda Pharmaceuticals, Senior Distinguished Clinical Scientist, (July 2020- December 2020)

Leader of workgroup to repurpose drugs for the treatment of COVID-19 infection

Takeda Pharmaceuticals, Vice President and Head, Clinical Science, Neuroscience Therapeutic Area Unit (April 2017- June 2020)

- Leader of Neuroscience TAU clinical group, accountable for all Neuroscience studies, Phases 1-3
- Member of the Neuroscience TAU leadership team

Staff Psychiatrist, McLean Hospital, Belmont, Massachusetts (September 2017 – January 2021)

Pfizer, Cambridge, Massachusetts (May 2015 – April 2017)

Vice President and Head, Clinical Neuroscience and Pain Research Unit (May 2015 – April 2017)

- Leader of NPRU clinical
- Member of the NPRU leadership team

Chief Medical Officer, BioTherapeutics (BioTx) (July 2015 – October 2016)

- As CMO, ensured the protection of study subjects, the ethical conduct of all clinical trials and contribute to overall benefit-risk assessments and compliance for entire BioTx portfolio (included Rare Diease, Neuroscience, and CTI)
- Leader of clinical neuroscience, and the clinical pharmacology and statistics groups within BioTx

AstraZeneca, Cambridge, Massachusetts (April 2012 – April 2015)

Vice President, Neuroscience Innovative Medicines (iMed) Unit

- Leader of the iMed clinical group
- Member of the iMed leadership team and contributor to shaping the iMed strategy, portfolio, and operating model. The iMed took a "virtual" approach to neuroscience drug development.
- Co-Chair of Joint Development Committee (with Lilly) of AZD3293 in Alzheimer's Disease
- AstraZeneca representative to the Alzheimer's Research Roundtable and Coalition Against Major Diseases (CAMD) at the Critical Path Institute

AstraZeneca, Södertälje, Sweden and Wilmington, Delaware (October 2010 – March 2012)

Vice President, CNS and Pain Innovative Medicines (iMed) Unit

- Leader of a group of approximately 40 physicians and other scientists who were accountable for the design and delivery of early phase clinical programs (Phase I through IIB) within the iMed for both small and large molecule programs targeted for disease-modifying and symptomatic treatments of Alzheimer's Disease, pain, and psychiatric indications
- Member of iMed executive team

Consultant in CNS Drug Development (August 2010-October 2010)

- Consultant for Afraxis focused on the development of p21 activated kinase (PAK) inhibitors for the treatment of Fragile X as well as other CNS disorders
- Consultant for Otsuka

GlaxoSmithKline (Verona, Italy October 2006 –December 2009, King of Prussia, PA January 2010 to July 2010)

Vice President and Head, Discovery Medicine, and Chief Medical Officer Neurosciences Centre for Excellence in Drug Discovery (CEDD)

- Directed a large global department of physicians and other scientists and who were responsible for all clinical trials from first time in man through proof of concept for a large psychiatry and neurology portfolio (>£30 million/year in grant spending).
- Member of CEDD executive team and key participant in the development and implementation of
 the overall strategy, including decisions regarding candidate selection and progression, ensuring
 development plans support a "reimbursable file," and the review and approval of in-licensing
 opportunities.
- Guided unit that developed a number of translational clinical paradigms in neuropsychiatric disorders.
- Co-chair of the Peer Review Forum, which reviewed Phase I and II protocols across all therapeutic areas at GSK.

Acting Head, Mood and Anxiety Drug Performance Unit Neurosciences Centre for Excellence in Drug Discovery

- Leader of a 50 person group of biologists and chemists dedicated to the discovery of novel treatments for depression, anxiety and bipolar disorder.
- Developed a 3-year business plan for our current and future compounds for depression, anxiety and bipolar disorder.

Merck & Co., Inc. (July 1998 – September 2006) Blue Bell, Pennsylvania

Senior Director, Clinical Pharmacology and Clinical Neuroscience	2004 -2006
Director, Clinical Neuroscience	2001 - 2003
Associate Director, Clinical Neuroscience	1998 - 2000

- Directed the team conducting Phase III program and the preparing the gaboxadol NDA filing; previously led group which completed all required Phase I studies
- Led team that submitted successful sNDA for the registration of the losartan 100 mg and hydrochlorothiazide 12.5 mg fixed-dose combination tablet (HYZAAR)
- Project leader for Phase II novel anxiolytic and 3 different antipsychotics (including lurasidone) and design of Phase III plans; participant in Phase II-III substance P major depression program including End of Phase II meetings

Adjunct Associate Professor, Department of Psychiatry, University of Pennsylvania, Philadelphia, Pennsylvania (2003 – 2010)

July 1997 – June 1998 Belmont Center for Comprehensive Treatment Philadelphia, Pennsylvania Chief of the Addictions Service

September 1995 - June 1997 University of Pennsylvania Philadelphia, Pennsylvania Visiting Assistant Professor Department of Psychiatry Center for Studies of Addiction

July 1991 – August 1995

Thomas Jefferson University Hospital

Philadelphia, Pennsylvania

Associate Professor 1993-1995 Assistant Professor 1991-1993

Department of Psychiatry and Human Behavior

Jefferson Medical College

October 1990 – June 1991 Columbia University New York, New York Research Fellow

Department of Psychiatry

College of Physicians and Surgeons

July 1987 – September 1990 National Institute of Mental Health Washington, D.C.

Senior Staff Fellow 1989-1990 Medical Staff Fellow 1987-1989 Neuropsychiatry Branch

July 1985 – June 1988 Harvard Medical School Belmont, Massachusetts Resident in Adult Psychiatry McLean Hospital

July 1984 – June 1985 Harvard Medical School Boston, Massachusetts Intern in Internal Medicine New England Deaconess Hospital

Education:

July 1980 – June 1984 University of Chicago, Pritzker School of Medicine, Illinois

(M.D., 1984)

September 1976 – June 1980 University of Chicago, Illinois (A.B., 1980)

Professional Certification:

1998- 2008 Added Qualifications in Addictions, American Board of

Psychiatry and Neurology

1989 Diplomate, American Board of Psychiatry and Neurology

(31695)

1985 Diplomate, National Board of Medical Examiners (291661)

Other Professional Activities:

2019 - 2020 Industry Co-Chair, Critical Path for Parkinson's Consortium

2016 Member, Planning committee for *Multimodal Therapies for*

Nervous System Disorders workshop, sponsored by

National Academy of Sciences, Engineering and Medicine's Forum on Neuroscience and Nervous System Disorders

1991 Examiner, American Board of Psychiatry and Neurology

1989 - 1990 Guest Researcher, National Cancer Institute, Immunology

Branch, Bethesda, Maryland

1987 - 1998 Private Practice of Psychiatry

Military Service (United States Public Health Service):

1990 - Inactive Reserve

1989 - 1990 Senior Assistant Surgeon - Lieutenant (O-3)

Medical Licensure:

 2021 Arizona (64152)

 2016 Massachusetts (55341)

 1991 - 2016
 Pennsylvania (MD044532L)

Awards:

2020 Takeda R&D Applause Award

2019 Takeda R&D Talent Developer Award

2019 Critical Path for Alzheimer's Disease Data Sharing Pioneer

Award

2015 AstraZeneca CEO Award

2015 AstraZeneca iMed Science Award
2005 Merck Division/Staff Award
2004 Merck Division/Staff Award
2004 Merck Special Achievement Award
1999 Merck Special Achievement Award

1993 Junior Investigator Travel Award for World Congress on

Psychiatric Genetics

1980 National Institutes of Health Summer Research Award

1980 General Honors with Baccalaureate Degree

1977 Abram L. Harris Prize 1976 - 1980 National Merit Scholarship

Societies: American Academy of Neurology

American College of Neuropsychopharmacology American Psychiatric Association (Life Member)

Massachusetts Medical Society

Grant and Journal Reviewer: Alzheimer's Association 2020 Part the Cloud - Gates (PTC-

G) Review Committee

U.S. Department of Veterans Affairs Ontario Mental Health Foundation Michael J. Fox Foundation P2P Therapeutic Evaluation Committee

Biological Psychiatry
British Journal of Psychiatry
BJPsych Open
Clinical Microbiology Reviews
Clinical Pharmacology and Therapeutics
CNS Drugs
Journal of Clinical Psychopharmacology
Journal of Nervous and Mental Disease
Journal of Psychiatric Practice
Neuropsychopharmacology
Schizophrenia Bulletin

Grants:

Title: Alzheimer's Prevention Initiative ADAD Colombia Trial

Major Goals: This grant will permit the Alzheimer's Prevention Initiative (API) to complete the first funded prevention trial of an investigational anti-amyloid treatment in cognitively unimpaired individuals from the world's largest autosomal dominant Alzheimer's disease (AD) kindred, incorporate a new brain imaging tool for the assessment of neurofibrillary tangles, and provide an invaluable public resource of data and biological samples to advance the scientific fight against AD. The trial is intended to evaluate the ability of the investigational amyloid antibody therapy crenezumab to slow down the decline in memory and thinking performance associated with AD, do so in a way that might lead to regulatory agencies to approve the treatment, provide a better test of the amyloid hypothesis, clarify the treatment's effects on the best established biological measurements of AD, set the stage to rapidly evaluate the range of promising prevention therapies, and help find ones that work as soon as possible.

<u>Project Number</u>: 1R01AG055444-04 Name of PD/PI: Reiman/Tariot/Lopera

<u>Role</u>: Co-Investigator Source of Support: NIH/NIA

<u>Primary Place of Performance</u>: Banner Alzheimer's Institute <u>Project/Proposal Start and End Date</u>: 4/1/17-3/31/2023 Total Award Amount (including Indirect Costs): \$14,893,051

Title: API / A4 Alzheimer's Prevention Trial

<u>Major Goals</u>: The goals of this study are to evaluate a potentially license-enabling prevention trial of an amyloid plaque-clearing antibody therapy and, if the treatment works, find and support the accelerated approval of an AD prevention therapy by 2025.

<u>Project Number</u>: R01 AG058468 Name of PD/PI: Reiman, Eric

Role: Multi-PI

Source of Support: NIH/NIA

Primary Place of Performance: Banner Alzheimer's Institute

Project/Proposal Start and End Date: (MM/YYYY) (if available): 09/2018-11/2024

Total Award Amount (including Indirect Costs): \$32,005,950

Title: TRAILBLAZER-ALZ3

Major Goals: For this Clinical Trial Collaboration agreement, Lilly and Banner will collaborate

with respect to conduct of certain activities relating to the Study.

Name of PD/PI: Langbaum, Jessica (Operational Contact)

Source of Support: Eli Lilly and Company

Primary Place of Performance: Banner Alzheimer's Institute

Project/Proposal Start and End Date: (MM/YYYY): 07/2021-6/30/2027

Total Award Amount (including Indirect Costs): \$XXX

Title: Safety/Tolerability/Immunogenicity of first-in-human Aβ DNA vaccine, AV-1959D Phase 1 trials

in early-stage AD subjects: based on IND18953 cleared by FDA. Source of Support: NIH/NIA via The Institute for Molecular Medicine

Name of PD/PI: Agadjanyan, Michael

Role: Co-Investigator

Primary Place of Performance: Banner Alzheimer's Institute Project/Proposal Start and End Date: 08/2022-11/2027 Total Award Amount (including Indirect Costs): \$95,630

Title: Clinicopathological Correlates of Rapidly Progressive Alzheimer's Disease

Major Goals: The specific aim of this project is to investigate the prevalence, clinical profiles, and already characterized neuropathological assessments of rapidly progressive Alzheimer's Disease (AD) patients using data from the Brain Body Donation Program (BBDP) and the National Alzheimer's Coordination Center (NACC).

Name of PD/PI: Alexander, Robert C

Source of Support: Arizona DHS via Arizona Alzheimer's Consortium

Primary Place of Performance: Banner Alzheimer's Institute

Project/Proposal Start and End Date: (MM/YYYY) 07/2021-6/30/2022

Publications:

1. Eliot, M., Alexander, R. and Goodfriend, T.: Aspects of angiotensin action in the adrenal: Key roles of calcium and phosphatidyl inositol. Hypertension, Supplement II, Vol. 4(3): II-52-II-58, May-June, 1982.

- 2. Goldman, D., Alexander, R. and Luchins, D.: Monoamine oxidase inhibitors and tricyclic antidepressants: Comparison of their cardiovascular effects. Journal of Clinical Psychiatry, Vol. 47: 225-229, May, 1986.
- 3. Silvestri, R., Jensen, W., Zibrak, J., Alexander, R., and Rose, R.: Pulmonary infiltrates and hypoxemia in patients with acquired immunodeficiency syndrome re-exposed to trimethoprim-sulfamethoxazole. American Review of Respiratory Diseases, Vol. 136(4), 1003-1004, October, 1987.
- 4. Wyatt, J., Alexander, R., Egan, M., and Kirch, D.: Schizophrenia, just the facts: What do we know, how well do we know it? Schizophrenia Research, Vol. 1: 3-18, 1988.
- Alexander, R., Salomon, M., Ionescu-Pioggia, M. and Cole, J.: Convulsive therapy in the treatment of mania. Convulsive Therapy, Vol. 4 (2), 115-125, 1988.
- 6. Alexander, R. and Wyatt, R.: Messages from afar (letter). Journal of the American Medical Association, Vol. 260 (1), 33-34, 1988.
- 7. Lipinski, J. and Alexander, R.: Possible antidepressant/mania-inducing effects of methionine: a reappraisal of the effects of methionine in chronic psychosis using modern diagnostic criteria. Psychiatrie & Psychobiologie, Vol 4(3), 175-18,1989.
- 8. Alexander, R., Coggiano, M., Daniel, D. and Wyatt, R.: HLA antigens in schizophrenia. Psychiatry Research, Vol. 31, 221-233, 1990.

- 9. *Alexander, R.*, Coggiano, M. and Wyatt, R.: Failure to find interference between anti-HLA antibodies and chlorpromazine. <u>Biological Psychiatry</u>, Vol. 27, 642-648, 1990.
- 10. *Alexander, R.*: Fluoxetine treatment of trichotillomania (letter). <u>Journal of Clinical Psychiatry</u>, Vol. 52, 88, 1991.
- 11. LeGuern, C., Shafer, G., *Alexander, R.*, Germana, S., Gustaffson, K., El-Gamil, M. and Sachs, D.: Expression of swine class II genes using recombinant retroviral vectors. <u>Transplantation Proceedings</u>, Vol. 23, 427-428, 1991.
- 12. *Alexander*, *R.*, Illowsky, B., Khot, V. and Kirch, D.: A double-blind, placebo-controlled trial of demeclocycline treatment of polydipsia-hyponatremia in chronic psychotic patients. <u>Biological Psychiatry</u>, Vol. 30, 417-420, 1991.
- 13. Magin, G., Robison, S., Breslin, N., Wyatt, R. and *Alexander, R.*: DNA repair and mutant frequency in schizophrenia. <u>Mutation Research, DNA Repair</u>, Vol. 255, 241-246, 1991.
- 14. Coggiano, M., *Alexander, R.*, Kulaga, K. and Kirch, D.: The continued search for evidence of retroviral infection in schizophrenic subjects. <u>Schizophrenia Research</u>, Vol. 5, 243-247, 1991.
- 15. Berrettini, W., Detera-Wadleigh, S., Goldin, L., Martinez, M., Hsieh, W., Hoehe, M., Choi, H., Muniec, D., Ferraro, T., Guroff, J., Kazuba, D., Harris, N., Kron, E., Nurnberger, J., *Alexander, R.*, and Gershon, E.: Genomic screening for genes predisposing to bipolar disease. <u>Psychiatric Genetics</u>, Vol. 2, 191-208, 1991.
- 16. Kirch, D. and *Alexander, R*.: Viruses, autoimmunity and psychiatric illness. In: <u>American Psychiatric Press Review of Psychiatry, Volume 11</u>, (Stein, M. and Miller, A., Eds.), APA Press, Washington, D.C., pp 202-218, 1992.
- 17. Egan, M., Hyde, T., Albers, G., Elkashef, A., *Alexander, R.*, Reeve, A., Blum, A., Saenz, R. and Wyatt, R.: Treatment of tardive dyskinesia with vitamin E. <u>American Journal of Psychiatry</u>, Vol. 149, 773-777, 1992.
- 18. *Alexander, R.*, Spector, S., Casanova, M., Kleinman, J., Wyatt, R. and Kirch, D.: Search for cytomegalovirus in the post-mortem brains of schizophrenic patients using the polymerase chain reaction. <u>Archives of General Psychiatry</u>, Vol. 49, 47-53, 1992.
- 19. Kirch, D., *Alexander, R.*, Suddath, R., Papadopoulos, R., Kaufmann, C., Daniel, D., and Wyatt, R.: Blood-CSF barrier permeability and central nervous system immunoglobulin G in schizophrenia. Journal of Neural Transmission, Vol. 89, 219-232, 1992.
- 20. *Alexander, R.*, Breslin, N., Molnar, C., Richter, J., and Mukherjee, S.: Counter clockwise scalp hair whorl in schizophrenia. Biological Psychiatry, Vol. 32, 842-845, 1992.
- 21. *Alexander*, *R.*, Cabirac, G., Lowenkopf, T., Casanova, M., Kleinman, J., Wyatt, R. and Kirch, D.: Search for evidence of herpes simplex virus or varicella-zoster infection in post-mortem brain tissue from schizophrenic patients. Acta Psychiatrica Scandinavica, Vol. 86, 418-420, 1992.
- 22. *Alexander*, *R.*, Duda, J., Garth, D., Vogel, W., and Berrettini, W.: Morphine and cocaine preference in inbred mice. <u>Psychiatric Genetics</u>, Vol. 3, 33-38, 1993.
- 23. *Alexander, R.*, Lowenkopf, T., Certa, K., and Luchins, D.: Repetitive behaviors in schizophrenic patients admitted to an acute care unit: a replicative study. <u>Journal of Nervous and Mental Disease</u>, Vol. 181, 763-764, 1993.

- 24. Berrettini, W., Detera-Wadleigh, S., Goldin, L., Martinez, M., Hsieh, W., Hoehe, M., Choi, H., Muniec, D., Ferraro, T., Guroff, J., Kazuba, D., Harris, N., Kron, E., Nurnberger, J., *Alexander, R.*, and Gershon, E.: A systematic search for vulnerability genes in manic-depressive illness. In: Genetic Approaches to Mental Disorders, (Gershon, E.S. and Cloninger, C.R., Eds.) APA Press, Washington, D.C., 1994.
- 25. Berrettini, W., Ferraro, T., *Alexander, R.*, Buchberg, A. and Vogel, W.: Quantitative trait loci study of morphine preference in inbred mouse strains. <u>Nature Genetics</u>, Vol. 7, 54-58, 1994.
- 26. Berrettini, W., *Alexander, R.*, Ferraro, T. and Vogel, W.: A study of morphine preference in inbred mouse strains. Psychiatric Genetics, Vol. 4, 81-86, 1994.
- 27. *Alexander, R.*, Mukherjee, S., Richter, J., and Kaufmann, C.: Minor physical anomalies in schizophrenia. Journal of Nervous and Mental Disease, Vol. 182, 639-644, 1994.
- 28. Gladis, M. and *Alexander, R.*: Statistics and Research Design. In: <u>The Behavioral Sciences in Psychiatry</u>, (Wiener, J.M. and Breslin, N.A., Eds.) Williams and Wilkins, Malvern, PA, pp 107-118, 1995.
- 29. *Alexander, R.*, Heydt, D., Ferraro, T., Vogel, W., and Berrettini, W.: Further evidence for a quantitative trait locus on murine chromosome 10 controlling morphine preference in inbred mice. <u>Psychiatric Genetics</u>, Vol. 6, 29-32, 1996.
- 30. *Alexander, R.*, Wright, R., and Freed, W.: Quantitative trait loci contributing to phencyclidine- and amphetamine-induced locomotor behavior in inbred mice. <u>Neuropsychopharmacology</u>, Vol. 15(5), 484-490, 1996.
- 31. Patkar, A., *Alexander, R*: Parotid enlargement associated with clozapine (letter). <u>Journal of Clinical</u> Psychiatry, Vol. 57, 488, 1996.
- 32. Patkar, A., Peng, A., and *Alexander, R.*: Neurosyphilis occurring in a patient with schizophrenia: a cautionary tale. Journal of Nervous and Mental Disease, Vol. 185, 119-120, 1997.
- 33. Richt, J.A., *Alexander, R.*, Hooper, D.C., Kean, R., Spitsin, S., Bechter, K., Schuettler, H., Feldmann, H., Hoiska, A., Fu, Z.F., Dietzschold, B., Rott, R., and Koprowski, H.: Failure to detect Borna disease virus infection in peripheral blood leucocytes from humans with psychiatric disorders. <u>Journal of Neurovirology</u>, Vol. 3, 174-178, 1997.
- 34. *Alexander*, *R.*, Patkar, A., Lapointe, J., Flynn, S., Honer, W.: Schizencephaly associated with psychosis. <u>Journal of Neurology</u>, <u>Neurosurgery</u>, and <u>Psychiatry</u>, Vol. 63, 373-375, 1997.
- 35. Patkar, A., *Alexander, R.*, Lundy, A. and Certa, K.: Changing patterns of illicit substance use among schizophrenic patients: 1984-1996. <u>American Journal on Addictions</u>, Vol. 8, 65-71, 1999.
- 36. Shimada, H., *Alexander, R.*, Germana, S., Sachs, D.H., and LeGuern, C.: Recombinant retrovirus vectors for the expression of MHC class II heterodimers. <u>Surgery Today</u>, Vol. 29(6), 533-41, 1999.
- 37. Boyle, J., Danjou, P., *Alexander, R.*, Calder, N., Brown, K., Gargano, C., Agrawal, N., Fu, I., McCrea, J., Ahmed, T., Cerchio, K., Murphy, M.G. Night-time effects of gaboxadol, a selective extrasynaptic GABA-A agonist, on postural sway and critical flicker fusion in elderly subjects. British Journal of Clinical Pharmacology, Vol. 67(2), 180-190, 2009.

- 38. Domenici, E., Willé, D., Tozzi, F., Prokopenko, I., Miller, S., McKeown, A., Brittain, C., Rujescu, D., Turck, C., Holsboer, F., Middleton, L., Merlo-Pich, E., *Alexander, R.*, Muglia, P.: Plasma protein biomarkers for depression and schizophrenia by multi analyte profiling of case-control collections. PLoS One, Vol. 5(2), e9166, 2010.
- 39. Merlo-Pich, E., *Alexander, R.*, Fava, M., Gomeni, R.: Re-engineering placebo controlled clinical trials for novel antidepressant discovery using prior information and signal pre-processing. <u>Journal of Clinical Pharmacology and Therapeutics</u> Vol. 88(5), 634–642, 2010.
- 40. Merlo-Pich, E., *Alexander, R.*, Fava, M., Gomeni, R.: Response to "Clinical Trials of Antidepressants: 'Enrichment Strategies'" and "The Placebo Response Is Part of Good Medicine" (letter) <u>Clinical Pharmacology & Therapeutics</u> Vol. 89, 486-487, 2011.
- 41. Bettica, P.; Nucci, G.; Pyke, C.; Squassante, L.; Zamuner, S.; Ratti, E.; Gomeni, R.; *Alexander, R.*: Phase I studies on the safety, tolerability, pharmacokinetics and pharmacodynamics of SB-649868—A novel dual orexin receptor antagonist. .Journal of Psychopharmacology Vol. 37(5), 1224–1233, 2012.
- 42. Learned, S., Graff, O., Roychowdhury, S., Moate, R., Morrison, D., Lavergne, A., Krishnan, R., Archer, G., Modell, J., *Alexander, R.*, Ratti, E.: Efficacy, safety, and tolerability of a triple reuptake inhibitor GSK372475 in the treatment of patients with Major Depressive Disorder: Two randomized, placebo and active controlled clinical trials. <u>Journal of Psychopharmacology</u> Vol. 26(5), 653-62, 2012.
- 43. Rivkin, A., *Alexander, R.*, Hutson, P., Wang, J., Snavely, D., Rosahl, T., Adler, L., Reimherr, F., Watt, A.: A randomized, double-blind, crossover comparison of MK-0929 and placebo in the treatment of adults with Attention Deficit Hyperactivity Disorder. <u>Journal of Attention Disorders</u> Vol. 16, No. 8, 664-674, 2012.
- 44. Murthy, V., Mahnke, H., Wexler, B., Maruff, P., Inamdar, A., Zuchetto, M., Lund, J., Shabbir, S., Shergill, S., Keshavan, M., Kapur, S., Laruelle, M., *Alexander, R.*: Computerised cognitive remediation training for schizophrenia: A single-arm, open label, multi-site, multinational feasibility study. Schizophrenia Research Vol. 139, Issue 1-3, 87-91, 2012.
- 45. Streffer, J., Fitzer-Attas, C., Grachev, I., Gomezmancilla, B., Reum, T., Willmer, T., Ostrowitzki, S., Fontoura, P., Victor, S., Bronzova, J., *Alexander, R.*: What do we need to launch neuroprevention trials in Parkinson's Disease. <u>Movement Disorders</u> Vol. 27, No. 5, 2012.
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- 47. Michelson, D., Hargreaves, R., *Alexander, R.*; Ceesay, P., Hietala, J., Lines, C.; Reines, S.: Lack of efficacy of L-759274, a novel neurokinin (substance P) receptor antagonist, for the treatment of generalized anxiety disorder. <u>International Journal of Neuropsychopharmacology</u>, Vol. 16(1), 1-11, 2013.
- 48. Ratti, E., Bettica, P., *Alexander, R.*, Evoniuk, G., Archer, G., Gomeni, R., Millns, H., Rabiner, I., Trist, D., Trower, M., Zamuner, S., Krishnan, R., Fava, M.: Full central NK1 receptor blockade is required for efficacy in depression: Evidence from orvepitant clinical studies. <u>Journal of Psychopharmacology</u>, Vol. 27, No. 5, 424-434, 2013.
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- antagonism and serotonin reuptake inhibition: effects on emotional processing in humans. <u>Journal of Psychopharmacology</u>, Vol. 27, No. 5: 435-443, 2013.
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Selected Presentations at Scientific Meeting:

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- 2. *Alexander, R.*, Coggiano, M. and Wyatt, R.: Anti-HLA antibodies and chlorpromazine. 142nd Annual Meeting of the American Psychiatric Association, San Francisco, California, 1989.
- 3. *Alexander, R.*, Spector, S., Casanova, M., Kleinman, J., Wyatt, R.: Search for cytomegalovirus in the post-mortem brains of schizophrenic patients using the polymerase chain reaction. Fifth Biennial Winter Workshop on Schizophrenia, Badgastein, Austria, 1990.
- 4. Glovinsky, D., *Alexander, R.*, Kulaga, H., Adams, T., Wyatt, R. and Kirch, D.: Gene amplification and viruses. 143rd Annual Meeting of the American Psychiatric Association, New York, New York, 1990.
- 5. Glovinsky, D., Kulaga, H., *Alexander, R.*, Adams, T., Coggiano, M., Truckenmiller, M., Murray, R., Wyatt, R. and Kirch, D.: Gene amplification of endogenous retrovirus-like sequences from brain tissue of multiple sclerosis patients and controls. Annual Meeting of the Federation of American Societies of Experimental Biology, Atlanta, Georgia, 1991.
- 6. Egan, M., Hyde, T., Albers, G., Elkashef, A., *Alexander, R.* and Wyatt, R.: Treatment of tardive dyskinesia with vitamin E. 144th Annual Meeting of the American Psychiatric Association, New Orleans, Louisiana, 1991.
- 7. *Alexander, R.*, Kirch, D., Papadopoulos, N., Suddath, R., Kaufmann, C., and Wyatt, R.: Blood-brain barrier permeability in schizophrenia. 144th Annual Meeting of the American Psychiatric Association, New Orleans, Louisiana, 1991.
- 8. *Alexander, R.*, Magin, G., Robison, S., Wyatt, R.: DNA repair and mutant frequency in schizophrenia. Sixth Biennial Winter Workshop on Schizophrenia, Badgastein, Austria, 1992.

- 9. Berrettini, W., Detera-Wadleigh, S., Goldin, L., Ferraro, T., Martinez, M., Hsieh, W., Hoehe, M., Nurnberger, J., *Alexander, R.*, and Gershon, E.: Linkage studies of bipolar illness. 46th Annual Meeting of the Society of Biological Psychiatry, Washington, D.C., 1992.
- 10. *Alexander, R.*, Reddy, R., and Mukherjee, S.: Minor physical anomalies in schizophrenia. 46th Annual Meeting of the Society of Biological Psychiatry, Washington, D.C., 1992.
- 11. Hideaki, S., *Alexander, R.*, Emery, D., Fraser, C., Bozza, M., Sachs, D., and LeGuern, C.: Cell surface expression of swine SLA-DQ class II heterodimers through retroviral mediated gene transfer. Transplantation Society Annual Meeting, Paris, France, 1992.
- 12. Kirch, D. and *Alexander, R*.: Viruses, autoimmunity and psychiatric illness. 145th Annual Meeting of the American Psychiatric Association, Washington, D.C., 1992.
- 13. *Alexander, R.*, Vogel, W., and Berrettini, W.: Morphine and cocaine preference in inbred mice. 1992 Annual Meeting of the American College of Neuropsychopharmacology, San Juan, Puerto Rico, 1992.
- 14. *Alexander, R.*, Breslin, N., Molnar, C., and Mukherjee, S.: Hair whorl patterning in schizophrenia. 4th International Congress on Schizophrenia Research, Colorado Springs, Colorado, 1993.
- 15. *Alexander, R.:* Evidence for a viral etiology of schizophrenia. 146th Annual Meeting of the American Psychiatric Association, San Francisco, California, 1993.
- 16. *Alexander, R.*, Ferraro, T., Vogel, W., Buchberg, A., and Berrettini, W.: A mouse model for studying genetic factors involved in morphine preference. Third World Congress on Psychiatric Genetics, New Orleans, Louisiana, 1993.
- 17. *Alexander, R.*, Ferraro, T., Vogel, W., Buchberg, A., and Berrettini, W.: A mouse model for studying genetic factors involved in morphine preference. 23rd Annual Meeting of the Society for Neuroscience, Washington, D.C., 1993.
- 18. *Alexander*, *R.*, Giordano, M., Wright, R. and Freed, W.: Genetics of PCP-induced behavior in inbred mice. Seventh Biennial Winter Workshop on Schizophrenia, Les Diablerets, Switzerland, 1994.
- 19. Giordano, M., Wright, R., *Alexander, R.*, and Freed, W.: Effects of PCP- and amphetamine-induced locomotor activity in recombinant inbred strains of mice. Third Meeting of the International Behavioral Neuroscience Society, Clearwater, Florida, 1994.
- 20. Berrettini, W., *Alexander, R.*, Ferraro, T., and Vogel, W.: A study of morphine preference in inbred mouse strains. 48th Annual Meeting of the Society of Biological Psychiatry, Philadelphia, Pennsylvania, 1994.
- 21. Donovan, M., *Alexander, R.*, Certa, K. and Park, C.: Blood-brain barrier permeability in schizophrenia. 147th Annual Meeting of the American Psychiatric Association, Philadelphia, Pennsylvania, 1994.
- 22. Berrettini, W., *Alexander, R.*, Ferraro, T., and Vogel, W.: A study of morphine preference in inbred mouse strains. Canadian College of Neuropsychopharmacology, Quebec, Canada, 1994.
- 23. Berrettini, W., Ferraro, T., *Alexander, R.*, Buchberg, A. and Vogel, W.: Quantitative trait loci study of morphine preference in inbred mouse strains. 19th Collegium Internationale Neuro-Psychopharmacologicum, Washington, D.C., 1994.

- 24. Goldstein, H. and *Alexander, R.*: Quantitative measurement of SPEM in schizophrenia using the search coil technique. 24th Annual Meeting of the Society for Neuroscience, Miami, Florida, 1994.
- 25. *Alexander, R.*, Wright, R., and Freed, W.: Genetics of PCP-induced behavior in inbred mice. Annual Meeting of the American College of Neuropsychopharmacology, San Juan, Puerto Rico, 1994.
- 26. *Alexander, R.*, Wright, R., and Freed, W.: QTL analysis of amphetamine- and phencyclidine-induced behavior in mice. Fourth World Congress on Psychiatric Genetics, Cardiff, United Kingdom, 1995.
- 27. *Alexander, R.*: Quantitative trait loci studies in psychiatry. International Convention of Biological Psychiatry, Bombay, India, 1996.
- 28. *Alexander*, R.: Clinical usage of risperidone. International Convention of Biological Psychiatry, Bombay, India, 1996.
- 29. Lipska, B., *Alexander, R.*, Ellenbroek, B., and McClearn, G.: Nature versus nurture in animal models of complex traits. 29th Winter Conference on Brain Research, Snowmass Village, Colorado, 1996.
- 30. Goldstein, H. and *Alexander, R*.: Horizontal and vertical pursuit maintenance in schizophrenia and normal subjects. ARVO Meeting, Ft. Lauderdale, Florida, 1996.
- 31. Berrettini, W., Vuoristo, J., Ferraro, T., Ala-Kokko, L., *Alexander, R.*, Hoehe, M., Buchberg, A., Vogel, W. and Prockop, D.: Genetic study of a murine model for opioid addiction. 50th Annual Meeting of the Society of Biological Psychiatry, New York, New York, 1996.
- 32. Patkar, A., *Alexander, R.*, Certa, K., and Boardman, C.: Trends and patterns of substance use among schizophrenic patients: a ten-year study of emergency room visits. 149th Annual Meeting of the American Psychiatric Association, New York, New York, 1996.
- 33. *Alexander, R.*, Wright, R., and Freed, W.: QTL analysis of phencyclidine-induced behavior in mice. Second Biennial Workshop in Mouse Molecular Neurogenetics, Bar Harbor, Maine, 1996.
- 34. Patkar, A., *Alexander, R.*, Lundy, A. and Certa, K.: Cocaine use and negative symptoms among schizophrenic patients. Regional Meeting of the World Psychiatric Association, Jaipur, India, 1998.
- 35. Kramer, M., *Alexander, R.*, Ball, W., Shedden, A., and Reines, S.: The therapeutic potential of substance p (NK-1 receptor) antagonists (SPA). Second International Congress on Hormones, Brain, and Neuropsychopharmacology, Rhodes, Greece, July, 2000
- 36. Danjou, D., *Alexander, R.*, Calder, N., Brown, K., Gargano, C., Agrawal, N., Fu, I., Cerchio, K., Murphy, M.G. and Hindmarch, I.: Gaboxadol, a selective extrasynaptic GABA agonist (SEGA): Safety and pharmacokinetics in elderly subjects with bedtime dosing. 20th Annual Meeting of American Professional Sleep Society, Salt Lake City, Utah, 2006.
- 37. Ramakrishnan, R., Cerchio, K., Talaty, J., Danjou, P., Gargano, C., Lasseter, K., Murphy, M.G. *Alexander, R.* Gaboxadol does not affect the single dose pharmacokinetics of the R(+) and S(-) enantiomers of warfarin and the pharmacodynamics of warfarin. 20th Annual Meeting of American Professional Sleep Society, Salt Lake City, Utah, 2006.
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- 40. Romach, M., Schoedel, K., Rosen, L., *Alexander, R.*, Wang, J., Snavely, D., Murphy, M.G., Chodakewitz, J., and Sellers, E. Adverse effects of gaboxadol and zolpidem at high doses In recreational drug users. 47th Annual Meeting of the American College of Neuropsychopharmacology, Scottsdale, Arizona, 2008.
- 41. Schoedel, K., Rosen, L.B., *Alexander, R.C.*, Wang, J., Snavely, D.B., Murphy, M.G., Mengel, H., Romach, M., and Sellers, E. A single-dose randomized, double-blind, crossover abuse liability study to evaluate the subjective and objective effects of gaboxadol and zolpidem in recreational drug users. American Society for Clinical Pharmacology and Therapeutics, Washington, DC, 2009.
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- 43. Ziviani, L., Piubello, G., Beltrami, P., Madeo, B., Scardigli, B., Vecchio, D., Zattoni, F., Granata, A., Guidi, A., Bettica, P., *Alexander, R.*, Lund, J., Milleri, S.: Messa a punto di un modello sperimentale per valutare il tempo di eiaculazione durante la masturbazione in soggetti maschi con eiaculazione precoce. XXV Congresso Nazionale della Società Italiana Di Andrologia, Catania, Sardinia, 2009.
- 44. Carpenter, D., Fong, R., Graff, O., Learned, S., Moate, R., Kraus, J., *Alexander, R.*: A comparison of SSRI treatment effects in MDD based on three different clinician-administered depression rating. 50th Annual Meeting of NCDEU, Boca Raton, Florida, 2010.
- 45. Ali, Z., Giménez, M., Pujol, J., López-Solà M., Contreras-Rodríguez, O., Stylianou, A., Tate, S., *Alexander, R.*, Ortiz, H., Soriano-Mas, C., Monfort, J.: A placebo controlled functional magnetic resonance (fMRI) study in subjects with osteoarthritis (OA) pain of the knee to evaluate effects of naproxen on bold in responses to painful pressure stimulation. International Pain Summit of International Association for the Study of Pain, Montreal, Canada, 2010.
- 46. *Alexander, R.*: Building commercial risk models in CNS. CNS Leaders Forum, Boston, Massachusetts, 2011.
- 47. *Alexander, R.*: Discovering and developing transformative medicines to treat nervous system diseases and pain. ILSI-Biomed, Tel Aviv, Israel, 2011.
- 48. Inamdar, A., Zucchetto, M., Gilleen, J., Maruff, P., Wexler, B., Shabbir, S., Lund, J., Shergill, S., Laruelle, M., *Alexander, R.*, Murthy, N.V.: Cognitive remediation training effects are not influenced by IQ in patients with schizophrenia. British Association of Pharmacology Summer Meeting, Harrowgate, UK, 2012.
- 49. Jucaite, A., Cselényi, Z., Varrone, A., Varnäs, K., Johnström, P., Halldin, C., Salter, H., McLoughlin, M., Rinne, J., Svenningsson, P., *Alexander, R.*, Kugler, A., Farde, L.: Translocator protein (TSPO) as a biomarker of microglia activation: PET imaging using [11C]PBR28 in Parkinson's disease. Psychoneuroimmunology Society Meeting, Stockholm, 2013

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- 51. Hannesdottir, K., Minkwitz, M., Raudibaugh, K., Vis, P., Ackaert, O., *Alexander, R.*: A phase 2 safety and tolerability study to investigate the effect of AZD5213 on sleep in subjects with Mild Cognitive Impairment and mild Alzheimer's disease. Alzheimer's Association International Conference, Boston, Massachusetts, 2013.
- 52. *Alexander, R.*: Increasing clinical trial efficiency in early CNS drug development. 1st Annual MGH CTNI Europe Meeting on CNS Drug Development, Cortina d'Ampezzo, Italy, 2013.
- 53. Johnsen, K., Brynne, N., Annas, P., Hannesdottir, K., *Alexander, R.*, Segerdahl, M.: Pharmacologic reversal of AZD1446 and Donepezil after scopolamine injections to healthy volunteers. Quantitative measurements using a qEEG cholinergic index. Clinical Trials on Alzheimer's Disease (CTAD), San Diego, 2013.
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- 57. Williams, J., Randolph, R., Eureyecko, E., Hannesdottir, K., Langbaum, J., Tariot, P., Farlow, M., Galvin, J., Langlois, C., Hunt, C., Olsson, T., Poole, M., Weber, C., Boehm, P., Cohen, E., Garzio, L., *Alexander, R.*: Telephone administration of the CDR excellent agreement with face-to-face. Alzheimer's Association International Conference, Copenhagen, Denmark, 2014.
- 58. Höglund, K., Salter, H., Zetterberg, H., Andreason, U., Olsson, T., *Alexander, R.*, Kugler, A., Cebers G., Ye, N., Burdette, D., Budd Haeberlein, SL. Monitoring the soluble Amyloid Precursor Protein alpha (sAPPα) and beta (sAPPβ) fragments in plasma and CSF from healthy individuals treated with BACE inhibitor AZD3293 in a Multiple Ascending Dose study pharmacokinetic and pharmacodynamic correlations. Alzheimer's Association International Conference, Copenhagen, Denmark, 2014.
- 59. Mather, J., Burdette, D., Cebers, G., Posener, J., Leventer, S., Ye, N., Johnston, T., Brotchie, J., *Alexander, R.*, Poole, M., Dunlop, J.: Utility of a novel nicotinic agonist for treating levodopa-induced dyskinesia. Nicotinic Acetylcholine Receptors Churchill College, Cambridge, UK, 2014.
- 60. Ackaert, O., van Steeg, T., Hannesdotir, K., *Alexander, R.*, Raudibaugh, K., Burdette, D., Vis, P.: Quantification of the effect of AZD5213 on sleep in subjects with Alzheimer's disease or mild cognitive impairment using a two state Markov model. Population Approach Group Europe (PAGE), Alicante, Spain, 2014.

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- 62. *Alexander*, *R.*, Budd Haeberlein, S., Rosen, L., Russell, M., Kugler, A., Cebers, G., Ye, N., Olsson, T., Han, D., Ereshefsky, L.: AZD3293 A novel BACE1 inhibitor: pharmacokinetics and effects on plasma and CSF Aβ peptides following multiple dose administration in Alzheimer's Disease patients. Clinical Trials in Alzheimer's Disease (CTAD), Philadelphia, Pennsylvania, 2014.
- 63. Williams, J., Randolph, R., Eureyecko, E., Hannesdottir, K., Langbaum, J., Tariot, P., Farlow, M., Galvin, J., Langlois, C., Hunt, C., Olsson, T., Poole, M., Weber, C., Boehm, P., Cohen, E., Garzio, L., *Alexander, R.*: Telephone administration of the CDR excellent agreement with face-to-face. 53rd Annual Meeting of the American College of Neuropsychopharmacology, Phoenix, Arizona, 2014.
- 64. Olsson, T., *Alexander, R.*, Hannesdottir, K., Andrews, T., Curry, L., Middleton, L., Kieburtz, K., Olanow, C., Williams, J., Kamp, C., Levy, B., Daly, J., Rolston, D., Dulin, M., McWilliams, A., Dorsey, E.: Use of a telephone interview methodology to identify subjects with cognitive impairment among those reporting subjective memory complaints. International Conference on Alzheimer's and Parkinson's Diseases, Nice, France, March 2015.
- 65. Alexander, R., Rosen, L., Russell, M., Kugler, A., Cebers, G., Ye, N., Olsson, T., Han, D., Ereshefsky, L.: AZD3293 A novel BACE1 inhibitor: Pharmacokinetics and effects on plasma and CSF Aβ peptides following multiple-dose administration in Alzheimer's Disease patients. International Conference on Alzheimer's and Parkinson's Diseases, Nice, France, March 2015.
- 66. Kugler, A., Stieber, M., *Alexander, R.* Mirkin, I., Weidolf, L., Elmore, C., Campbell, A., Hosagrahara, V., Whifield, L., Olsson, T., Cebers, G., Posener, J.: AZD3293 a novel BACE1 inhibitor: Clinical, pharmacokinetics and mass balance after oral administration of [14C]-AZD3293. American Association of Pharmaceutical Science meeting, Orlando, Florida, 2015.
- 67. Azuma, F., Sakamoto, K., Uchida, N., Russell, M., *Alexander, R.*, Kugler, A.: Pharmacokinetics and Effects on Plasma and Cerebrospinal Fluid Aβ Peptides Following Administration of AZD3293, a Novel BACE1 Inhibitor, in Japanese Adult Healthy Subjects. Annual Meeting of Japan Society for Dementia Research, Aomori, Japan, 2015.
- 68. Crema MD, Roemer FW, Li L, Rosen LB, Dudley A, Alexander, RC, Guermazi A.: Comparison between semiquantitative and quantitative methods for the assessment of knee synovitis using non-enhanced and gadolinium-enhanced MRI. ACR/AHRP Annual Meeting, San Francisco, 2015.
- 69. Yoshihara, T., Sakamoto, K., Matsuki, S., Matsuguma, K., Uchida, N., Azuma, F., Russell, M., Hughes, G., Budd Haeberlein, S., *Alexander, R.*, Kugler, A.: Assessment of the safety, tolerability, pharmacokinetics and effects on plasma and cerebrospinal fluid Aβ peptides of AZD3293, a novel BACE1 inhibitor, in healthy Japanese adults. Alzheimer's Association International Conference, Toronto, Canada, 2016.
- 70. Qiu, R., Liu, R., Wills, A., He, P., Leurent, C., Hajos-Korcsok, E., Mendes da Costa, L., *Alexander, R.*: PF-06648671 A novel gamma secretase modulator: safety, tolerability, pharmacokinetics and effects on plasma amyloid-β levels following single oral ascending dosing in healthy volunteers. Alzheimer's Association International Conference, Toronto, Canada, 2016.
- 71. Leurent, C., Goodman, J., Pickering, E., He, P., Duvvuri, S., Martucci, E., Kellogg, S., Purcell, D., Barakos, J., Kupiec, J., *Alexander, R.*: Low prevalence of amyloid positivity in healthy elderly

- participants of a methodology study evaluation remote tablet-based cognitive learning. Alzheimer's Association International Conference, Toronto, Canada, 2016.
- 72. Cebers, G., Lejeune, T., Attalla, B., Soderberg, M., *Alexander, R.*, Budd Haeberlein, S., Kugler, A., Ingersoll, E.; Platz, S., Scott, C.: Reversible and species-specific depigmentation effects of AZD3293, a BACE inhibitor for the treatment of Alzheimer's disease, are related to BACE2 inhibition and confined to epidermis and hair. Kloster Seeon BACE meeting, Bavaria, Germany, 2016.
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