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

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Personal Information:

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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, Loss 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:

- American College of Rheumatology, Lupus Nephritis Guidelines, 2024-Present
- American College of Rheumatology, SLE Guidelines, 2024-Present
- 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 #2RolAR4252-04, $442,670, 1997-1999
    - "Abnormal IL-6 Production in SLE", Co-investigator with Dr. Mariana Linker-Israeli
- NIH Grant, Agency Award #2RolAR4252-04, $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:

- 219240 BE-EARLY: A Phase 4, multicenter, prospective, open-label study describing the efficacy and safety of belimumab administered subcutaneously in adult participants with early systemic lupus erythematosus, 2024
- 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, 2021-2023IDEAL 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 (SJIA 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 3Study 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-Cantered, 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 erytematosus, 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
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- 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
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- 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, Dynaxax, 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
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- 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
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- 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

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- 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
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- 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
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- 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
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- 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

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- The systemic lupus erythematosus (SLE) activity gene expression (SAGE) sudy, 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
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- 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.
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- 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
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- 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
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- 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
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- Biogen C99-1021, An open label, multiple dose study to evaluate the efficacy, safety and pharmokinetics 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
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