

# **CURRICULUM VITAE: DANIEL J. WALLACE, M.D., F.A.C.P., M.A.C.R**

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## **Personal Information:**

**Address:** 8750 Wilshire Blvd, Suite 210  
Beverly Hills, CA 90211

**Phone:** 310-652-0920

**Fax:** 310-360-4812

**E-mail:** [drwallace@walleemed.com](mailto:drwallace@walleemed.com), [danielwallac@gmail.com](mailto:danielwallac@gmail.com), [daniel.wallace@cshs.org](mailto:daniel.wallace@cshs.org)

**Website:** [www.walleemed.com](http://www.walleemed.com)

## **Education:**

- University of Southern California, M.D., 1970-1974
- University of Southern California, BA Medicine, 1967-1970

## **Postgraduate Training:**

- Rheumatology Fellow, UCLA School of Medicine, Los Angeles, CA, 1977-1979
- Medical Resident, Cedars-Sinai Medical Center, Los Angeles, CA, 1975-1977
- Medical Intern, Rhode Island (Brown University) Hospital, Providence, RI, 1974-1975

## **Medical Boards and Licensure:**

- Board Certified, Rheumatology subspecialty, 1982
  - California License No. G-30533
- Board Certified, American Board of Internal Medicine, 1978
- Diplomate, National Board of Medical Examiners, 1975

## **Present Appointments:**

- Board of Directors, Sjogren's Foundation, 2022-
  - Chairman Clinical Trials Consortium, 2022-
- Co-director, Cedars Sinai Lupus Clinic, 2022-
- Board of Directors, Lupus Therapeutics Board, 2020-
- Board of Directors, Lupus Research Alliance, 2020-
- Member, OMERACT Sjogren's Domain Special Interest Group, 2019-
- Member, FNIH Biomarkers Sjogren's Committee, 2019-
- Member, Medical Policy Committee, United Rheumatology, 2017-
- Board of Governors, Cedars-Sinai Medical Center, 2016-
- Professor of Medicine, Cedars-Sinai Medical Center, 2012-
- Member, Sjogren's Foundation Medical Advisory Board, 2010-
- Associate Director, Rheumatology Fellowship Program, Cedars-Sinai Medical Center, 2010-
- Expert Reviewer, Medical Board of California, 2007-
- Professor of Medicine, David Geffen School of Medicine at UCLA, 1995-
- Medical Director, Wallace Rheumatic Studies, 1994-

## **Honorary Appointments:**

- Master, American College of Rheumatology, 2015-Present
- Organizing Committee, Lupus (Quebec, Canada), 2014

- Fellow, American College of Physicians (FACP), 1985-Present
- Member, Royal College of Physicians (London), 1985-Present
- Fellow, American College of Rheumatology (FACR), 1979-2015

### **Hospital Appointments:**

- Cedars-Sinai Medical Center, Beverly Hills, CA
  - Co-Director Lupus and Sjogren's Clinic, Kao Autoimmunity Center, 2022-
  - Division of Rheumatology Executive Committee, 2011-Present
  - Clinical Academic Promotions and Appointment Council, 2011-2014
  - Chairman of Department of Medicine Search Committee, 2011-2012
  - Pharmacy Gamma Globulin Committee, 2002-2015
  - Performance Improvement Committee, 1991-1996
  - Clinical Chief of Rheumatology, 1991-1996
  - Division of Rheumatology Reappointment/Peer Review, 1988-Present
  - Hospital Peer Review Committee, 1986-1989 and 1992-1994
  - Medical Advisory Committee, 1985-1988 and 1991-1996
  - Chairman, Medical Peer Review, 1985-1987
  - Member, Medical Peer Review, 1982-1989
  - Intern Selection Committee, 1979-1993
- UCLA Center for the Health Sciences, Los Angeles, CA
  - Attending Physician, 1981-Present
- City of Hope Medical Center, Duarte, CA
  - Chief Rheumatology Consultant, 1980-1988

### **Prior Academic Appointments:**

- Clinical Professor, UCLA School of Medicine, 1988-1995
- Assistant Clinical Professor, UCLA School of Medicine, 1981-1988
- Assistant Clinical Professor, USC School of Medicine, 1979-1981

### **Organizations and Positions Held:**

- Lupus Research Alliance
  - Lupus Therapeutics Board of Directors, 2020-Present
  - Executive Board, Lupus Clinical Investigative Network, 2016-Present
  - Co-chairman, Lupus Industry Council, 2016-2019
- OMERACT Sjogren's Domain Special Interest Group
  - Member, 2019
- FNIH Biomarkers Sjogren's Committee
  - Member, 2019-Present
- Master, American College of Rheumatology
  - Rheumatology Research Foundation, Ambassador, 2018-
  - Lupus Abstract Selection Committee, 2010-2015
  - Nominating Committee, 2005-2007
  - Chairman, 1995-1999
  - Research & Education Foundation Board of Directors, 1993-1999
  - Nominations Committee, 1991-1994
  - Chairman, 1990-1991
  - Lupus Council, 1986-Present

- Committee on Rheumatologic Practice, 1982-1985
- 23andme
  - Scientific Advisory Board for Lupus, 2015-2018
- NYU Judith and Stewart Colton Center for Autoimmunity, NYU Langone Medical Center
  - External Advisory Committee, 2014-Present
- Lupus Research Institute
  - Co-Chairman, Industrial Relations Council, 2012-Present
  - Member, Lupus Clinical Trials Consortium (LCTC), 2005-2010
  - Board of Directors, 2000-2015
- Lupus Foundation of America
  - Co-chairman, 1999-2000
  - Vice President, 1999-2000
  - Member, Board of Directors, 1991-1998
  - Co-Chair, Los Angeles Chapter Medical Advisory Board, 1989-1999
  - National Medical Advisory Board, 1988-2000
- NIH Lupus Biomarkers Committee
  - Committee Member, 2004-2010
- SLICC (Systemic Lupus International Coordinating Committee)
  - Member, 2003-Present
- Maryland Lupus Foundation
  - Medical Advisory Board, 2001-2004
- Scleroderma Foundation, Southern California
  - Board of Directors, 2001-2004
- Lupus LA
  - Founder, 2000-Present
- Member, Los Angeles County Medical Association, 1979-Present
- Sjogren's Syndrome Foundation
  - Medical Advisory Board, 1997-Present
- American Board of Internal Medicine
  - Examination writer for Internal Medicine Boards, 1994, 1995
- American Fibromyalgia Syndrome Association
  - Medical Advisory Board, 1994-Present
- Arthritis Foundation Pacific Region
  - Board of Directors, Southern California, 1994-2006
  - Chairman 1990-1995
  - LA. Metro Committee Chairman, 1989-1994
  - Community Services Committee, 1989-1994
  - Medical and Scientific Committee, 1989-1994
  - Institutional Grants Committee, 1989-1994
  - Fibromyalgia Subcommittee, 1988-Present
  - Representative, National House of Delegates, 1987, 1990
- United Scleroderma Foundation
  - Board of Directors, 1990-1997
- The American Lupus Society (merged with Lupus Foundation of America, 1996)
  - National Medical Advisory Board, 1988-1996
  - Los Angeles Chapter Medical Advisory Board, 1980-1996

- Los Angeles Chapter Chief Medical Advisor, San Fernando Valley Medical Advisory Board, 1980-1996
- American Society for Apheresis
  - Medical Executive Committee, 1987-1989
  - Editor, ASFA Newsletter, 1987-1989
  - Member, 1980-Present
- Member, California Medical Association, 1979-Present
- Member, American Medical Association, 1979-Present
- Member, Southern California Rheumatism Society, 1979-Present

### **Laboratory Experience:**

- Cedars-Sinai Lupus Research Laboratory, 1990-Present
- Therapeutic apheresis project, Cedars-Sinai Medical Center, 1977-1997
- USC Cancer Virology Laboratory, Dr Murray Gardner and J. Earle Office, PhD, 1972-1974
  - retroviruses and aging.
- Summer research fellow, Cedars-Sinai Medical Center, 1968-1970
  - under Dr Leon Morgenstern, Chairman, Department of Surgery, dealing with wound healing of intestinal anastomoses and synthesizing trypsin inhibitor.

### **Publication Review Experience:**

- Editorial Board, Future Rheumatology, 2006-2016
- Editor-in-Chief, Current Rheumatology Reviews, 2005-2008
- Editorial Board, Journal of Clinical Rheumatology, 2003-Present
- Editorial Board, Journal of Rheumatology, 1999-Present
- Editorial Board, Journal of Musculoskeletal Pain, 1999-Present
- Editorial Board, Arthritis & Rheumatism, 1998-2003
- Editorial Board, Bulletin on the Rheumatic Diseases, 1998-2004
- Editorial Board, Lupus, 1997-Present
- Editor, Current Opinion in Rheumatology, Lupus issues, 1994-2000
- Editorial Board, Journal of Clinical Apheresis, 1982-2004
- Reviewer for over 50 medical journals

### **Honors**

- Master Clinician Award, Cedars-Sinai, 2023
- Distinguished Clinical Scholar Award, American College of Rheumatology, 2023
- Dorothy Ellis Memorial Clinician Award, Lupus LA, 2023
- Lifetime Achievement Award, California Rheumatology Alliance, 2023
- Jane Wyman Humanitarian Award, Arthritis Foundation, 2018
- Innovation Award for Community Service, Los Angeles County Medical Association, 2017
- Lupus Foundation of Northern California, Outstanding Commitment to Treatment and Research, 2016
- Sjogren's Syndrome Foundation, Healthcare Professional Leadership Award, 2012
- Medical Achievement Award, SLE Foundation, 2011
- Top Doctor, US News and World Report, 2011-Present
- Founder's Award, Lupus LA, SLE Foundation, 2008
- James R Klinenberg Achievement Award, Arthritis Foundation Southern California Chapter, 2004

- Achievement Award, SLE Foundation, 2002
- “Spirit of Hope” Award, Southern California Scleroderma Foundation, 2001
- Outstanding Service Award, Lupus Foundation of America, 1997
- Jane Wyman Humanitarian Award, Arthritis Foundation, 1996
- Best Doctors in Los Angeles, Los Angeles Magazine, 1996
- Expert Consultant, Medical Board of California, 1995-Present
- “The Best Doctors in America,” Woodward/White, Aiken, SC, 1994
- Lupus Hall of Fame, The American Lupus Society, 1989
- Best Doctors in the United States, Town and Country Magazine, October 1989
- Humanitarian Award, Lupus Foundation of America, 1989, 1991
- Globus Award, Best Medical Paper, Mt. Sinai J Medicine, 1984-1985

### **Research Grants**

- 1R01AI164504-01, 09/01/2021 – 08/31/2025
  - “Sex and gender differences in lupus - intersection between immunometabolism, epigenetic remodeling and cardiac involvement”, Caroline Jefferies (PI), Role: Co-Investigator
- CDMRP Lupus Research Program (LRP) Impact Award, LR17014, 10/01/2017 – 09/31/2022
  - “Inflammation and Metabolic Reprogramming of Lupus Monocytes - Mechanisms of the Pathobiology of Lupus Cardiovascular Disease”, Caroline Jefferies (PI), Role: Co-Investigator
- U01AR076092-01, 06/15/2020 – 05/31/2025
  - “SLE Treatment with N-acetylcystine, (SNAC)”, Perl (PI), Role: Co-Investigator
- MUSC18-055-8D365, 10/01/2017 – 09/30/2022
  - “A Phase II Sequential Dose-escalation Study Evaluating the Safety and Feasibility of Allogenic Umbilical Cord Derived Mesenchymal Stromal Cells for the Treatment of Adults w/ Treatment Refractory Lupus”, Gilkeson (PI), Role: Co-Investigator
- PCORI, \$8,000, 2021
  - “Implementing the DeCision- AID for Lupus (Ideal strategy)”, Principal Investigator: Jasvinder A. Singh, MD, MPH, IND/IDE Sponsor: University of Alabama at Birmingham, Funded by: Patient-Centered Outcomes Research Institute
- Department of Defense Grant, Award ID: CSR206754, 2020-2021, \$164,000
  - Cedars-Sinai Precision Health RFP 2020 Decision Notification, “Investigating the link between elevated IDH2 levels and epigenetic regulation of type I interferons in Lupus” Contact Principal Investigator: Dr. Caroline Jefferies, Role: Co Investigator
- NIH Grant, # U01AR076092-01A1 #101,320, Direct costs awarded: \$1,289,962, Total costs awarded: \$1,500,000, 2020
  - “SLE Treatment with N-acetylcystine, (SNAC)”, Principal Investigator: Andras Perl, Role: Co-Principal Investigator
- Department of Defense, LR170141, 2018
  - “Inflammation and Metabolic Reprogramming of Lupus Monocytes – Mechanism of the Pathobiology of Lupus Cardiovascular Disease”, Caroline Jefferies (PI), Role: Co-Investigator
- Center for Disease Control, CDC RFA DP15-1511, \$5,000, 2017-2021
  - “Developing and Disseminating Programs to Build Sustainable Lupus Awareness, Knowledge, Skills and Partnerships”, Co-Investigators with Lupus Foundation of America
- NIH/NIAMS, #U34 AR067392, 2015-2017

- “Hydroxychloroquine Treatment for Prevention of Systemic Lupus Erythematosus”, Planning grant for a multicenter, placebo-controlled trial of hydroxychloroquine in incomplete lupus patients to determine whether this can ameliorate, delay or prevent progression to SLE. Olsen & Karp (MPIs), Role: Co-investigator
- Department of Defense, Award Number W81XWH-13-1-0392, 2014
  - Subject: Introduction and Contact Information for the Protocol, “A Phase Ib Study of Milatuzumab Administered Subcutaneously in Patients with Active Systemic Lupus Erythematosus (SLE),” Submitted by Daniel Wallace MD, Cedars-Sinai Medical Center, Los Angeles, California in Support of Proposal, “CD74 Immunotherapy of Systemic Lupus Erythematosus,” William Wegener MD, Immunomedics, Incorporated, Morris Plains, New Jersey, Proposal Log Number PR121764, HRPO Log Number A-17786
- NIH Grant, #R34A114453, 2014-2015
  - “Mesenchymal Stem Cell Therapy for Active Systemic Lupus Erythematosus”, Planning grant. The goal is to complete protocol development and set up administrative and regulatory structures at participating trial sites for implementation of a multicenter trial of MSCs for patients with active SLE. Gilkeson & Kamen (MPIs), Role: Co-investigator
- NIH/NIAMS Grant, Oklahoma Sjogren’s Syndrome Center of Research Translation, #P50AR060804-03, 2013-2016
  - The overall specific aim is to establish the Oklahoma Sjogren’s Syndrome Center of Research Translation (OSSCORT) with the goal of bridging the gap between the advances in the basic-science understanding of Sjogren’s syndrome and clinical research geared to improving better diagnostics, disease predictors, and prognostic tests, as well as to advance therapeutic options, Sivils (PI), Role: Co-Investigator
- Autoimmune Centers of Excellence, 2012-2016
  - “BASJ02-A randomized, double-blind, placebo-controlled trial of Baminercept, a omphotoxin-B receptor fusion, protein, for the treatment of primary Sjogren’s syndrome”, Role: Principal Investigator
- Cedars-Sinai Medical Group, France Foundation, \$150,000, 2012-Present
  - “Improving the Recognition, Diagnosis, and Referral Patterns of Patients with Systemic Lupus Erythematosus Through Enhanced Care Coordination and Practice Efficiencies” – A QI/PI CME Demonstration Project, Role: Principal Investigator
- Canadian Arthritis Society, 2009-2011
  - “Lymphoma Risk in SLE: A Consequence of Immune Suppression or Stimulation?” The purpose of this research is to help identify SLE patients at highest risk for lymphoma and provide guidance regarding the appropriate use of ISDs in both inducing and maintaining remission in SLE. Clarke/Bernatsky (PI), role: Co-Investigator
- NIH Grant, #N01A115416, 2008-2012
  - “The use of abatacept in lupus nephritis”, Role: Co-investigator, HHSN268200700036C, Langford (PI)
- NIH Grant, #N01-AR-4-2273, 2007-2010
  - “Rituxan in the treatment of refractory adult and juvenile dermatomyositis (DM) and adult polymyositis”, Role: Co-investigator
- Alliance for Lupus Research, \$72,500, 2006-2008
  - “Concurrent Pilot Studies in Giant Cell Arteritis and Takayasu Arteritis to Examine the Safety, Efficacy, and Immunologic Effects of Abatacept (CTLA4-IG) in large Vessel Vasculitis.” The purpose of this study is to determine the effectiveness and safety of the medication abatacept in giant cell arteritis or Takayasu’s arteritis, role: Co-Investigator

- Aspreva, \$62,500, 2006-Present
  - “The role of mycophenolate mofetil in patients with extra-renal lupus.” A study to investigate pro inflammatory HDL cholesterol as an indication of risk for atherosclerosis in subjects with systemic lupus erythematosus.
- NIH Grant, Lupus Foundation of America, NIH-NIAMS ARO051871-013, 2004-2009
  - “AROSE: Revising ACR diagnostic/classification criteria for lupus”
- NIH/NIAID Grant, #U19 AI056363, 2003-2016
  - “Mechanisms of B Cell Responses in Autoimmune Diseases”, This Autoimmunity Center of Excellence based at Duke University focuses on the modulation of B cell responses in autoimmune diseases. St. Clair (PI), Role: Co-Investigator
- NIH Grant, Grant #R01AR4912501, National Institute of Arthritis, Musculoskeletal and Skin Disorders, 2003-Present
  - “Brain Connections: Cognitive function in SLE”, Co-investigator with Dr. Michelle Petri
- Food and Drug Administration, RF 412-3324A, \$24,000, 2000-2002
  - “Comparison of IV cyclophosphamide to mycophenolate mofetil for induction therapy of active Class III-IV nephritis in systemic lupus erythematosus.” Co-investigator with M Weisman for Cedars effort
- American Fibromyalgia Syndrome Association, \$24,600, 1998-1999
  - “The role of the Th-1/Th-2 axis in fibromyalgia”
- NIH Grant, Agency Award #2R01AR4252-04, \$442,670, 1997-1999
  - “Abnormal IL-6 Production in SLE”, Co-investigator with Dr. Mariana Linker-Israeli
- NIH Grant, Agency Award #2R01AR4252-04, \$350,000, 1994-1996
  - “Interleukin-6 genetic polymorphisms”, Co-investigator with Dr. Mariana Linker-Israeli
- Winthrop Pharmaceuticals Grant, \$7,500, 1991-1993
  - “Cytokines and their influence on hydroxychloroquine”
- The American Lupus Society Grant, \$28,000, 1990-1992
  - “An index of lupus literature”
- Winthrop Pharmaceuticals Grant, \$5,000, 1989-1999
  - “The role of hydroxychloroquine on lipids”
- Parker Foundation Grant, \$76,250, 1983-1985
  - “Selective immunoadsorption in rheumatoid arthritis”
- Haemonetics Research Institute Grant, \$25,000, 1982
  - “The immunology of apheresis”
- Kroc Foundation Grant, \$59,000, 1981-1982
  - “Apheresis in systemic lupus erythematosus”
- Haemonetics Research Institute Grant, \$25,000, 1980-1981
  - “Double-blind controlled trial of apheresis in rheumatoid arthritis”
- BSRG Cedars-Sinai Research Grant, \$10,000, 1978-1979
  - “Apheresis in rheumatoid arthritis”

#### **Department of Defense Review Panels**

- “Lupus Grants Review”, 2016
- “Gulf War Illness Research Program”, 2010, 2019

#### **Data Safety and Monitoring Board (DSMB)**

- NIAID Autoimmune Centers for Excellence, Clinical Research Program, UM-1 Grants, 2018
- Department of Defense, Peer Review of Autoimmune Grant Proposals, 2016

- Novo Nordisk Anti IL-21, Protocol NN8828-4002, 2012- 2013
- Celecoxib for rheumatoid arthritis, 2006

### **Present Drug Study Collaborative Protocols:**

- AMPEL SLE, AMP-005: An Open Label Multicenter Study to Assess the Relationship Between Data Obtained with the LuGENE® Multiparameter Transcriptomics Blood Test and Clinical and Standard Laboratory Features of Patients with, Systemic Lupus Erythematosus (SLE), 2023
- Abbvie SLE, M23-699: A Phase 3 Program to Evaluate the Safety and Efficacy of Upadacitinib in Subjects with Moderately to Severely Active SLE, 2023
- Novartis LN, CVAY736K12301: A randomized, double-blind, parallel group, placebo- controlled, multicenter phase 3 trial to evaluate the efficacy, safety and tolerability of ianalumab on top of standard-of-care therapy in participants with active lupus nephritis (SIRIUS-LN), 2023
- Horizon SJS, HZNP-DAZ-301: A Phase 3 Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of Dazodalibep in Participants With Sjögren’s Syndrome With Moderate-to-severe Systemic Disease Activity
- Horizon SJS, HZNP-DAZ-303: A Phase 3 Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of Dazodalibep in Participants With Sjögren’s Syndrome With Moderate-to-Severe Symptom State, 2023
- Biogen SLE, 230LE306: A Multicenter, Randomized, Dose-Blind, Phase 3 Long-Term Extension Study to Evaluate Continuous Safety and Efficacy of Litifilimab (BIIB059) in Adult Participants with Active Systemic Lupus Erythematosus, 2023
- LRA SLE, LNX001: Lupus Landmark Study A Prospective Registry and Biorepository
- Cedars SLE, RA, SJS, RAISE QT: Rheumatic Disease Patients: Assessment of Hydroxychloroquine’s Effect on QT-c Intervals with Weight-Based Dosing (RAISE-QT)
- UCB SLE, SL0046: A Multicenter, Open-Label Extension Study to Assess The Long-Term Safety and Tolerability of Dapirolizumab Pegol Treatment in Study Participants with Systemic Lupus Erythematosus, 2022
- Biogen SLE, 230LE303: A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of BIIB059 in Adult Participants With Active Systemic Lupus Erythematosus Receiving Background Nonbiologic Lupus Standard of Care
- EnlightLN: A Prospective Observational Registry of Patients Treated with Lupkynis (voclosporin) in the US, 2022
- SL0043 UCB SLE: A multicenter, randomized, double-blind, placebo-controlled, parallel-group study to evaluate the efficacy and safety of Dapirolizumab Pegol in study participants with moderately to severely active systemic lupus erythematosus, 2021
- CA41705: A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Obinituzumab in Patients with ISN/RPS 2003 Class III or IV Lupus Nephritis, 2020

### **Past Drug Study Collaborative Protocols:**

- Abbvie LTE, M20-186: A Phase 2, Long-Term Extension (LTE) Study with Elsubrutinib and Upadacitinib Given Alone or in Combination (ABBV-599) in Subjects with Moderately to Severely Active Systemic Lupus Erythematosus Who Have Completed the M19-130 Phase 2 Randomized Controlled Trial (RCT), 2020 - 2023
- Protocol 20-FMS1-BETTER Biomarker evaluation for the differential diagnosis and monitoring of fibromyalgia compared to autoimmune rheumatic diseases, other pain syndromes, and normal subjects, 2020 - 2023



- Corrona Rheumatoid Arthritis (RA) Drug Safety & Effectiveness Registry, 2021-2023 IDEAL Study: Implementing the DeCision-Aid for Lupus (Ideal Strategy), 2020 - 2023
- United Rheumatology, Blue Shield: Value-Based Targeted Immune Modulator (TIM) Dose Optimization Program, 2022 - 2022
- GILEAD CLE, GS-US-497-5888: A Randomized, Blinded, Placebo-Controlled, Phase 1b Study of GS-5718 in Subjects with Cutaneous Lupus Erythematosus (CLE), 2021-2022
- Servier Sjogren's: A phase IIa efficacy and safety trial with intravenous S95011 in primary Sjögren's Syndrome patients. An international, multicentre, randomised, double-blind, placebo-controlled study., 2021-2022
- Kiniksa RA: A Phase 2, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Assess the Safety, Pharmacokinetics, and Efficacy of KPL-404 in Subjects with Moderate to Severe, Active Rheumatoid Arthritis with Inadequate Response or Intolerance to at Least One Biologic Disease-modifying Anti-rheumatic Drug or a Janus Kinase Inhibitor, 2021-2022
- Abbvie SLE: A Phase 2 Study to Investigate the Safety and Efficacy of ABBV-105 and Upadacitinib Given Alone or in Combination (ABBV-599 Combination) in Subjects with Moderately to Severely Active Systemic Lupus Erythematosus, 2019-2022
- Lilly SLE Extension: Eli Lilly and Company / A Phase 3, Double-Blind, Multicenter Study to Evaluate the Long-Term Safety and Efficacy of Baricitinib in Patients with Systemic Lupus Erythematosus (SLE), 2019-2022
- Pfizer SLE: A Phase 2B, Double-Blind, Randomized, Placebo-Controlled, Multicenter, Dose-Ranging Study to Evaluate the Efficacy and Safety Profile of PF-06700841 in Participants with Active Systemic Lupus Erythematosus (SLE), 2019-2020
- Amgen SLE: A Phase 1b/2a Study to Evaluate the Safety and Efficacy of AMG 592 in Subjects With Active Systemic Lupus Erythematosus With Inadequate Response to Standard of Care Therapy, 2019-2020
- RA Study: OSCO-P2201: A Phase 2, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Dose Study to Evaluate the Efficacy and Safety of Oral SKI-O-703 in Patients With Active Rheumatoid Arthritis Despite Treatment With Conventional Therapies, 2019-2020
- Sobi.ANAKIN-301 The anaSTILLS Study, A Randomized, Double-blind, Placebo-Controlled, Multicenter, Phase 3 Efficacy and Safety Study of 2 Dose Levels of Subcutaneous Anakinra (Kineret) in Patients with Still's Disease (SJA and AOSD), 2018-2019
- Krill Oil Study, A Double-Blind, Placebo-Controlled Randomized, Multicenter Study to Assess Changes in Omega-3 Index in Erythrocytes and Health Benefit after 24 Weeks of Daily Consumption of AKBM-3031 (Omega-3 Phospholipids from krill), Followed by a 24 Week Open-Label Extension, in Patients with Systemic Lupus Erythematosus (SLE), 2018-2022  
*Lupus Clinical Investigators Network (LuCIN)*
- Protocol I4V-MC-JAIA, A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Phase 3 Study of Baricitinib in Patients with Systemic Lupus Erythematosus, Eli Lilly, 2018-2021
- Auronia Extension Study, A Randomized, Controlled, Double-blind, Continuation Study Comparing the Long-term Safety and Efficacy of Orelvo (voclosporin) (23.7 mg Twice Daily) with Placebo in Subjects with Lupus Nephritis, 2018-2021
- Lupuzor Extension Phase 3 Study 1PP-20110L006, Lupuzor Extension, An Open-Label Study of the Safety and Tolerability of Repeated Administration of a 200-mcg Dose of IPP-201101 Plus Standard of Care in Patients with Systemic Lupus Erythematosus, 2018-2020
- Protocol CNTO1275SLE3001; Phase 3, A Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel-group Study of Ustekinumab in Subjects with Active Systemic Lupus Erythematosus, Janssen, 2018

- A Phase 1, Randomized, Multi-centered, Double-blind, sponsor open, Placebo-controlled, Single and Multiple Dose- escalation Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of PF-06835375 in Subjects with Seropositive Systemic Lupus Erythematosus or Rheumatoid Arthritis, 2018, Pfizer
- 2017, AstraZeneca SPOCS D3461R00001, Prospective Observational Cohort of patients with moderate-to-severe SLE to characterize cross-sectional and longitudinal disease activity, treatment patterns and effectiveness, outcomes and comorbidities, healthcare resource utilization, and the impact of SLE on quality of life by type I interferon gene expression
- Exagen 17-SLE1 CARE Study, Clinical Laboratory Assessments and Recommendations for Lupus, 2017
- GA30044, A Phase II, Randomized, Double-blind, Placebo-controlled Study of the Safety and Efficacy of GDC- 0853 in Patients with Moderate to Severe Active Systemic Lupus Erythematosus, 2017
- AMPEL, A Randomized, Double-Blind, Active Comparator-Controlled, Crossover Study to Assess the Capacity of Delayed-Release Prednisone (RAYOS®) Compared to Immediate-Release Prednisone to Improve Fatigue and Control Morning Symptoms in Subjects with Generalized Systemic Lupus Erythematosus, 2017
- GILEAD A Phase 2, Randomized, Double-blind, Placebo-controlled Study to Assess the Safety and Efficacy of Filgotinib and GS-9876 in Female Subjects with Moderately-to-Severely Active Cutaneous Lupus Erythematosus (CLE), 2017
- Aurina Pharma, A Randomized, Controlled Double-blind Study Comparing the Efficacy and Safety of Voclosporin (23.7 mg Twice Daily) with Placebo in Achieving Renal Response in Subjects with Active Lupus Nephritis, 2017
- Protocol: MS200527-0018, 2017 A Phase II, Randomized, Double-Blind, Placebo-Controlled Dose-Ranging Study To Evaluate the Safety and Efficacy of M2951 in Subjects with Systemic Lupus Erythematosus (SLE), 2017
- A Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Phase 2A Study to Assess the Efficacy of RO5459072 in Patients with Sjogren 's Syndrome, 2017
- Protocol SL0023, UCB, A Multi-Centered, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Dose-Ranging Study Followed by an Observation Period to Evaluate the Efficacy and Safety of Dapirolizumab Pegol in Subjects with Moderate to Severely Active Systemic Lupus Erythematosus, Phase 2B, 2016
- RSLV-132 Protocol 132-03, Resolve A Phase 2A, Double-Blind, Placebo Controlled Study of RSLV-132 in Subjects with Systemic Lupus Erythematosus, 2016
- Protocol I4V-MC-JAHH, Lilly, A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Phase 2 Study of Baricitinib in Patients with Systemic Lupus Erythematosus (SLE), 2016
- A Phase III, Randomized, Multicenter, Double-Blind, Safety Study of Ferumoxytol Compared to Ferric Carboxymaltose for the Treatment of Iron Deficiency Anemia (IDA), 2016-2017
- Janssen, A Multicenter, Randomized, Double-blind, Placebo-controlled, Proof-of-Concept Study of Ustekinumab in Subjects With Active Systemic Lupus Erythematosus, 2016
- WA29748 Genentech Lupus Nephritis study, A randomized, double-blind, placebo-controlled, multicenter study to evaluate the safety and efficacy of obinutuzumab in patients with ISN/RPS 2003 Class III or IV nephritis, 2016
- EMR Serono Research & Development Institute, Protocol EMR200527-002 Protocol Title: A Phase Ib study to evaluate the safety, tolerability, PK and Biological Effect of MSC2364447 in systemic lupus erythematosus, 2015-2017

- A 52-week, randomized, double-blind, parallel-group, placebo-controlled study to evaluate the efficacy and safety of a 200-mcg dose of IPP-201101 plus standard of care in patients with SLE, ImmuPharm-Orion-Simbec (Lupuzor), 2015
- An open-label, Non-randomized, 52-week study to evaluate treatment Holidays and rebound phenomenon after treatment with Belimumab 10mg/kg in Systemic Lupus Erythematosus subjects, 2015-2016
- An International, Open Label, Randomized Controlled Trial Comparing Rituximab with Azathioprine as Maintenance Therapy in Relapsing ANCA-Associated Vasculitis (RITAZAREM) 2014-2020
- Pharmacokinetic Evaluations of Tabalumab Following Subcutaneous Administration by Prefilled Syringe or Auto Injector in Patients with Systemic Lupus Erythematosus, 2014-2015
- Protocol IMMU-115-04: A Phase Ib Study of Milatuzumab Administered Subcutaneously in Patients with Active Systemic Lupus Erythematosus (SLE) 2014
- A Phase IIb, Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Multidose, 24-Week Study to Evaluate the Efficacy and Safety of Atacicept in Subjects with Systemic Lupus Erythematosus (SLE), 2013
- Ignyta – Molecular Analysis in Biological Specimens from Subjects with Rheumatoid Arthritis (RA) Protocol – IGN- RA104Ignyta – Molecular Analysis in Biological Specimens from Subjects with Systemic Lupus Erythematosus (SLE) and Non-Lupus Control Protocol – IGN-SLE104, 2013-2014
- Nodality – Characterization of Immune Alterations in Systemic Lupus Erythematosus (SLE) using Single Cell Network Profiling (SCNP) Protocol 2012087 SLE Landscaping, 2013-2014
- A phase 111, Multicenter, Randomized, Double-blind Placebo-controlled Study to Assess The efficacy and Safety of Tocilizumab in Subjects with Giant Cell Arteritis, Roche, 2013-2015
- A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Tolerability of BIIB023 in Subjects with Lupus Nephritis, Biogen, 2012-2013
- A Study to Evaluate the Efficacy and Safety of R333 6% Ointment Administered Topically to DLE and SLE Patients with Active Cutaneous Discoid Lesions, Rigel, 2012-2013
- Protocol WA 27893: Prospective, observational safety study of patients with Granulomatosis with polyangiitis (Wegener's) or microscopic polyangiitis treated with rituximab, Genentech 2012-2014
- A longitudinal observational study of CXCR5, CXCL13 and other biomarkers in patients with lupus and healthy control subjects, Sanofi, 2012-2015
- A Phase 3, multicenter, randomized, double-blind, placebo-controlled study to evaluate the safety and efficacy of subcutaneous LY2127399 in patients with systemic lupus erythematosus (SLE), 2012- 2014, Lilly, 2012-2015
- A dose escalation, multi-center study to evaluate the safety, tolerability and proof of mechanism of DV1179 in Subjects with Systemic Lupus Erythematosus, Dynavax, 2012
- OMRF Sjogren's Studies: Gene Expression Profiling in Primary Sjogren's Syndrome, 2012-2014
- A Double Blind, Randomized, Placebo-controlled, Multicenter, dose ranging study to evaluate the efficacy and safety of PF-04236921 in subjects with Systemic Lupus Erythematosus, Pfizer, 2012-2013.
- A Randomized, Double-Blind, Placebo-controlled, multiple dose, parallel, Multiple dose-level study to evaluate the safety, tolerability and efficacy of AMG 557 in (SLE) subjects with active Lupus Arthritis, Amgen, 2012-2014

- A Phase 3/4, Multi-Center, Randomized, Double-Blind, Placebo Controlled, 52-week study to evaluate the efficacy and safety of Belimumab (HGS1066) in Adult subjects of Black Race with Systemic Lupus Erythematosus (SLE), Human Genome Sciences, 2012
- Vasculitis Clinical Research Consortium (VCRC) Genetic Repository DNA Protocol, 2011-2016,
- A study to learn about the safety, effectiveness and effects on the body of abatacept in large vessel vasculitis. Concurrent pilot studies in Giant cell arteritis and Takayasu's arteritis, Vasculitis Clinical Research Consortium, 2011-2012
- ACR/EULAR Diagnostic and Classification Criteria for Vasculitis, ACR, EULAR, Vasculitis Foundation, Oxford University, 2011-2012
- Protocol Summacta WA22762, 2011 –2014
- UCB, Inc. - A Phase 3, Multicenter, open label, extension study to assess the safety and tolerability of Epratuzumab treatment in Systemic Lupus Erythematosus Subjects (Embody 4) Protocol SL0012, 2011
- UCB, Inc. - A Phase 3, Randomized, Double blind, placebo controlled, multicenter study of the Efficacy and Safety of Four 12-Week Treatment Cycles (48 Weeks Total) of Epratuzumab in Systemic Lupus Erythematosus Subjects with Moderate to Severe Disease (Embody1). Protocol SL0009, 2011-2012
- Teva Pharmaceutical Industries, LLC - A Phase IIa, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Study to Evaluate the Safety, Tolerability and Clinical Effect of Laquinimod in Active Lupus Nephritis Patients, in Combination with Standard of Care (Mycophenolate Mofetil and Steroids) Protocol LN-LAQ-201, 2011-2012
- Eli Lilly and Company – A Phase 3, MultiCenter, Randomized, Double-Blind, Placebo Controlled study to evaluate the efficacy and safety of Subcutaneous LY2127399 in patients with Systemic Lupus Erythematosus (SLE), Protocol H9B-MC- BCDS, 2011-2012
- GlaxoSmithKline - Lupus Impact Tracker: A Longitudinal Validation Study Protocol GHO-09-1621, 2011-2012
- IRBIS (Internal Registry for Biologics in SLE) Phase I, Retrospective data collection, SLICC (Systemic Lupus International Collaborative Clinics), 2010-2012, Phase II and III, 2012
- Hp-MMP 9 levels in humans: a pilot study, 2010
- Concurrent pilot studies in Giant cell arteritis and Takayasu's arteritis to examine the safety, efficacy, and immunologic effects of abatacept (CTLA4-Ig) in large vessel vasculitis, 2010
- Studies of B cell abnormalities in Systemic Lupus Erythematosus via MiRNA, 2010-2011
- Study of Epratuzumab in systemic lupus erythematosus, NCT00383513, 2010
- Duke Autoimmunity Pregnancy Registry (DAP Registry), 2010-2012
- UCB. - Phase 3, multicenter, randomized, double-blind, parallel-group, placebo-controlled study to evaluate the efficacy and safety of certolizumab pegol in subjects with adult-onset active and progressive psoriatic arthritis (PsA), 2010-2011
- UCB - A phase 3, multicenter, randomized, double-blind, placebo-controlled study to evaluate efficacy and safety of certolizumab pegol in subjects with active axial spondyloarthritis (AS001), 2010-2011
- Sanofi Aventis US Inc. - A randomized double blind-placebo controlled dose ranging study to evaluate the efficacy and safety of SAR153191 in patients with Ankylosing Spondylitis (AS). Protocol Number: DRI11073 – ALIGN, 2010-2011
- Cephalon, Inc. - A Randomized, Double-Blind, Parallel-Group, Placebo-Controlled Study to Evaluate the Efficacy and Safety of a 200-mcg Dose of CEP-33457 in Patients with Systemic Lupus Erythematosus, 2010

- TEVA Pharma - A Phase IIa, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety, Tolerability and Clinical Effect of Laquinimod in Systemic Lupus Erythematosus Patients with Active Lupus Arthritis. PROTOCOL LA-LAQ-202, 2010 NCT01085084
- Study of Lymphoma in Systemic Lupus Erythematosus, SLICC (Systemic Lupus International Collaborative Clinics), 2009-2011
- Roche - A randomized, double-blind, parallel group study of the safety and effect on clinical outcome of tocilizumab SC versus tocilizumab IV, in combination with traditional disease modifying anti-rheumatoid arthritis drugs (DMARDs), in patients with moderate to severe active rheumatoid arthritis, 2009
- Cedars Sinai Medical Center, Cross Cultural Spanish Validation of Lupus Pro: A Patient Reported Outcome Measure for Lupus, 2009
- SLICC, Lymphoma Risk in SLE: A Consequence of Immune Suppression or Stimulation? 2009-Lupus Clinical Trials Consortium, Inc., LCTC Lupus Data Registry, 2009-2010.
- Roche Laboratories Inc. ML22533/A, an open-label, randomized study to evaluate the safety, tolerability and efficacy of tocilizumab (TCZ) monotherapy or TCZ in combination with non-biologic disease modifying antirheumatic drugs (DMARDs) in patients with active rheumatoid arthritis who have an inadequate response to current non-biologic or biologic DMARDs, 2009-2011.
- Array BioPharma Inc. 797-201, A Phase 2, Randomized, Double-Blind, Multicenter, Placebo-Controlled, Parallel-Group Study To Investigate The Safety, Efficacy, Pharmacokinetics and Pharmacodynamics Of 12 Weeks Of Treatment With ARRY-371797 In Patients With Active Ankylosing Spondylitis And Inadequate Response To Conventional Therapy, 2009
- Immune Tolerance Network: Protocol ITN034AI, A randomized, double-blind, controlled, phase II Multicenter trial of CTLA4Ig (Abatacept) Plus Cyclophosphamide vs Cyclophosphamide Alone in the Treatment of Lupus Nephritis, 2009-2010
- Crescendo Bioscience, Inc. CR10, Index for Rheumatoid Arthritis Measurement (InFoRM) Study, 2009
- Amgen (AMG 827) 20070264, A Randomized, Double-blind, Placebo-controlled, Ascending Multiple-dose Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Efficacy of AMG 827 in Subjects with Rheumatoid Arthritis, 2009-2010
- Genentech IFN4575g, A phase II, Randomized, Double-blind, placebo-controlled study to evaluate the efficacy and safety of Rontalizumab (rhuMAb IFNalpha) in patients with moderately to severely active Systemic Lupus Erythematosus, 2009
- Novo Nordisk NN8360-3559, A randomized, double-blind, placebo-controlled, single dose-escalation and multiple dose extension trial of NNC 0152-0000-0001 administered i.v. or s.c. in subjects with Systemic Lupus Erythematosus, 2009
- UCB C87094, A Phase IIIB, multi-centre study with a 12-week double-blind, placebo-controlled, randomized period, followed by an open-label extension phase to evaluate the safety and efficacy of certolizumab pegol administered to patients with active rheumatoid arthritis, 2008-2010
- BMS IM 101-167, A Phase IIIB, Multicenter, Randomized, Withdrawal study to evaluate the Immunogenicity and safety of Subcutaneously Administered Abatacept in Adults with Active Rheumatoid Arthritis, 2008
- Human Genome Sciences C1066, A Multi-Center, Continuation Trial of Belimumab (HGS1006, LymphoStat-B\_), a Fully Human Monoclonal Anti-BLyS Antibody, in Subjects with Systemic Lupus Erythematosus (SLE) who Completed the Phase 3 Protocol HGS1006-C1056 in the United States, 2008

- UCB SL0007, A Phase IIB, Randomized, Double Blind, Placebo controlled, dose and dose regimen-ranging study of the Safety and Efficacy of Epratuzumab in Serologically-positive Systemic Lupus erythematosus patients with Active Disease, 2008-2009
- The systemic lupus erythematosus (SLE) activity gene expression (SAGE) study, XDx protocol SL 105, 2007-2009
- BMS Lupus Nephritis IM 101-075, A sequential adaptive phase II/III multi-center, randomized, double-blind, placebo controlled study to evaluate the efficacy and safety of Abatecept versus Placebo on a background of Mycophenolate Mofetil and Glucocorticoids in subjects with active Proliferative Glomerulonephritis due to Systemic Lupus Erythematosus (SLE), 2007
- Human Genome Sciences C1056, A Phase 3, Multi-Center, Randomized, Double-Blind, placebo-controlled, 76-Week Study to Evaluate the Efficacy and Safety of Belimumab (HGS1006, LymphoStat-B™), a Fully Human Monoclonal Anti-Bly Antibody, in Subjects with SLE, 2007-2010.
- MedImmune MPI-CP152, A Phase IB, Multicenter, Randomized, Double-blind, Placebo-controlled, dose escalation study with an open label extension to evaluate the safety and tolerability of multiple intravenous doses of MEDI-545, a fully human Anti-Interferon-Alpha Monoclonal Antibody, in patients with Systemic Lupus Erythematosus 2007-2010.
- UCB SL0006, An Open-Label Re-Treatment Trial for Patients Previously Randomized into the SL0003 and SL0004, Randomized, Double-Blind, Placebo-Controlled, Multi-Center Studies of Epratuzumab in patients with SLE, 2007
- Genentech IFN 3958g, A Phase I, Randomized, Double-blind, Placebo-controlled, escalating single and multiple dose study of the safety, tolerability, and Pharmacokinetics of rhuMAB IFNalpha in adults with mildly active SLE, 2007-2009.
- A Multi Center, open label, continuation trial of lymphostat b antibody (monoclonal anti-bly antibody) in subject with Systemic Lupus Erythematosus (SLE) who completed the phase 2 protocol lbsl02. Protocol LBSL9, Human Genome Sciences, 2006
- “A Phase III, Randomized, Double-Blind, Placebo Controlled, Multicenter study to evaluate the Efficacy and Safety of Rituximab in Subjects with ISN/RPS Class III or IV Lupus Nephritis” Protocol Lunar, Genentech, 2006-2008
- MedImmune, 2006-2008
- A Phase I, Randomized, Double-Blind, Placebo-Controlled, Dose-Escalation Study to Evaluate Safety and Tolerability of a Single IV Dose of MEDI-545, a Fully Human Monoclonal Antibody Directed Against Interferon Alpha Subtypes, in Patients Who Have Mild System Lupus Erythematosus (SLE) With Cutaneous Involvement. Protocol MI-CP126, An Exploratory study to characterize biomarker assays in healthy subjects and in subjects with Rheumatoid Arthritis. Protocol 92005637, Amgen 2006-2007
- A Phase III, Multicenter, Open-Label, Continuation Trial of LymphoStat-B Antibody (Monoclonal Anti-BLys Antibody) in Subjects with Rheumatoid Arthritis (RA) who Completed the Phase II LBRA 01. Protocol LBRA99, Human Genome Sciences, 2006-2009
- A Phase 2 study to evaluate the safety, tolerability and activity of fontolizumab (HuZaf) in patients with active rheumatoid arthritis, Protocol ZAF-711, sponsored by Protein Design Labs, Inc (PDL), 2006-2007
- Immunomedics, 2005-2006
- A Phase III, Randomized, Double-Blind, Placebo Controlled, Multi-Center study of Epratuzumab in Patients with Active Systemic Lupus Erythematosus. Protocol Immu-103-03, 2005-2009

- A randomized, double-blind, parallel group, international study to evaluate the safety and efficacy of Ocrelizumab compared to placebo in patients with active Rheumatoid Arthritis continuing Methotrexate treatment. Protocol WA20494/ACT3985g, Genentech, 2005- 2007
- Genmab, 2005-2007
- A double-blind, randomised, placebo controlled, dose escalating, multi-center phase I/II trial of HuMax-CD20, a fully human monoclonal anti-CD20 antibody, in patients with active rheumatoid arthritis who have previously failed one or more disease modifying anti-rheumatic drugs. Protocol Hx-CD20-403, 2005
- A randomized, double-blind, placebo-controlled study to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of AMG 623 following multidose administration in subjects with SLE, Amgen, 2005-2006
- A Phase Ib, multi-centre, double-blind, placebo-controlled, dose-escalating, single dose study to assess the safety, pharmacokinetics and pharmacodynamics of TACI-Fc5 when administered subcutaneously to patients with SLE, Serono, 2005-2006
- A Phase 2, Multi-Center, Double-Blind, Placebo-Controlled, Dose-Ranging Study to Evaluate the Safety, Tolerability, and Efficacy of LymphoStat-B™ Antibody (Monoclonal Anti-BLyS Antibody) in Subjects with Systemic Lupus Erythematosus (SLE), Human Genome Sciences, 2005-2007
- A phase III, Randomized, Double blind, Placebo controlled, multi center study of Epratuzumab in patients with acute severe SLE Flares Excluding the Renal or Neurologic Systems, Immunomedics, 2005-2006
- A Multi national, Multi center, randomized, double blind, placebo controlled, multiple dose, four arm study to assess the efficacy, tolerability and safety, of three different doses of Edratide (TV-4710) Subcutaneous injections in SLE patients, TEVA, 2005-2007
- A Randomized, Double-Blind, Placebo-Controlled Multicenter Phase II/III Study to Evaluate the Efficacy and Safety of Rituximab in Subjects with Moderate to Severe SLE, Genentech, 2005-
- A Phase IIB MultiCenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Abatacept in Combination Therapy with Glucocorticosteroids vs. Placebo plus Glucocorticosteroids in the Treatment of Active SLE and the Prevention of Subsequent Lupus Flares, BMS, 2005-2007
- Amgen B cell: An exploratory study to characterize the variability in circulating B cell populations in subjects with systemic lupus erythematosus (SLE), 2004-2006
- Orphan Medical, Inc.: Protocol OMC-SXB-26: Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multi- Center Trial Comparing the Effects of Orally Administered Xyrem (sodium oxybate) with Placebo for the Treatment of Fibromyalgia, 2004-2005
- Phase 1 Single Ascending Dose Study of the Safety, Pharmacokinetics, and Pharmacodynamics of TRU-015 Administered Intravenously in Subjects with Rheumatoid Arthritis. Protocol 15001, Trubion 2004
- Scios: Protocol B007: A 24-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of the Efficacy of Oral SCIO-469 in Subjects with Active Rheumatoid Arthritis Who are not Receiving DMARDS Other than Hydroxychloroquine, 2004-2006
- LJP: Protocol 394-90-14: A Randomized, Double-Blind, Placebo-Controlled, Four-Arm Parallel-Group, Multicenter, Multinational Safety and Efficacy Trial of 100mg and 300mg of LJP 394 in Systemic Lupus Erythematosus (SLE) Patients with a History of Renal Disease, 2004-2007.
- Wyeth Research: Protocol 3140A1-200-WW: A Double-Blind, Placebo-Controlled, Parallel, Randomized Study to Evaluate the Efficacy and Safety of 3 Oral Dose Levels of TMI-005 in Subjects with Active Rheumatoid Arthritis on a Background of Methotrexate, 2004-2005.

- Prometheus Imuran SLE: An Open Label Safety and Efficacy Trial of Imuran for Patients with Systemic Lupus Erythematosus, 2004-2006
- Bio-rad, Collection of Prospective Samples for Investigational Studies of Bio-Rad BioPlex 2200 ANA Screen on the BioPlex 2200, 2004
- SLICC (Systemic lupus erythematosus International Coordinating Committee) Registry for Human Genome Science, LBRA01, A Phase 2, Multicenter, Double-Blind, Placebo-Controlled, Dose-Ranging Study to evaluate the safety, tolerability and Efficacy of LymphoStat-B™ (LSB) in subjects with RA, 2004-2005
- Atherosclerosis, 2003, Registry for central nervous system lupus, 2003
- Abbott, M02-537, A Multicenter continuation trial for Patients Completing Study M02-518 and M02-570 of the Human Anti-TNF Monoclonal Antibody Adalimumab (D2E7) in Patients with Moderate to Severely Active Psoriatic Arthritis, 2003-2006
- Prometheus, 03-MTX-02, Measurement of Methotrexate and Folate Polyglutamate Levels and MTHFR Polymorphisms in a Cross-Section of Rheumatoid Arthritis Patients to Assess Correlations of Toxicity and Efficacy, 2003-2006
- Novartis, CCOX189A2335, A 13-Week, multicenter, international, randomized, double-blind, placebo-controlled, parallel-group study of COX189 200mg in patients with rheumatoid arthritis using naproxen 500mg b.i.d. as comparator, 2003-2004
- IDEC, 102-20/WAI17042, A Randomized, Placebo-Controlled, Double-Blind, Multicenter Study to Evaluate the Safety and Efficacy of Rituximab in Combination with MTX in Subjects with Active Rheumatoid Arthritis Who have had an inadequate Response to MTX and Anti-TNFalpha Therapies 2003
- Glaxo Smith Kline, CXA20006, A Multicenter, Randomized, Double-Blind, Placebo and Active-Controlled, Phase 2, Parallel Group, dose-ranging Finding study To assess the Safety and efficacy of GW406381 Administered For 42 days to Subjects with Rheumatoid Arthritis, 2003-2005
- Amgen MRI, The use of MRI to Describe and Identify the Early Findings Leading to Foot Erosions in High Risk Subjects with Rheumatoid Arthritis, 2003
- Centocor OPPOSITE, Open label, Pilot Protocol of Patients with Rheumatoid Arthritis who switch to Infliximab after incomplete response to etanercept, 2003-2005
- Centocor, A multicenter, double-blind trial of anti TNF alpha chimeric monoclonal antibody (Infliximab) for the treatment of subjects with psoriatic arthritis, 2003-2005
- Cipher Canada, A double-blind, randomized, placebo-controlled, multi-dose, Phase III, parallel group study of Tramadol ER in the relief of signs and symptoms of osteoarthritis of the hip and knee, 2003-2005
- Genelabs, The use of GL701 in the prevention of osteoporosis in patients on corticosteroids with lupus erythematosus, 2003-2005
- Amgen, Rheumatoid arthritis DMARD intervention and utilization study (RADIUS 2), 2002-2005
- Abbott, A multicenter study of the safety of human anti-TNF monoclonal antibody D2E7 in subjects with active rheumatoid arthritis, 2002
- Janssen Pharmaceutica Products, L.P., CIS-USA-154, Limited access protocol for the use of oral cisapride in the treatment of refractory gastroesophageal reflux disease and other gastrointestinal motility disorders, 2002-2005
- Scios, Inc., 782.344, A Phase II, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Dose-Escalating Study of SCIO-469 in Patients with Active Rheumatoid Arthritis Receiving Methotrexate, 2002-2004



- Isis Pharmaceuticals, Inc., ISIS 104838-CS7, A Double-blind, placebo-controlled, randomized trial of the safety, efficacy, and pharmacokinetic profile of ISIS 104838 (TNF<sup>®</sup>- antisense oligonucleotide) subcutaneous injections in active rheumatoid arthritis patients, 2002-2004
- Amgen, Inc., 20020103 KONTROL, Psychometric Assessment of the Cedars-Sinai Health Related Quality of Life (CSHQ- RA) Instrument in Rheumatoid Arthritis Subjects Receiving Kineret<sup>®</sup> (Anakinra) Therapy, 2002-2003.
- Immunex Corporation, 016.0037, Multicenter, Double-blind, Placebo-Controlled, Randomized Phase 3 Study of Etanercept in the Treatment of patients with Ankylosing Spondylitis, 2002-2003
- Immunex Corporation, 016.0034, Rheumatoid Arthritis DMARD Intervention and Utilization Study (RADIUS 1), 2001-2003. Immunex Corporation, 016.0036, Phase 3 Randomized, Double-Blind, Placebo-controlled Study of 50mg Etanercept (Enbrel<sup>®</sup>) Administered SC Once Weekly in Patients with Active Rheumatoid Arthritis, 2002-2003
- Cypress Bioscience, Inc., FMS-021, A Phase II, Multicenter, Double-Blind, Randomized, Placebo-Controlled Study of Milnacipran for Treatment of Fibromyalgia, 2002-2003.
- XOMA, HURA 501.02, A Phase II, Double-blind, Placebo-controlled Study to Determine the Safety, Efficacy, Pharmacokinetics and Pharmacodynamics of Efalizumab in Subjects with Moderate to Severe Rheumatoid Arthritis on a Stable Dose of Methotrexate, 2002-2004
- Centocor, START Protocol CO1168T41, A randomized, double-blind trial of the safety of TNF-alpha chimeric monoclonal antibody (Infliximab) in combination with methotrexate compared to methotrexate alone in patients with rheumatoid arthritis on standard disease modifying anti-rheumatic background therapy, 2001-2003.
- Optime Therapeutics, LEDA.C.001, A phase II study of the safety and efficacy of topical liposome-encapsulated diclofenac analgesic (LEDA) in patients with osteoarthritis of the knee, 2001-2002
- Pharmacia, 872-IFL-0513-004, Clinical protocol for a double-blind, placebo-controlled, randomized six week comparison study for the efficacy of valdecoxib 20 mg q d and rofecoxib 25 mg q d in relieving the signs and symptoms of osteoarthritis of the knee, 2001-2002
- Proctor and Gamble, The effect of testosterone patch on activity of systemic lupus erythematosus, 2001
- Knoll, DE020, A multicenter 2 year continuation study of the human anti-TNF antibody D2E7 administered as a subcutaneous injection in patients with rheumatoid arthritis, 2001
- Vertex, VX00-745-102, A 12 week, randomized, double-blind, placebo-controlled, dose-ranging study of VX-745 in patients with rheumatoid arthritis, 2001-2002
- Allergan, 192371-011-01, A multicenter, double masked, randomized, vehicle controlled parallel group study of the safety and efficacy of cyclosporin ophthalmic emulsion used twice daily for 6 months in patients with moderate to severe keratoconjunctivitis, 2001-2002
- Amgen, 2000223, A multicenter double-blind study to evaluate the safety and efficacy of anakinra (r0metHul IL-ra) and etanercept in subjects with rheumatoid arthritis using methotrexate, 2001
- Bristol-Myers Squibb, IM 101-101, A multicenter, randomized, double-blind, placebo controlled study to evaluate the safety and efficacy of intravenous infusions of BMS-188667 given monthly in combination with sub-cutaneous injections of etanercept given twice weekly to subjects with active rheumatoid arthritis, 2001-2008
- Hoffman-LaRoche, WA15541c, A double-blind, randomized, placebo controlled study to evaluate the safety and efficacy of Ro32-3555 (Trocade) as adjunct to background antirheumatoid therapy, in preventing structural damage in rheumatoid arthritis, 2000-2002

- Centocor, MEDIII Pso-A-1, A multicenter placebo, controlled, double blind, randomized study of anti-TNF chimeric monoclonal antibody (cA2, infliximab) in patients with active psoriatic arthritis, 2000-2002
- La Jolla Pharmaceuticals, LJP 394-90-09, A randomized, double-blind, placebo-controlled, multicenter safety and efficacy trial of LJP 394 in systemic lupus erythematosus (SLE) patients with a history of renal disease, 2000-2002
- Knoll DE013, A prospective multicenter randomized double-blind active comparator-controlled parallel-groups study comparing the fully human monoclonal antibody TNF alpha antibody D2E7 every second week with methotrexate given weekly and the combination of D2E7 and methotrexate administered over 2 years in patients with early rheumatoid arthritis, 2000-2008
- Knoll, Study of New Onset Rheumatoid Arthritis (SONORA), 2000-2006
- Knoll DE031: A multicenter randomized double-blind placebo-controlled study of the safety of human anti-TNF monoclonal antibody D2E7 in patients with active rheumatoid arthritis, 2000-2008
- Fujisawa, a randomized double-blind placebo controlled study to assess the efficacy and safety of prograf (tacrilimus) in the treatment of rheumatoid arthritis in patients who have failed one or more disease modifying antirheumatic drugs, 2000-2002
- Amgen, A double-blind extension study to provide treatment with PEGylated recombinant human methionyl soluble tumor necrosis factor Type I (PEG sTNF-R1) to subjects completing trials TNF 980246 and TNF 990136, 2000 Fujisawa, An open-label, long-term study to evaluate the safety of Prograf (tacrilimus) for the treatment of rheumatoid arthritis, 2000-2002
- Knoll, A multicenter Phase II study of the human anti-TNF antibody D2E7 administered as subcutaneous injections in rheumatoid arthritis patients treated with methotrexate, 2000-2001
- Merck, A randomized, placebo-controlled, parallel group, double-blind study to evaluate the safety and efficacy of rofecoxib 25 mg and celecoxib 200 mg in patients with osteoarthritis of the knee or hip, 2000
- Knoll, A multicenter randomized placebo-controlled Phase II study of the human anti-TNF D2E7 administered as subcutaneous injections in rheumatoid arthritis patients treated with methotrexate, 1999-2001
- Searle, Clinical protocol of a multicenter, double-blind, placebo-controlled randomized, comparison study of the efficacy and safety of 3 valdecoxib doses and naproxen in treating the symptoms and signs of rheumatoid arthritis, 1999-2001
- Searle, Clinical protocol to evaluate the long-term safety of valdecoxib in treating the signs and symptoms of rheumatoid arthritis, 1999-2001
- Cypress, A post approval, market preference, unblinded general experience study to gather additional information about the ProSORBA column in general rheumatology practice settings, 1999-2000
- Centocor, An open-label trial of anti-TNF chimeric monoclonal antibody Infliximab in patients with active rheumatoid arthritis, 1999-2000
- IDEC, Phase II randomized, double blind, placebo-controlled, multiple center, multiple dose, dose finding safety, tolerance and efficacy study of IDEC-131 in patients with active SLE, 1999-2000
- Anergen, A phase I double blind, randomized placebo controlled, dose escalation study to evaluate the safety, tolerability and biological activity of a 2-week induction course and 1 maintenance cycle of AG 4263 in subjects with rheumatoid arthritis, 1999-1999
- Biogen C99-1021, An open label, multiple dose study to evaluate the efficacy, safety and pharmacokinetics of BG 9588 (anti CD40 antibody) in subjects with proliferative lupus glomerulonephritis, 1999-2001

- Zeneca, Randomized, double blind placebo controlled, parallel group multicenter trial to assess the analgesic efficacy and tolerability of treatment with multiple doses of 1600 mg ZD6416 bid compared with treatment with placebo in patients with osteoarthritis of the hip or knee, 1999-1999
- Merck, Randomized, double-blind multicenter study to evaluate tolerability and effectiveness of rofecoxib (MK-0966) 25 mg/d vs naproxen 500 mg bid in patients with osteoarthritis, 1999-2000
- Merck, An active comparator and placebo controlled, parallel group, double-blind 52 week study to assess safety and efficacy of MK-0966 in rheumatoid arthritis patients, 1999-2000
- Amgen, A randomized, placebo controlled double-blind, multicenter, dose-finding study to evaluate the safety and efficacy of weekly administration of PEGylated recombinant methionyl human soluble tumor necrosis factor receptor Type I (PEGsTNF-RI) in patients with rheumatoid arthritis, 1999-2000
- Roche, Randomized, double-blind trial of Ro32-3555 (Trocade) for rheumatoid arthritis, 1998-2000
- Smith Kline, SB 217969/Clenolixib (Open Label), for rheumatoid arthritis 1998-1999
- La Jolla Pharmaceuticals/Abbott, LJP 394 for Lupus nephritis, open label #90-11, 1998-2000  
Merck, MK-0966 for osteoarthritis, 1998-1999
- Smith Kline, SB 217969/Clenolixib for Rheumatoid Arthritis, 1998-1999
- Biogen, Anti-CD40L therapy for lupus nephritis, 1998-1999
- Merck, MK-0966 for Rheumatoid Arthritis, 1998
- Boehringer-Ingelheim, Meloxicam for Rheumatoid Arthritis, 1998-1999  
Boehringer-Ingelheim, Meloxicam for Osteoarthritis, 1998-1999
- Immunex, Open-label trial of TNA-alpha (Enbrel) for Rheumatoid Arthritis, 1997
- Immunex, Double-blind trial of TNF-alpha (Enbrel) for Rheumatoid Arthritis, 1997-1999
- Genelabs, Dehydroepiandrosterone (DHEA) for Lupus, 1994-1997, an open label and double-blind trial  
La Jolla Pharmaceuticals, LJP 394 for Lupus Nephritis, 1996-1999, Double-blind trial
- Smith-Kline, Namebutone for Osteoarthritis, 1991-1992
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### **Meeting Abstracts:**

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