Curriculum Vitae
W. David Hardy, M.D.

PERSONAL HISTORY:

Office Address: 6123 Maryland Drive
Los Angeles, California 90048
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E-mail: wdavidhardymd@gmail.com
Place of Birth: Dallas, Texas
Citizenship: United States of America
Partner: Barry Goldblatt

EDUCATION & TRAINING:

1974-1977	University of Texas at Austin, Texas; (Zoology/Classics) *Summa Cum Laude*
1977-1981	Baylor College of Medicine, Houston, Texas; Doctor of Medicine with Honors
1981-1982	Internship in Internal Medicine, Department of Medicine, Baylor College of Medicine Affiliated Hospitals, Houston, Texas
1982-1984	Residency in Internal Medicine, Department of Medicine, Harbor-UCLA Medical Center, Torrance, California
1984-1986	Clinical Fellowship in Infectious Diseases and Clinical Immunology (Mentors-Michael S. Gottlieb, MD/Lowell Young, MD), Department of Medicine, University of California - Los Angeles School of Medicine, Los Angeles, CA
1984-1986	Clinical Research Fellowship (Mentor-Michael S. Gottlieb, MD), UCLA AIDS Center, Department of Medicine, University of California – Los Angeles School of Medicine, Los Angeles, California
1998-2002	Laboratory Research Fellowship, Laboratory of Irvin S. Y. Chen, Ph.D., Department of Microbiology, Immunology and Molecular Genetics, David Geffen School of Medicine, UCLA, Los Angeles, CA

LICENSURE:

State of Texas: #F-9536, (inactive)
State of California: #C-40623, (active)
District of Columbia: #MD043801, (active)

BOARD CERTIFICATION:

1984	Diplomat, Internal Medicine, American Board of Internal Medicine
2015	Diplomat, Infectious Diseases, American Board of Internal Medicine

PROFESSIONAL EXPERIENCE:

1984-1986	Staff Physician, Department of Medicine, UCLA School of Medicine, Los Angeles, California

1986	Visiting Assistant Professor, Division of Clinical Immunology/Allergy, Department of Medicine, University of California-Los Angeles School of Medicine, Los Angeles, California
1986-1987	Assistant Clinical Professor of Medicine, Division of Infectious Diseases, Department of Medicine, University of California-San Diego School of Medicine, San Diego, California (Full-time Faculty)
1986-1987	Co-Investigator, NIH/NIAID-sponsored AIDS Clinical Trials Unit (ACTU), University of California-San Diego School of Medicine, San Diego, California
1986-1987	Staff Physician, Owen Clinic (HIV Outpatient Clinical Services), University of California-San Diego School of Medicine, San Diego, California
1987-1993	Assistant Clinical Professor of Medicine, Division of Infectious Diseases, Department of Medicine, University of California-Los Angeles School of Medicine, Los Angeles, California (Full-time Faculty)
1987-1996	Director, Infectious Diseases/Immunology (HIV/AIDS) Clinic, Department of Medicine, UCLA Medical Center, Los Angeles, California
1987-1996	Co-Investigator, NIH/NIAID-sponsored AIDS Clinical Trials Unit (ACTU), University of California-Los Angeles School of Medicine, Los Angeles, California
1988-2010	President and Cofounder, Los Angeles Physicians AIDS Forum (LAPAF), UCLA Center for AIDS Research and Education (CARE; 1988-1996), Independent HIV/AIDS-focused Continuing Medical Education (CME) Provider, Los Angeles, California
1990-1996	Co-Principal Investigator, NIH/NEI-sponsored Studies of the Ocular Complications of AIDS (SOCA), Department of Ophthalmology, University of California-Los Angeles School of Medicine, Los Angeles, California
1993-1996	Associate Clinical Professor of Medicine, Division of Infectious Diseases, Department of Medicine, University of California, Los Angeles, School of Medicine, Los Angeles, California (Accelerated Promotion on Full-time Faculty)
1993-1996	Principal Investigator, NIH/NIAID-sponsored, Multidisciplinary HIV/AIDS Training Grant (T32AI07388), UCLA AIDS Institute, University of California-Los Angeles School of Medicine, Los Angeles, California
1994-1996	Associate Director for Community Liaison, UCLA AIDS Institute, University of California-Los Angeles School of Medicine, Los Angeles, California
1994-1996	Program Director, Infectious Diseases Fellowship Training Program, Division of Infectious Diseases, Department of Medicine, University of California-Los Angeles School of Medicine, Los Angeles, California
1996-2002	Clinical Associate Professor of Medicine, Department of Medicine, University of California-Los Angeles School of Medicine, Los Angeles, California (Volunteer Teaching Faculty)

1996-2002 Scientific Director of Research, Research Department, Pacific Oaks Medical Group, Beverly Hills, California

1996-2002 Private Practice Specializing in Infectious Diseases and HIV Medicine, Pacific Oaks Medical Group, Beverly Hills, California

1998-2002 Post-doctoral Research Fellow, Laboratory of Irvin S. Y. Chen, Ph.D., Department of Microbiology, Immunology and Molecular Genetics, David Geffen School of Medicine, UCLA, Los Angeles, CA. [funded by NIH/NIAID-sponsored, Multidisciplinary HIV/AIDS Training Grant (T32AI07388) UCLA AIDS Institute]

2002-2009 Principal Investigator, NIH/NIAID - K08 AI-49759-01A2, *"Developing Foamy Virus Vectors for HIV-1 Vaccine Applications"*, Cedars-Sinai Medical Center, Los Angeles, California (5-year grant with 2, 1-year no-cost extensions)

2002-2013 Director, Division of Infectious Diseases, Department of Medicine, Cedars-Sinai Medical Center, Los Angeles, California

2002-2012 Associate Professor of Medicine-in-Residence, Division of Infectious Diseases, Department of Medicine, David Geffen School of Medicine, University of California-Los Angeles, Los Angeles, California

2002-2013 Associate Program Director, Cedars-Sinai-UCLA Multi-campus Infectious Diseases Fellowship Training Program (Cedars-Sinai Medical Center, Olive View-UCLA Medical Center, Greater Los Angeles VA Medical Center), Los Angeles, California

2003-2012 Co-Principal Investigator, NIH/ NIAID-funded U01, "*Solid Organ Transplantation in HIV: Multi-site Study*", Departments of Medicine and Surgery, Cedars-Sinai Medical Center, Los Angeles, California

2007-2012 Co-Investigator, NIH/NIMH-funded R01, "*HIV, Aging and Cognition: A Synergism?*", Department of Psychiatry and Behavioral Medicine, Cedars-Sinai Medical Center, Los Angeles, California

2008-2011 Associate Program Director, NIH/NCRR-sponsored General Clinical Research Center (GCRC), Cedars-Sinai Medical Center, Los Angeles, California

2011-2013 Associate Program Director, NIH/NCATS-sponsored Clinical and Translational Research Center (CTRC), UCLA CTSI, Cedars-Sinai Medical Center site, Los Angeles, California

2012-2013 Clinical Professor of Medicine, Department of Medicine, David Geffen School of Medicine, University of California-Los Angeles, Los Angeles, California

2013-2014 U.S. Medical Officer, State of California Institute of Regenerative Medicine (CIRM)-funded/private (Calimmune) collaborative phase I studies of gene-modified CD4+ T cells and CD34+ hematopoietic stem/progenitor cells to cure HIV infection

2014-2015 Chief Medical Officer, State of California Institute of Regenerative Medicine (CIRM)-funded/private (Calimmune) collaborative phase I studies of gene-modified CD4+ T cells and CD34+ hematopoietic stem/progenitor cells to cure HIV infection

2015-2018 Senior Director of Evidence-based Practices (Research), Whitman-Walker Health; Clinical Research Site (CRS) Leader, AIDS Clinical Trials Group (ACTG); Co- Investigator, Multicenter AIDS Cohort Study (MACS), Investigator and Executive Committee, District of Columbia Center for AIDS Research (CFAR); Investigator and Steering Committee, Martin Delaney HIV Cure Collaboratory, Washington DC

2015-2020 Adjunct Professor of Medicine, Division of Infectious Diseases, Department of Medicine, School of Medicine, Johns Hopkins University, Baltimore, MD

2016-2018 Clinical Professor of Medicine, Division of Infectious Diseases, Department of Medicine, School of Medicine and Health Sciences, George Washington University, Washington, DC

2018-2022 Scientific and Medical Consultant/Acting CMO, Enochian Biosciences, Los Angeles, CA

2019-present Member, FDA Antimicrobial Drugs Advisory Committee (AMDAC)

2020-2022 Co-Principal Investigator, Coronavirus Prevention Network (CoVPN), Clinical and Translational Research Center (CTRC), Charles Drew University of Medicine and Science, Los Angeles, CA

2021-present Adjunct Clinical Professor of Medicine, Division of Infectious Diseases, Keck School of Medicine of University of Southern California (USC), Los Angeles, CA

PROFESSIONAL ACTIVITIES:

Quality Improvement Committees:

2002-2013 Co-Chairman, Pulmonary-Infectious Diseases Performance Improvement Committee, Department of Medicine, Cedars-Sinai Medical Center, Los Angeles, California

2002-2013 Member, Department of Medicine Performance Improvement Committee, Cedars-Sinai Medical Center, Los Angeles, California

2002-2013 Member, Antibiotic Utilization Review Committee, Pharmacy Department, Cedars-Sinai Medical Center, Los Angeles, California

2008-2013 Member, Hospital-acquired Infection Task Force, Cedars-Sinai Medical Center, Los Angeles, California; Hand Hygiene Working Group; Antibiotic Stewardship

Academic Service Committees

2005-2013 Member, Institutional Biosafety Committee (IBC), Burns Research Institute, Cedars-Sinai Medical Center, Los Angeles, California

2006-2012 Member, Committee on Academic Appointments and Promotions, Department of Medicine, David Geffen School of Medicine, UCLA, Los Angeles, California

2007-2013 Member, Scientific Advisory Committee, General Clinical Research Center, Burns Research Institute, Cedars-Sinai Medical Center, Los Angeles, California

2007-2013 Member, Physician Well-Being Committee, Medical Staff Office Cedars-Sinai Medical Center, Los Angeles, California

2009-2013 Member, Graduate Medical Education Committee, Academic Affairs, Cedars-Sinai Medical Center, Los Angeles, California

2010-2013 Member, Institutional Review Board (IRB), Burns Research Institute, Cedars-Sinai Medical Center, Los Angeles, California

Scientific Committees

1988-1993 NIH/NIAID-AIDS Clinical Trials Group (ACTG) Opportunistic Infection Committee and Protozoan Pathogen Study Group

1990-1996 NIH/NEI-Steering Committee for Studies of the Ocular Complications of AIDS (SOCA)

1992-2010 Co-Chairman, 2nd, 3rd, 4th, 5th, 6th, 7th, 8th, 9th, 10th ,11th, 12th, 13th, 14th, 17th, 19th and 20th National HIV Clinical Care Options (CCO) for HIV CME Conference

1993-1996 NIH/NIAID-ACTG Opportunistic Infection Committee – Viral Pathogen Study Group

1993-1996 NIH/NIAID-ACTG Primary Infection, Phase II/III Clinical Trials Working Group

1992, 1994, Scientific Organizing Committee, 1st, 2nd, 5th and 6th International Congress

2000, 2002 on Drug Therapy in HIV Infection, Glasgow, Scotland

2007 American Academy of HIV Medicine (AAHIVM)/American Heart Association (AHA) Joint Committee on Cardiovascular Complications in HIV-infected Patients, AAHIVM, Washington, DC (prevention strategies for cardiovascular diseases in HIV-infected patients writing subcommittee)

2010-2013 Centers for Disease Control and Prevention (CDC) Prevention with Positives (PwP) Review Committee and Consultant, CDC, Atlanta,Georgia

2016-2018 Performance Evaluation Committee (PEC), AIDS Clinical Trials Group (ACTG)

2016-2020 Investigator Member-at-Large, Viral Reservoirs and Eradication (Cure) Transformative Science Group (TSG), AIDS Clinical Trials Group (ACTG)

2017-2024 Co-chair, ACTG 5370 (Phase 1/2a Study of Safety and Immunoactivity of Anti-PD-1 Antibody (cemiplimab) in Virologically-suppressed HIV+ Persons)

Community Organizations

1990-1996 Medical Advisory Board (Chairman), Los Angeles Gay and Lesbian

Community Services Center, Los Angeles, California

1990-1996 Board of Directors, AIDS Project - Los Angeles (APLA), Los Angeles, California – Chairman, Public Policy Committee (1991-1992)

1990-2000 Scientific Advisory Committee, Search Alliance (Community-based clinical research organization), Los Angeles, California

1991-1994 Board of Directors, Southwest Community-based AIDS Trials Group [NIH-sponsored Community Program for Clinical Research on AIDS (CPCRA)], Los Angeles, California

1996-present Ambassadors Council, AIDS Project – Los Angeles (APLA), Los Angeles, California

1996-2007 Medical Advisory Committee, AIDS Healthcare Foundation (AHF; HIV healthcare providing organization), Los Angeles, California

2000-2006 Board of Directors, Project Angel Food (home delivery of meals to person with AIDS and other life-threatening illnesses), Los Angeles, California

2008-2015 Board of Directors, Aid for AIDS (housing, financial assistance and food for persons and families with AIDS), Los Angeles, California

2012-2015 Board of Directors, AIDS Research Alliance (community-based, HIV Cure and clinical research organization), Los Angeles, California

2013-2015 Chairman, Board of Directors, AIDS Research Alliance (community- based, HIV Cure and clinical research organization), Los Angeles, California

2020-present Board of Directors, Foundation for the AIDS Monument, (community-based Remembrance, Celebration and Education of AIDS Pandemic), West Hollywood, California

PROFESSIONAL ASSOCIATIONS

1984-present American College of Physicians (ACP), Member

1985-present American Society for Microbiology (ASM)

1985-present Infectious Diseases Society of America (IDSA)

1988-present International AIDS Society (IAS)

1988-2010 Los Angeles Physicians AIDS Forum (President and Co-founder)

1989-present International Society for Antiviral Research

2001-present HIV Medicine Association (HIVMA) – Research Awards Committee (2010-2014); Board of Directors, Infectious Disease Representative (2011-2014),

Board of Directors (2016-2020), Vice-chair (2016-2017), Chair-Elect (2017-2018), Chair (2018-2019), Immediate-Past-Chair (2019-2020)

2000-present American Academy of HIV Medicine (AAHIVM)

2005-2008 Chairman, Board of Directors, California Chapter of the AAHIVM

2005-present National Board of Directors, AAHIVM – Chairman, Education Committee (2008-2022) – Treasurer (2022-present) and Member, Executive Committee (2008-present)

HONORS AND SPECIAL AWARDS

1993	Commitment to Service Award from Los Angeles Shanti Foundation (provider of emotional and psychological support for persons with HIV/AIDS; $30,000 Research Award)
2007	Spirit of Hope Award from Being Alive – Empowering People with HIV/AIDS (Community-based HIV/AIDS Service Organization)
2010	Clinical Trial Exceptional Service Award from the Pharmaceutical Researchers and Manufactures Association (PhRMA)
2011	Alliance Humanitarian Award from Alliance for Housing & Healing (Aid for AIDS/Serra Project – provides house and direct financial grants to persons and families with HIV)
2012	Research Achievement Award; AIDS Research Alliance, World AIDS Day Concert Ceremony, Los Angeles, California

RESEARCH GRANTS

<u>Previous Research Support as Senior Director of Research Department, Whitman-Walker Health (2015-2018)</u>

2014/04/01 – 2019/03/31
U01 AI035042 Margolick (PI) 2.4 calendar
NIH/NIAID $1,869,107
Subcontract: Hardy (site PI)
Multicenter AIDS Cohort Study: Natural History Study of HIV-1 in Gay and Bisexual Men
The MACS is an ongoing prospective study of the natural and treated histories of HIV-1 infection in homosexual and bisexual men.

2015/12/01 – 2018/11/30
3U01 AI069503-03S2 Greenberg (PI) 0.84 calendar
NIH/NIAID, $161,565
Subcontract: Hardy (site PI)
Development of a Citywide Cohort of HIV-infected Persons in Care in the District of Columbia: The DC Cohort
This project will establish a city-wide cohort that will describe clinical outcomes, and improve the quality of care for outpatients with HIV/AIDS in Washington, DC.

2017/06/01-2018/31/08
5P30AI117970-03 Greenberg (PI)
NIH/NIAID $12,000 0.6 calendar
Subcontract Hardy (PI)
DC CFAR Executive Leadership Board

2013/10/12-2020/11/30 UM1 AI069465-10 Flexner (PI) NIH/NIAID Subcontract: Hardy (PI)	$2,047,780	2.4 calendar

Johns Hopkins Baltimore-Washington-India Clinical Trials Unit (BWI CTU)
The goals of this project are to support AIDS research through support of clinical studies. The studies of the AIDS Clinical Trials Group (ACTG) are supported through this grant.
Role: CRS Leader

2016/07/01-2021/06/30
1UM1AI12661701 Nixon (PI)
NIH/NIAID $291,076 1.44 calendar
Subcontract: Hardy (site PI)
BELIEVE: Bench-to-Bed Enhanced Lymphocyte Infusions to Engineer Viral Eradication
BELIEVE is a new Martin Delaney HIV Cure Collaboratory seeking to create and translate new technologies aimed at curing HIV infection.

2017/07/01-2022/06/30
R01DA043089 Celentano (PI)
NIH/NIDA $429,521 0.6 calendar
Subcontract: Hardy (site PI)
Identifying and Engaging Urban HIV-infected and -uninfected Young Black and Latino Men Who Have Sex with Men (YBLMSM) in Care.
This 3-city proposal seeks to address disparities of HIV in YBLMSM in a multilevel intervention to identify, link retain and engage, high-risk uninfected and HIV infected urban YBLMSM in prevention and treatment cascade.

2017/12/01-2022/11/30
UG3AI133669 Wirtz/Reisner (co-PIs)
NIH/NIAID/NIMH/NICHD $140,000 0.42 calendar
Subcontract: Hardy (site PI)
American Cohort to Study HIV Acquisition among Transgender Women at High Risk (LITE Cohort)
The American Cohort study proposes to establish multi-site, longitudinal cohort of transgender women in the eastern and southern U.S. (Boston, New York City, Baltimore-Washington, Atlanta, and Miami) to characterize risk factors for HIV acquisition, access to biobehavioral HIV prevention methods, and linkage to care for those who HIV seroconvert.

<u>Previous Research Support as Associate Professor/Professor of Medicine, UCLA School of Medicine and Director, Division of Infectious Diseases, Cedars-Sinai Medical Center (2002-2013)</u>

<u>NIH and Foundation Support</u>

NIH NCATS CTSI – UL1RR033176 (PI-Melmed)
Clinical and Translational Research Institute (CTSI) at UCLA
Clinical and Translational Research Institute (CTSI) is funded by the NIH NCRR to provide an infrastructure to investigators to facilitate their clinical and translational research, in a primarily outpatient and community-based settings and with access to core lab facilities.
Role: Assistant Program Director – .4 calendar
Cost: $72,000 (in annual salary support)
Duration: 3/01/2011-2/29/16

Cedars-Sinai Medical Center Finance Department and Intellectual Property Department
East Meets West: In-Vitro Study of Herbal Medicines against Resistant Bacteria
This project analyzes the antibacterial activity of herbal extracts in in vitro experiments alone as well as in combination with synthetic antibiotics against multidrug-resistant(MDR) bacteria. The goal of this research is to identify a specific molecularcompound conferring antibacterial properties.
Role: Principal Investigator – 0.12 calendar
Cost: $391,158
Duration: 10/1/2009-9/30/2013

NIH/NIAID - K08 AI-49759-01A2 (PI-Hardy)
Number: PA-00-003
Developing Foamy Virus Vectors for HIV-1 Vaccine Applications
The goals of the study are to develop and optimize recombinant HIV-1/Foamy virus vectors. KO8 Mentored Clinical Scientist Development Award.
Role: Principal Investigator; 75% Effort Total
Direct Costs: $515,000
Duration: 08/01/02 – 04/30/09 (no cost extensions)

NIH/NIAID - 1 U01 AI052748-01A1 (PI-Stock)
Solid Organ Transplantation in HIV; Multi-Site Study
The primary aim of this study is to evaluate the safety and efficacy of solid organ transplantation in people with HIV disease by conducting a prospective, multi-center cohort study of HIV-positive (+) patients who undergo kidney or liver transplantation.
Role: Site Co-PI - .012 calendar
Annual Direct Cost: $120,000
Duration: 08/15/03 – 01/31/10; 2/1/2010 – 7/31/2013

NIH/NIMH – 5R01MH058532-10 (PI-Goodkin)
HIV, Aging and Cognition: A Synergism?
The goal of this project is to determine if age interacts with HIV infection to result in a higher prevalence and more rapid progression of cognitive-motor impairment, decreases in functional status, decreases in CD4+ cell count, increases in viral load, progression of CDC stage, and decreased survival time.
Role: Co-investigator – 0.12 calendar
Annual Direct Cost: $436,665
Duration: 01/26/2007 – 11/30/2008; 12/1/2008 – 12/31/2012

NIH/NCRR – M01-RR00425 (PI-Melmed)
General Clinical Research Center
General Clinical Research Center is funded by the NIH NCRR to provide an infrastructure to investigators to facilitate their clinical research, in a primarily outpatient setting and with access to core lab facilities.
Role: Assistant Program Director - .4 calendar

Cost: $72,000 (in salary support)
Duration: 11/30/2008 – 12/01/2011

UCLA AIDS Institute/Pendelton Trust Seed Grant
Foamy Virus Vectors for Gene Therapy and Vaccine Studies
The purpose of this study is to optimize foamy virus vectors for future use as HIV vaccine and potential gene therapy applications.
Role: Principal Investigator
Cost: $50,000
Duration: 05/01/2004 – 04/30/2006

International Antiviral Therapy Evaluation Consortium (IATEC)
05-IAT-0110
A Randomized, Controlled, Open-label, 48-week Study to Assess Differences in Changes in Plasma Lipid Profile Between Patients on Saquinavir/Ritonavir or Atazanavir/Ritonavir in Combination with Tenofovir Disoproxil Fumarate and Emtricitabine as a First-line Regimen
The purpose of this study is to compare several outcomes to two different once-daily protease inhibitor PI-based + Truvada® anti-HIV treatment medication regimens.
Role: Principal Investigator - .012 calendar
Cost: $46,067
Duration: 10/01/2006 – 09/30/2009

Industry-sponsored Research

Gilead Sciences
Protocol # GS-US-236-0102
A Phase3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of Elvitegravir/Emtricitabine/Tenofovir Disoproxil Fumarate/GS-9350 vs (Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate in HIV-1 Infected, Antiretroviral Treatment-Naïve Adults
The primary objective of this study is to evaluate the safety and efficacy of a regimen containing the quadruple agent co-formulated single tablet of elvitegravir/emtricitabine/tenofovir disoproxil fumarate/cobicistat vs triple agent co-ormulated single tablet of efavirenz/emtricitabine/tenofovir disoproxil fumarate in HIV-1 infected, antiretroviral treatment-naïve adult subjects.
Role: Principal Investigator
Cost: $167,400
Duration: 2/1/2010 – 12/31/2013

GSK/ViiV Healthcare
GSK-113086/SPRING2
A Phase III Randomized, Double-blind Study of the Safety and Efficacy of GSK1349572 50 mg Once Daily vs Raltegravir 400 mg Twice Daily Both Administered with Fixed-dose Dual Nucleoside Reverse Transcriptase Inhibitor Therapy Over 96 Weeks in HIV-1 Infected Antiretroviral Therapy-naïve Adult Subjects

The goal of this study is to compare a new investigational integrase inhibitor drug dolutegravir (GSK 1349572) dosed at 50 mg once daily vs raltegravir 400mg twice daily, currently the only FDA-approved integrase inhibitor and thus the current standard-of-care, both with either abacavir/lamivudine or tenofovir DF/emtricitabine, in treatment-naïve, HIV-1-infected subjects.
Role: Principal Investigator
Cost: $57,425
Duration: 11/1/2010 – 10/31/2013

GSK/ViiV Healthcare
GSK-111761/SAILING

A Phase III Randomized, Double-blind Study of the Safety and Efficacy of GSK 1349572 50 mg Once Daily vs Raltegravir 400 mg Twice Daily, both Administered with an Investigator-selected Background Regimen Over 48 Weeks in HIV-1 Infected, Integrase Inhibitor-Naïve, Antiretroviral Therapy-Experienced Adults

The goal of this study is to compare the antiviral efficacy of the new investigational integrase inhibitor dolutegravir (GSK 1349572) dosed at 50 mg once daily compared to raltegravir 400 mg twice daily both in combination with a background regimen consisting of one to two fully active agents in HIV-1-infected, integrase inhibitor naïve, therapy-experienced subjects.
Role: Principal Investigator
Cost: $50,888
Duration: 12/6/2010 – 12/5/2013

Gilead Sciences
GS-US-264-0110

A Phase 3, Randomized, Open-label Study to Evaluate the Safety and Efficacy of a Single Tablet Regimen of Emtricitabine / Rilpivirine / Tenofovir Disoproxil Fumarate Compared with a Single Tablet Regimen of Efavirenz / Emtricitabine / Tenofovir Disoproxil Fumarate in HIV-1 Infected, Antiretroviral Treatment-naïve Adults

The primary objective of this study is to evaluate the efficacy of a single tablet regimen of emtricitabine/rilpivirine/tenofovir disoproxil fumarate (FTC/RPV/TDF) compared with a single tablet regimen of efavirenz/emtricitabine/tenofovir disoproxil fumarate (EFV/FTC/TDF) in HIV-1 infected, antiretroviral treatment-naïve adult subjects.
Role Principal Investigator
Cost: $118,675
Duration: 3/1/2012 – 3/1/2014

Pfizer/ViiV
A4001095

A Multicenter, Randomized, Double Blind, Comparative Trial of Maraviroc + Darunavir/Ritonavir versus Emtricitabine/Tenofovir + Darunavir/Ritonavir for Treatment of Antiretorviral-Naive HIV-infected Patients With CCR5 Tropic HIV-1

The study aims to examine whether or not a once-daily dosing of the new combination of maraviroc (Selzentry®) with darunavir (Prezista®) and ritonavir (Norvir®) will be as safe and effective as another once-daily combination routinely used containing darunavir,

ritonavir, and Truvada® (a combination of entricitabine and tenofovir). Maraviroc belongs to a relatively new class of drugs called CCR5 inhibitors which block HIV from entering a target cell.
Role: Principal Investigator
Cost: $96,000
Duration: 12/1/2011 – 11/3/2013

Vertex
VX11-950-115
An Open-Label, Phase 3 Study of Telaprevir in Combination With Peginterferon Alfa-2a (Pegasys®) and Ribavirin (Copegus®) in Subjects Coinfected With Genotype 1 Hepatitis C Virus and Human Immunodeficiency Virus Type 1(HCV/HIV-1)
The proposed study (Vx 11-950-115) is a phase III clinical study to confirm the effectiveness of the new protease inhibitor, telaprevir in HCV treatment in HIV co- infected patients. This study will enroll individuals infected with HIV and HCV genotype 1 who have or have not received prior anti-HCV drug treatment.
Role: Principal Investigator
Cost: $120,000
Duration: 3/1/2012 – 2/28/2014

Gilead
GS-US-334-0123
*A Phase 3, Open-label Study to Investigate the Efficacy and Safety of GS-7977 (sofosbuvir) plus Ribavirin for 12 Weeks in Chronic Genotype 1, 2 and 3 Hepatitis C Virus (*HCV) and Human Immunodeficiency Virus (HIV) Co-Infected Subjects*
This is a phase III clinical study to investigate the effectiveness and safety of a new HCV drug, GS-7977 plus Ribavirin for 12 weeks or 24 weeks for HCV treatment in HIV-HCV co-infected patients.
Role: Principal Investigator
Cost: $130,000
Duration: 9/1/2012 – 8/31/2014

Gilead Sciences
GS-US-236-0103
A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of Elvitegravir/Emtricitabine/Tenofovir Disoproxil Fumarate/cobicistat vs. Ritonavir-boosted Atazanavir Plus Emitricitabine/Tenofovir Disoproxil Fumarate in HIV-1 Infected, Antiretroviral Treatment-Naïve Adults
The primary objective of this study is to evaluate the safety and efficacy of a regimen containing the quadruple agent co-formulated single tablet of elvitegravir/emtricitabine/tenofovir disoproxil fumarate/cobicistat vs ritonavir-boosted atazanavir plus emitricitabine/tenofovir disoproxil fumarate in HIV-1 infected, antiretroviral treatment-naïve adult subjects.
Role: Principal Investigator
Cost: $20,125
Duration: 2/1/2010 – 1/31/2013

Bionor Immuno AS (Norwegian biotech company)
CSR202258; Proj ID #217810

Protocol CT-BI Vacc-4x2007/1: A Phase II, Randomized, Double-Blind, Multicenter, Immunogenicity Study of Vacc-4x versus Placebo in Patients Infected with HIV-1 Who Have Maintained an Adequate Response to ART

The primary purpose of this study is to evaluate the effect of Vacc-4x immunization versus placebo on CD4+ cell counts, T-cell function and T-cell proliferation, response to treatment interruption of antiretroviral therapy and the proportion of subjects restarting treatment within 24 weeks after stopping ART.

Role: Principal Investigator
Cost: $108,328
Duration: 05/19/2008 – 04/18/2012

Merck – CSRI #200387
V520-022

A phase II, multi-center, double-blind, randomized, placebo- controlled probe study with an additional open-label control arm to evaluate the safety and immunogenicity of a 3-dose regimen of the MRKAd5 HIV-1 gag Vaccine in subject with chronic hepatitis C virus infection

Role: Principal Investigator - .06 calendar
Cost: $15,750
Duration: 05/014/04 – 9/30/2005

Boehringer Ingelheim
1182.12

Phase III, Open-label, Randomized, Parallel Group Pharmacokinetics Trial of Tipranavir (TPV/RTV), Alone or in Combination with Saquinavir (SQV), Amprenavir (APV) or Lopinavir (LPV), Plus an Optimized Background Regimen, in Multiple Antiretroviral (ARV) Experienced Patients

Role: Principal Investigator
Cost: $51,110
Duration: 6/14/2004 – 1/31/2007

Boehringer Ingelheim
1182.17

Clinical Trial 1182.17 - A Long-term Open-label Rollover Trial Assessing the Safety and Tolerability of Combination Tipranavir and Ritonavir use in HIV-1Infected Subjects

Role: Principal Investigator
Cost: $13,814
Duration: 9/01/2004 – 8/31/2008

Pfizer
1029

A Multi-center, Randomized, Double-blind, Placebo-controlled Trial of a Novel CCR5 Antagonist, UK-427,857, in Combination with Optimized Background Therapy versus

Optimized Background Therapy Alone for the Treatment of Antiretroviral- Experienced, non-CCR5-tropic HIV-1 Infected Subjects
The purpose of this study is to determine wheter the new study drug, UK-427, 857 has effective anti-HIV activity in treatment-experienced patients with few remaining treatment options, who have either mixed tropic (both CCR5 and CXCR4) and non CCR- 5 tropic HIV.
Role: Principal Investigator - .06 calendar
Cost: $12,500
Duration: 01/01/2005 – 12/31/06

GlaxoSmithKline
GRZ107460
A Phase 2a, Multicenter, Randomized, Parallel, Double-Blind, Dose Ranging, Placebo-Controlled Study to Compare Antiviral Effect, Safety, Tolerability and Pharmacokinetics of GSK364735 Monotherapy Versus Placebo Over 10 days in HIV-1 Infected Adults
This study is to evaluate GSK364735 (an integrase inhibitor) for the treatment of HIV infection. Integrase inhibitors are a new class of anti-HIV medications. For HIV to reproduce, its genetic make-up must be spliced into the genetic make-up of the human T-cell (a type of immune cell attacked by HIV). This study is the first of its kind being done in HIV + persons to see if this investigational drug is safe and effective.
Role: Principal Investigator - .06 calendar
Cost: $26,559
Duration: 12/15/06 – 12/15/2007

Pfizer
A4001050
A multi-center, open label, expanded access trial of Maraviroc
This is an expanded access protocol for Pfizer's investigational anti-HIV medication, maraviroc which makes the drug available to persons needing new treatment options for their HIV infection. Maraviroc is currently in Phase III clinical trials as a new anti-HIV treatment for HIV infection. The study will make maraviroc available for free to HIV+ persons needing treatment and collecting safety and efficacy data.
Role: Principal Investigator - .06 calendar
Cost: $17,580
Duration: 02/01/2007 – 01/30/2008

Tibotec Pharmaceuticals - CSRI #201138
A Randomized, Controlled, Open-label Trial to Make TMC114/RTV Available to HIV+ Patients with Limited Treatment Options
The purpose of this study is to look at the long term safety, tolerabiity, and effectiveness of TMC114 combined with a low dose of Ritonavir (RTV) compared to Kaletra (the current gold-standard protease inhibitor for HIV treatment) when used in subjects with HIV infection.
Role: Principal Investigator - 1% effort
Cost: $25,350

Duration: 11/11/05 – 12/11/07; 12/12/2007 – 06/11/2008

Pfizer
1026

A Multi-center, Randomized, Double-blind, Comparative Trial of a Novel CCR5 Antagonist, UK-427,857, in Combination with Zidovudine/Lamivudine versus Efavirenz in Combination with Zidovudine / Lamivudine for the Treatment of Antiretroviral-naïve HIV-1 Infected Subjects

The purpose of this study is to determine the anti-HIV effectiveness of the new anti-HIV drug, UK 427, 857 in combination with other anti-HIV medications against HIV infection in HIV+ patients who have never taken HIV medications and whose HIV is CCR5 tropic (i.e., selects the cell surface marker CCR5 to gain entry into an uninfected cell).
Role: Principal Investigator - .06 calendar
Cost: $43,483
Duration: 01/01/2005 – 12/31/07; 01/01/2008 – 09/10/2010

Pfizer, Inc.
A400-1078

Phase IIb, Pilot Study of Novel Combination of Maraviroc + Atazanavir/Ritonavir vs Atazanavir/Ritonavir + Tenofovir/Emtricitabine for the Treatment of Naïve HIV-Infected Patients with R5 HIV-1

Role: Principal Investigator
Cost: $32,290
Duration: 4/3/2009 – 4/02/2012

Pfizer
1027

A Multi-center, Randomized, Double-blind, Placebo-controlled Trial of a Novel CCR5 Antagonist, Maraviroc, in Combination with Optimized Background Therapy Versus Optimized Background Therapy Alone for the Treatment of Antiretroviral-experienced HIV-1 Infected Subjects

The purpose of this study is to determine the effectiveness of the new anti-HIV drug Maraviroc in combination with other anti-HIV medications against HIV infection in treatment-experienced patients whose HIV is CCR5 tropic).
Role: Principal Investigator - .012 calendar
Cost: $142,901
Duration: 01/01/2005 – 12/31/07; 1/01/2008 – 12/31/2010

INVITED LECTURES (beginning March, 2002)

1. Grand Rounds, Division of Pulmonary/Critical Care Medicine, Department of Medicine, Cedars-Sinai Medical Center, "Update on HIV Research", Cedars-Sinai Medical Center, Los Angeles, CA, August 27, 2002

2. Grand Rounds, Division of Pulmonary/Critical Care Medicine, Department of Medicine, Cedars-Sinai Medical Center, "Update from the XVth World AIDS Conference" Cedars-Sinai Medical Center, Los Angeles, CA, August 18, 2004

3. Second Annual Tough Decisions Made Easier: Clinical Management of Treatment-experienced HIV + Patients, UCLA Center for AIDS Research & Education (CARE), UCLA-Bradley International Hall, Los Angeles, CA, October 22, 2004

4. Grand Rounds, Division of Infectious Diseases, Department of Medicine, Feinberg School of Medicine, Northwestern University "Management of Neurologic Complications in the HAART Era", Chicago, Illinois, October 27, 2004

5. Post ICAAC/Glasgow Conferences Review: "Update on Antiretrovirals Therapy", AIDS Clinical Research Initiative of America (ACRIA), Plaza Hotel, New York, NY, December 2, 2004

6. Los Angeles Gay & Lesbian Center Visiting Faculty Program: "HIV Protease Inhibitor Update", Los Angeles, CA, March 4, 2005

7. Department of Medicine House staff Noon Conference: "Methicillin-resistant Staphylococcus aureus", Department of Graduate Medical Education, Cedars-Sinai Medical Center, Los Angeles, CA, March 28, 2005

8. Grand Rounds, Divisions of Infectious Diseases, Department of Medicine, and Department of Pediatrics, University of Texas at Dallas School of Medicine "Treatment of HIV Infection: New Strategies, New Agents", Dallas, TX, April 8 and 9, 2005.
(two separate lectures; one emphasizing treatment for adult patients, one for pediatric patients)

9. Grand Rounds, Division of Maternal-Child Health, Department of Pediatrics, Keck School of Medicine, University of Southern California (USC), "Update of HIV Antiretroviral Therapy with Emphasis on Prevention of Mother-to-Child Transmission of HIV", USC School of Medicine/LAC-USC Medical Center, Los Angeles, CA, April 26, 2005

10. Grand Rounds, Department of Psychiatry and Behavioral Sciences, Cedars-Sinai Medical Center, "Update on HIV Treatment and Drug-Drug Interactions", Los Angeles, CA, April 28, 2005

11. Grand Rounds, Genitourinary and HIV Medicine Department, Royal Free Hospital," HIV Treatment Guidelines: An American Perspective", London, UK, August 25, 2005

12. Grand Rounds, Department of Medicine, Royal Free Hospital, "Novel Approach to HIV Vaccine Development", UK, August 29, 2005

13. European AIDS Clinical Society (EACS) Advanced Course on HIV, " "HIV Vaccine Development", Montpelier University, Montpelier, France, August 26-27, 2005

14. Grand Rounds, Department of Medicine, Cedars-Sinai Medical Center "HIV/AIDS: The Global and National Pandemic", Los Angeles, CA, September 16, 2005

15. Grand Rounds, Division of Infectious Diseases, Department of Pediatrics, Keck School of Medicine, University School of Medicine, "HIV as a Chronic Disease and Associated Complications ", Children's Hospital, Los Angeles, CA, October 25, 2005

16. Grand Rounds, Division of Pulmonary/Critical Care Medicine, Department of Medicine, Cedars-Sinai Medical Center, "Progress in HIV Research", Cedars-Sinai Medical Center, Los Angeles, CA, October 26, 2005

17. Didactic Lecture: "HIV Treatment Guidelines", ID Combined Conference, GLAVAMC, Los Angeles, CA, February 14, 2006

18. Los Angeles Physicians AIDS Forum: "Post 13th Conference on Retrovirus & Opportunistic Infections Update", March 7, 2006, Le Meridian Hotel, Los Angeles, CA

19. ID Combined Conference: "Post 13th Conference on Retrovirus & Opportunistic Infections Update", WVAHCS, Los Angeles, CA, March 7, 2006

20. "HIV Treatment: Recent Progress", Physicians from the California Men's Colony at San Luis Obispo, CA, May 30, 2006

21. Invited Lecture for Symposium on Advances in HIV Therapy, "HIV Tropism: Biology of Both Viral and Human Determinants and Therapeutic Applications", Paulista Congress of Infectology, Sao Paulo, Brazil, August 25, 2006

22. Los Angeles Physicians AIDS Forum: "Update from 2006 International AIDS Conference, Hyatt Regency Century Plaza, Los Angeles, CA, September 9, 2006

23. ICAAC Satellite Symposium: Consult with the HIV Experts: "Optimizing HIV Therapy for Treatment-experienced Patients, Moscone Center, San Francisco, CA, September 29, 2006

24. IDSA Satellite Symposium: Emerging Therapies in the Blockade of HIV Binding: "Early Inhibitors: Clinical Progress Thus Far", Sheraton Centre Toronto Hotel, Ontario, Canada, October 11, 2006

25. Continuing Medical Education Program: "Initiating HIV Therapy", Ecotrust Conference Center, Portland, OR, October 24, 2006

26. Infectious Diseases Noon Conference: "New Therapies for HIV Infection", El Rio Community Health Center, Tucson, AZ, February 2, 2007

27. Grand Rounds, Division of Infectious Diseases, Department of Pediatrics, Keck School of Medicine, University of Southern California,, "Long Term Safety & Efficacy of Tenofovir-

based Regimens Compared to Thymidine-analog Containing Regimens", Children's Hospital Los Angeles, CA, March 27, 2007.

28. Annual Investigators' Meeting of the NIH-sponsored Multi-Site Solid Organ Transplantation Study in HIV+ Patients, "Novel Therapies for HIV Infection: Use in Solid Organ Transplant Patients", Washington, DC, April 29, 2007

29. Grand Rounds, Division of Infectious Diseases, Department of Medicine, Harbor-UCLA Medical Center, "New Classes of Antiretrovirals: The Potential Clinical Role of Integrase Inhibitors and Entry Inhibitors", Torrance, CA, July 17, 2007

30. CME Dinner Program: "Current Perspectives on HIV-associated Metabolic and Morphologic Abnormalities", Boston, MA, August 17, 2007

31. National Minority AIDS Council (NMAC) Annual Conference, Seminar: Special Issues in HIV Care: "New Therapies and Treatments", Palm Springs, CA, November 8, 2007

32. HIV Grand Rounds, Howard Brown Health Center, "A New Class, A New Option: Understanding CCR5 Antagonists and Maraviroc", Chicago, IL, January 10, 2008

33. Grand Rounds, Department of Medicine, City of Hope Medical Center, "Strategies for Treatment-Naïve Patients with HIV Infection: When and What to Start?, Duarte, CA, February 19, 2008

34. Grand Rounds, Division of Pediatric Infectious Diseases, University of Nevada School of Medicine, "Optimizing Antiretroviral Therapy for the Treatment-Experienced Patient: A Case-based Approach", Reno, NV, February 21, 2008

35. Los Angeles Physicians AIDS Forum: "Update from the 15th Conference on Retroviruses and Opportunistic Infections (CROI)", InterContinental Hotel, Century City, CA, March 11, 2008

36. HIV Grand Rounds, University Medical Center Wellness Clinic, "Rising to the Challenge: CCR5 Antagonists in Treatment-experienced Patients", Las Vegas, NV, March 21, 2008

37. HIV Conference Program: "CCR5 Antagonists - A New Era in Patient Management", Orange County Public Health, Santa Ana, CA, April 2, 2008

38. Grand Rounds, Division of Infectious Diseases, Department of Medicine, Keck School of Medicine, University of Southern California, "Progress in Antiretroviral Therapy", LAC/USC Medical Center, Los Angeles, CA, May 8, 2008

39. Scientific Meeting on New Trends and New Perspectives for HIV Treatment, Federal University of Rio de Janeiro, "Efficacy and Safety of Maraviroc in HIV+ Patients", Rio de Janeiro, May, 12 2008

40. 16th Annual State of Texas, Department of HIV/STD Conference, "Protease Inhibitor-based HAART: Predictive Factors for Treatment Success", Austin, TX, May 18, 2008

41. HIV Minifellowship Program: Current Challenges in the Clinical Management of HAART: "Side Effect Issues and Management Strategies", Hollywood Roosevelt Hotel, Los Angeles, CA, June 7, 2009

42. Grand Rounds, USC Communicable Diseases Grand Rounds: "HIV in Young Adults: An Often Overlooked Epidemic", USC Medical Center, Los Angeles, July 11, 2008

43. Grand Rounds, Division of Infectious Diseases, Department of Medicine, "A New Era in Patient HIV Treatment", Olive View Medical Center, Sylmar, CA, August 15, 2008

44. UCLA Center for AIDS Research and Education (CARE), 6th Annual HIV Symposium – Tough Decisions Made Easier: "Antiretroviral Therapy in the Current Era: Case-Based Panel Discussion", Renaissance Hotel, Hollywood, CA, October 17, 2008

45. Los Angeles Physicians AIDS Forum, "HIV Highlights of the 2008 ICAAC/IDSA Annual Meeting", InterContinental Hotel, Los Angeles, CA December 2, 2008

46. Infectious Diseases Grand Rounds, "Post CROI Update: Best Practices in HIV Therapy, Kaiser West Los Angeles, CA, March 26, 2009

47. Grand Rounds, Infectious Diseases Section, Sunnybrook Hospital, "HIV-1 Tropism: How We Can Use it to Treat Human Infection", Toronto, Canada, March 30, 2009

48. HIV Rounds Noon Lecture: "Viral Tropism: Epidemiology, Natural History, and Therapeutics", St Michael's Hospital, Toronto, Canada, March 31, 2009

49. Infectious Diseases Morning Rounds, McMaster University School of Medicine, "Progress in Treating HIV Infection: Using Laboratory Technology to Make Therapeutic Decisions", McMaster University, Toronto, Canada, April 1, 2009

50. Ottawa HIV Physicians' Community Consortium, "HIV-1 Tropism: How We Can Use It To Treat Human Infection", Ottawa, Canada, April 1, 2009

51. The New York Course: HIV Management 2009: "HIV Prevention in Clinical Practice", Hudson Theatre, New York, May 15, 2009

52. Cedars-Sinai Department of Pharmacy Conference: "Centers for Disease Control STD Treatment Guidelines", Cedars-Sinai Medical Center, May 27, 2009

53. Grand Rounds, Division of Infectious Diseases, Department of Medicine, SUNY Downstate Medical Center, "A New Era in HIV Patient Management", Brooklyn, NY, June 24, 2009

54. Grand Rounds, Infectious Diseases Section, Department of Medicine, Beth Israel Medical Center, "Rising to the Challenge: CCR5 Antagonists in Treatment-experienced HIV+ Patients", Peter Kruger Clinic, New York, NY, June 25, 2009

55. Grand Rounds, Division of Infectious Diseases and HIV Medicine, New York Hospital of Queens, "Viral Tropism and How it can be Used as Treatment for HIV Infection", Queens, NY, June 26, 2009

56. Grand Rounds, Infectious Diseases Section, Department of Medicine, US Naval Medical Center at Balboa, "Current Considerations for the Management of Patients with HIV Infection", San Diego, CA, August 14, 2009

57. Plenary Session, Session 1, Basic Science, "HIV Infection: An Inflammatory Disease?", HIV Congress 2010, Mumbai, India, January 8, 2010

58. Plenary Session, Session 2, Future Therapies, "Stem Cell Therapy for Treatment of HIV Infection", HIV Congress 2010, Mumbai, India, January 9, 2010

59. Grand Rounds, Division of Infectious Diseases, Department of Medicine, Cedars-Sinai Medical Center, "HIV Infection is an Inflammatory Disease", Cedars-Sinai Medical Center, February 9, 2010

60. 20th Annual Clinical Care Options for HIV Symposium: Current Opportunities and Continuing Challenges in HIV Care: "Missed Opportunities: Practical Strategies for Enhancing Early HIV Diagnosis and Timely Treatment" - Sheraton Wild Horse Pass, Phoenix, AZ – April 8, 2010.

61. Satellite Symposium, XVIII International AIDS Society (IAS) Conference, "The Art of Orchestration: Achieving Treatment Harmony in HIV Patients- Cardiovascular Disease in HIV Infection", Vienna Austria, July 18, 2010.

62. Satellite Symposium, ICAAC-2010, "Asked and Answered: Frontline Providers Challenge the Experts on HIV Management Strategies, Boston, MA, September, 13, 2010.

63. Satellite Symposium, ICAAC-2010, "HIV: Assessing the Long-term Consequences of Therapy and Infection", Boston, MA, September 14, 2010.

64. Seventh Annual St Bernadine Infectious Disease Symposium: "HIV/AIDS: Three Decades of Medical Progress", St Bernadine Medical Center, San Bernardino, CA, March 26, 2011.

65. 20th Annual HIV/AIDS-On the Front Line: "Challenges of Diagnosing and Treating HIV Infection among Latinos", University of California at Irvine School of Medicine, Orange, CA, April 27, 2011.

66. Miami Community HIV Physician Forum, "The Overlooked Epidemic: Beyond the Basics: Meeting the Challenges of Caring for Women with HIV Infection", Miami Beach, FL, September 7, 2011.

67. Los Angeles InterCity HIV Rounds: "Current Clinical Controversies in the Treatment of HIV/AIDS", Hollywood Presbyterian Medical Center, Los Angeles, CA, February 1, 2012

68. Plenary Session: Current Research Questions: "Is HIV Infection a Cardiovascular Disease Risk Equivalent?", International HIV Congress 2012, Mumbai, India, March 15- 18, 2012.

69. Plenary Session: HIV Clinical Care: Renal Disease in HIV+ Persons-Diagnosis and Treatment", International HIV Congress 2012, Mumbai, India, March 15-18, 2012.

70. Department of Medicine Grand Rounds: "Emerging Issues in the Management of HIV Infection", WVA Medical Center, Los Angeles, CA, June 6, 2012.

71. Third Annual HIV Latina Forum: "Treating Beyond HIV", Renaissance Sao Paulo Hotel, Sao Paulo, Brazil, June 21 – 23, 2012.

72. Grand Rounds: "Post IAC 2012 Update: Assessing Best Practices in HIV/AIDS Therapy", Health Care Agency of Orange County, Santa Ana, CA, August 15, 2012

73. Department of Medicine Grand Rounds: "Prevention of HIV Infection-Current Research Progress", Cedars-Sinai Medical Center, Los Angeles, CA, September 7, 2012.

74. Department of Medicine Grand Rounds: "Curing HIV Infection: Is It Possible?", Cedars-Sinai Medical Center, Los Angeles, CA, March 29, 2013.

75. Puerto Rico HIV Physician Forum, "HIV Treatment in Latino Persons: Differences in Adherence, Virologic and Immunologic Response to ART?", San Juan, Puerto Rico, April 19, 2013.

76. Official Satellite Symposium of 7th International AIDS Society (IAS) Conference on HIV Pathogenesis, Treatment and Prevention, "Emerging Issues of Aging HIV-seropositive Persons", Kuala Lumpur, Malayasia, June 28, 2013.

<u>CME-Accredited Programs</u>

1. Foundation for Better Healthcare CME Program: "Fusion Inhibitors: Optimizing Response in Treatment-experienced HIV-infected Patients", Seattle, WA, January 13, 2004

2. CME Activity: "A New Class, A New Option: Understanding CCR5 Antagonists", Howard Brown Health Center, Chicago, IL, January 10, 2008

3. CME Activity: "A New Generation of Targets" Understanding Co-Receptor Antagonists", Milwaukee, WI, January 11, 2008

4. CME Activity for AdvanceMed: HIV Resistance Workshop, Renaissance New York Times Square Hotel, New York, NY, January 25, 2008

5. CME Activity for AdvanceMed: HIV Resistance Workshop, San Francisco, CA, February 22, 2008

6. CME Program: “Current Clinical Controversies in the Treatment of HIV/AIDS”; Case Discussion on Treatment-Experienced Patients: "How many Drugs Does a Patient Need?, Rancho Las Palmas, Rancho Mirage, CA, May 2, 2008

7. CME Program: “Novel Agents for Treatment-Experienced Patients” Faculty Mentoring for Managing Challenging Cases”, Rancho Las Palmas, Rancho Mirage, CA, May 3, 2008

8. CME Program: Simply Speaking HIV – An Expert Educators CME Lecture Series: “Current Clinical Controversies in the Treatment of HIV/AIDS”, Silver Fox, Dallas, TX, May 15, 2008

9. CME Dinner Program: “A New Era in Patient Management”, Simon LA, Los Angeles, CA, May 20, 2008

10. CME Certified Symposium: New Insights into the Use of Protease Inhibitors Across the Treatment Spectrum: Case Scenarios: Participant Polling with Panel Discussion, Inter-Continental Hotel, Los Angeles, CA, June 12, 2008

11. Web-based CME Program: HIV Knowledge Network Study Group, XVII International AIDS Conference: "Highlights of the 2008 IAS", Moderator, August 21, 2008

12. First Care Forums in HIV: “Best Practices Workshops for the Treatment Team”, Millennium UN Plaza Hotel, New York, NY, September 6, 2008.

13. CCO CME-Certified Expert Recap from the 17th International AIDS Conference, Mexico City, August 3-8, 2008: “Update on Timing and Choice of First-Line Therapy”, October 3, 2008

14. CME Dinner Program: Profiles in HIV: In-Depth Analyses and Case Studies of Unique Populations Living with HIV, Los Angeles, CA, January 15, 2009

15. CME Program: First Care Forums in HIV: Best Practices Workshops for the Treatment Team, Madison Hotel, Washington, DC, January 17, 2009

16. CME Program Simply Speaking HIV, Post ICAAC/IDSA 2008 CME Update: “Assessing Best Practices in HIV/AIDS Therapy”, Hollywood Presbyterian Medical Center, Hollywood, CA, January 21, 2009

17. CCO CME Program: Panel Discussion on Management of Antiretroviral Naïve Patients, Loews Hotel Vogue, Montreal, Canada, February 11, 2009

18. CME Program: The HIV Treatment Debate, Renaissance Hotel, Hollywood, CA, March 3, 2009

19. CME Program: "Integrating Resistance Testing into Clinical Practice", Los Angeles, CA, March 18, 2009

20. CCO CME/CE-Certified Video Module: "Planning and Strategizing for Long-term Success With Antiretroviral Therapy", April 6, 2009

21. CCO CME/CE-Certified Treatment Update Video Module: CCO HIV: Stay Tuned Evolving Concepts in Antiretroviral Therapy: "Stem Cell Therapy, SWITCHMRK, and HIV-Associated Inflammation", June 2009

22. CME Harkness Roundtable Program: Current challenges in HIV: Maximizing outcomes Through Case-Based Discussions, West Hollywood, CA, June 17, 2009

23. 5th IAS 2009 Preview from CCO Faculty Experts Audio Preview: "The Impact of Home-Based Compared with Facility-Based HIV Care on Virologic Failure and Mortality: A Cluster Randomized Trial", July 20, 2009

24. 2009 International AIDS Society (IAS) Conference on HIV Pathogenesis, Treatment and Prevention, "Highlights and Overview of Progress in Antiretroviral Therapy, July 19, 2009.

25. CME Dinner Program: "The Graying of an Epidemic: Clinical Considerations of HIV and Aging", San Francisco, CA, October 20, 2009

26. CME Dinner Program: "Effect of Resistance and Resistance Barriers on ARV Therapy Efficacy", Beverly Hills, CA, October 21, 2009

27. CME Dinner Program: "The Graying of an Epidemic: Clinical Considerations of HIV and Aging", New York, NY, October 22, 2009

<u>Cedars-Sinai Medical Center CME Conferences – Chairman & Speaker</u>

1. 5th Annual CSMC World AIDS Day Conference: A Promising Future - Chairman, Cedars-Sinai Medical Center, Hotel Sofitel, Los Angeles, CA, December 4, 2003

2. 6th Annual CSMC HIV/AIDS Update Conference: A Multidisciplinary Approach – Chairman, Cedars-Sinai Medical Center, Le Meridian Hotel, Los Angeles, CA, March 11, 2005

3. 1st CSMC Crystal Methamphetamine Medical Conference (Co-Chair, Organizer

& Speaker): "Treatment Options", Cedars-Sinai Medical Center, Los Angeles, CA, June 23, 2006

4. 7th Annual CSMC HIV/AIDS Medical Update Conference: 25 Years of Old Standards and New Frontiers-A Multidisciplinary Approach - Chairman, Cedars-Sinai Medical Center, Le Meridian Hotel, Los Angeles, CA, September 19, 2006

5. 8th Annual CSMC HIV/AIDS Medical Update Conference: Emerging Issues and Challenges - Chairman, InterContinental Hotel-Century City, Los Angeles, CA, September 28, 2007

6. 9th Annual CSMC HIV/AIDS Conference: "New Therapies, New Patient Populations, and New Global Challenges", September 26, 2008

7. 10th Annual CSMC HIV/AIDS Conference: "HIV Infections – Inflammation, Prevention and Sex Workers", September 25, 2009

8. 11th Annual HIV/AIDS Conference: Primary Care and ART Optimization in a Changing Healthcare System, Intercontinental Hotel, Los Angeles, CA, September 24, 2010

9. 12th Annual HIV/ AIDS Conference: Hepatitis C Co-infection, Cardiovascular Disease and Promising Gene Therapies", SLS Hotel, Los Angeles, CA, September 23, 2011

10. 13th Annual HIV/AIDS Conference: "Comparing First-line Antiretroviral Options, Update on Hepatitis C Treatment, Screening for HIV-associated Neurocognitive Disorders, and Prospects for Curing HIV", SLS Hotel, Los Angeles, CA, September 28, 2012

PUBLICATIONS/BIBLIOGRAPHY

Research Papers / Peer Reviewed Articles

1. Ahmed AR, **Hardy D.** Bullous pemphigoid family of autoimmune diseases. Int J Dermatol 20(8):541-3, 1981. doi: 10.1111/j.1365-4362.1981.tb02023.x. PMID: 7030983.

2. Ahmed RA, Kaplan RP, **Hardy WD**, Feldman E, Pitt H. Bullous pemphigoid and ulcerative colitis. Int J Dermatol 21:594-598, 1982.

3. Holland GN, Sakamoto MJ, **Hardy WD**, Sidikaro Y, Krieger AE, Frenkel LM. Treatment of cytomegalovirus retinopathy in patients with acquired immunodeficiency syndrome – Use of the experimental drug 9-(2-hydroxyl-1 (hydroxymethyl) ethoxymethyl) guanine (DHPG). Arch Ophthalmol 104:1794-1800, 1986.

4. Holland GN, Sidikaro Y, Kreiger AE, **Hardy WD**, Sakamoto MJ, Frenkel LM, Winston DJ, Gottlieb MS, Bryson YJ, Champlin RE, Ho WG, Winters RE, Wolfe PR, Cherry JD. Treatment of cytomegalovirus retinopathy with ganciclovir. Ophthalmology 94:815-823, 1987.

5. Fay MT, Freeman WR, Wiley CA, **Hardy WD**, Bozzette S. Atypical retinitis in patients with the acquired immunodeficiency syndrome. Am J Ophthalmol 105:483-490, 1988.
6. Fischl MA, Richman DD, Causey DM, Grieco MH and the AZT Collaborative Working Group-**Hardy, WD**. Prolonged zidovudine therapy in patients with AIDS and advanced AIDS-related complex. JAMA 262:2405-2410, 1989.

7. Holland GN, Buhles WC Jr, Mastre B, Kaplan HJ and UCLA CMV Retinopathy Study Group- **Hardy, WD**. A controlled retrospective study of ganciclovir treatment for cytomegalovirus retinopathy. Use of a standardized system for the assessment of disease outcome. UCLA CMV Retinopathy Study Group. Arch Ophthalmol. Dec; 107(12):1759-66, 1989.

8. Volberding PA, Lagakos SW, Koch MA, Pettinelli C, Myers M, Booth D, Balfour HH Jr, Reichman RC, Bartlett JA, Hirsch MS, Murphy RL, **Hardy WD**, et al. Zidovudine in asymptomatic human immunodeficiency virus infection: a controlled trial in persons with fewer than 500 CD4-positive cells per cubic millimeter. N Engl J Med 322:941-949, 1990.

9. Hochster H, Dieterich D, Bozzette S, Reichman RC, Connor JD, Liebes L, Sonke RL, Spector SA, Valentine F, Pettinelli C, Richman DD, ACTG 004 Investigators-**Hardy, WD**. Toxicity of combined ganciclovir and zidovudine for cytomegalovirus disease associated with AIDS. An AIDS Clinical Trials Group Study. Ann Intern Med. Jul 15;113(2):111-7, 1990.

10. Engstrom RE Jr, Holland GN, **Hardy WD**, Meiselman HJ. Hemorheologic abnormalities in patients with human immunodeficiency virus infection and ophthalmic microvascularpathy. Am J Ophthalmol 109:153-161, 1990.

11. Fischl MA, Richman DD, Hansen N, Collier AC, Carey JT, Para MF, **Hardy WD**, Dolin R, Powderly WG, Allan JD, et al. The safety and efficacy of zidovudine (AZT) in the treatment of subjects with mildly symptomatic human immunodeficiency virus type 1 (HIV) infection. A double-blind, placebo-controlled trial. Ann Inter Med 112:727-737, 1990.

12. **Hardy WD**. Combined ganciclovir and recombinant human granulocyte- macrophage colony-stimulating factor in the treatment of cytomegalovirus retinitis in AIDS patients. J Acquir Immune Defic Syndr 1:S22-28, 1991.

13. Wu AW, Rubin HR, Mathews WC, Ware JE Jr, Brysk LT, **Hardy WD**, Bozzette SA, Spector SA, Richman DD. A health status questionnaire using 30 items from the Medical Outcomes Study. Preliminary validation in persons with HIV infection. Med Care 29:786-798, 1991.

14. Janoff EN, **Hardy WD**, Smith PD, Wahl SM. Humoral recall responses in HIV infection. Levels, specificity and affinity of antigen-specific IgG. J Immunol 147:2130-2135, 1991.

15. **Studies of the Ocular Complications of AIDS (SOCA) Research Group**. Mortality in patients with the acquired immunodeficiency syndrome treated with either foscarnet or ganciclovir for cytomegalovirus retinitis. Studies of Ocular Complications of AIDS

Research Group, in collaboration with the AIDS Clinical Trials Group. N Engl J Med. Jan 23;326(4):213-20, 1992.

16. Kahn JO, Lagokos SW, Richman DD, Cross A, Pettinelli C, **Hardy WD**, et al and the NIAID AIDS Clinical Trials Group. A controlled trial comparing zidovudine with didanosine in human immunodeficiency virus infection. N Engl J Med 327:581-587, 1992.

17. **Studies of the Ocular Complications of AIDS (SOCA) Research Group**. Studies of ocular complications of AIDS Foscarnet-Ganciclovir Cytomegalovirus Retinitis Trial: 1. Rationale, design, and methods. AIDS Clinical Trials Group (ACTG). Control Clin Trials. Feb;13(1):22-39, 1992.

18. Bass HZ, **Hardy WD**, Mitsuyasu RT, et al. The effect of zidovudine treatment on serum neopterin and beta 2-microglobulin levels in mildly symptomatic, HIV type 1 seropositive individuals. J Acquir Immune Def Syndr 5:215-221, 1992.

19. Bass HZ, **Hardy WD**, Mitsuyasu RT, Wang YX, Cumberland W, Fahey JL. Eleven lymphoid phenotypic markers in HIV infection: selective changes induced by zidovudine treatment. J Acquir Immune Defic Syndr 5:890-897, 1992.

20. **Hardy WD**. Foscarnet treatment of acyclovir-resistant herpes simplex virus infection in patients with acquired immunodeficiency syndrome: preliminary results of a controlled, randomized, regimen-comparative trial. Am J Med 14;92(2A):30S-35S, 1992.

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22. Recommendations for prophylaxis against Pneumocystis carinii pneumonia for adults and adolescents infected with human immunodeficiency virus (Hardy WD-. MMWR Recomm Rep. 1992 Apr 10;41(RR-4):1-11. PMID: 1348843.

23. U. S. Public Health Service Task Force on Prophylaxis against Pneumocystis Pneumonia in HIV Infection (**Hardy WD** – member). Recommendations for prophylaxis against Pneumocystis carinii pneumonia for adults and adolescents infected with HIV. JAMA 267:2294-2299, 1992.

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ranging study of daily maintenance intravenous foscarnet therapy for cytomegalovirus retinitis in AIDS (ACTG 015/915). J Inf Dis 168:444-448, 1993.

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