

VIBEKE STRAND, MD, FACP

**ABIM Subspecialty
Immunology/Rheumatology**

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SUMMARY

I participate in the development of new therapies, planning regulatory strategy and clinical trials that will efficiently demonstrate their safety and efficacy. I also promote a variety of forums for discussion of rational product development among industry, FDA, and academia, with more than twenty five years of experience in clinical immunology include positions as clinical investigator and subspecialist in private practice, clinical research positions in pharmaceutical and biotechnology firms and as a consultant; planning and overseeing new product development in autoimmune diseases, AIDS, transplantation and cancer. I am an Adjunct Clinical Professor in the Division of Immunology/Rheumatology at Stanford University.

PROFESSIONAL HISTORY

9/91 to Present CONSULTANT – Portola Valley, CA

My expertise includes defining regulatory strategies and efficient clinical development programs for novel therapies for autoimmune diseases. I help to design, review and evaluate protocols, clinical development programs, analyze and interpret data, and facilitate interactions with US Food and Drug Administration (FDA).

- Preparation of Investigational New Drug Applications (INDs) for biologic and pharmaceutical agents, Investigational Device Exemption (IDEs) and 510 (k) applications for devices; clinical plans for product approval and operating budgets; initiation, monitoring and completion of phase I, II and III clinical trials in both US and Europe; preparation of end of phase II and pre-NDA, BLA summaries, final reports and integrated summaries of efficacy and safety (NDAs, BLAs, CTDs) as well as manuscripts.
- Regular interactions with FDA, Center for Drug Evaluation and Research (CDER), Center for Devices and Radiologic Health (CDRH) and former Center for Biologics Evaluation and Research (CBER). Preparation of applications and support of detailed review processes, including presentations of phase I–III data. Strategic planning, supervision and completion of clinical development of Arava™ in RA in US: design, initiation, completion of US301 trial; preparation; successful defense at FDA AAC of NDA [1998]; labeling for improvement of physical function/HRQOL over 2 years treatment [2003]. Similar support for Humira™ BLA in RA [2002], Cimzia™ BLA in RA [2007-8], Actemra™ BLA in RA [2007-8], Savella™ NDA in FMS [2008] and Krystexxa™ in Treatment Failure Gout [2009]. Preparation of briefing documents and data presentation for successful defense of NDA and BLA applications, including: Ganciclovir™ in CMV; Cellcept™ in transplantation; CD5 Plus™ in GvHD; Neoral™ in RA; Ontak™ in CTCL, Arava™ in RA; Celebrex™ and Bextra™ in RA, OA; Remicade™ in RA x-ray; Kineret™ in RA; Humira™ in RA; Actemra™ in RA; Supartz™ in OA, Krystexxa™ in Treatment Failure Gout, and Benlysta™ in SLE [2010]. Similar efforts for Prasterone™ NDA in SLE, unsuccessful FDA AAC panel, including extensive 'dispute resolution' meetings with FDA; as well as Riqent™ NDA in SLE.
- Participation in FDA meetings designed to develop consensus regarding outcome measures in randomized controlled trials in: Rheumatoid Arthritis, Juvenile Rheumatoid Arthritis, Osteoarthritis, Ankylosing Spondylitis, Systemic Lupus Erythematosus and Systemic Sclerosis. Executive committee member: "Outcome Measures in Rheumatology Clinical Trials: OMERACT 1-8" international consensus conferences, 1992-2008; co-founder and chair: "Biologic Agents in Autoimmune Diseases 1-4", "Innovative Therapies in Autoimmune Diseases 5-8", 1988-2005, co-chair: Clinical Immunology Society Spring Fellows School, 2004-2007; invited participant and/or speaker at NIH Consensus Conferences and FDA Arthritis Advisory Committee meetings.

3/93 to Present STANFORD UNIVERSITY SCHOOL OF MEDICINE – Palo Alto, CA

Adjunct Clinical Professor (9/00 – present), Division of Immunology and Rheumatology
Clinical Associate Professor (3/93 – 9/00)

Attending physician, clinics and in patient consult service and consultations regarding clinical trials.

7/81 to 6/93 UNIVERSITY OF CALIFORNIA SAN FRANCISCO SCHOOL OF MEDICINE – San Francisco, CA

Associate Clinical Professor (7/90 – 6/93)

Assistant Clinical Professor (7/81 – 6/90)

3/90 to 9/91 XOMA CORPORATION – Berkeley, CA

Senior Director of Clinical Research, Clinical Immunology

5/88 to 2/90 APPLIED IMMUNE SCIENCES, INC. – Menlo Park, CA

Director of Clinical Research

- 5/86 to 5/88** **SYNTEX RESEARCH: INSTITUTE OF CLINICAL MEDICINE – Palo Alto, CA**
Head, Section for Anti-Rheumatic and Immunotherapy (5/87– 5/88)
Associate Medical Director (5/86 – 5/87)
- 7/81 to 5/86** **PRIVATE PRACTICE - SUBSPECIALTY RHEUMATOLOGY/IMMUNOLOGY – San Francisco, CA**
including participation as an investigator in multiple clinical trials
- 7/84 to 5/86** **PHYSICIAN ADVISOR, SAN FRANCISCO PEER REVIEW – CALIFORNIA MEDICAL REVIEW**
San Francisco, CA
- 7/81 to 5/99** **MEDICAL CONSULTANT, RHEUMATOLOGY, SOCIAL SECURITY ADMINISTRATION, DIVISION OF**
DISABILITY SERVICES, US DEPARTMENT OF HEALTH AND HUMAN SERVICES – San Francisco, CA
- 4/78 to 6/79** **PHYSICIAN SUPERVISOR, CARDIAC REHABILITATION PROGRAM – Lansing, MI**
- 8/77 to 6/79** **PHYSICIAN, PLASMAPHERESIS PROGRAM, GREAT LAKES REGIONAL BLOOD PROGRAM, AMERICAN RED**
CROSS – Lansing, MI

EDUCATION

- 7/79 to 6/81** **UNIVERSITY OF CALIFORNIA SAN FRANCISCO SCHOOL OF MEDICINE – San Francisco, CA**
Fellowship, Rheumatology/Immunology
- 7/76 to 6/79** **MICHIGAN STATE UNIVERSITY – East Lansing, MI**
PGY I – III Internal Medicine Residency, Primary Care
- 1976** **MD, UNIVERSITY OF CALIFORNIA SAN FRANCISCO SCHOOL OF MEDICINE – San Francisco, CA**
- 1971** **BA, SWARTHMORE COLLEGE – Swarthmore, PA.**
Zoology & Sociology/Anthropology (with honors in both majors)

BOARDS and LICENSURE

- 1982** Diplomate, American Board of Internal Medicine, Subspecialty Rheumatology/Immunology
- 1979** Diplomate, American Board of Internal Medicine
- 1977** National Board of Medical Examiners – State of California; State of Michigan

AWARDS

- 1982** Who's Who in Science and Engineering
- 1981** Associate Investigator, Veterans Administration
- 1981** Postgraduate Fellow, Arthritis Foundation

SOCIETIES

- Member, Cosmos Club, Washington DC 1994
- Fellow, American College of Physicians 1984
- Fellow, American College of Rheumatology
- Member, Clinical Trials Steering Committee 1991; Clinical Studies Workshop 1996-7;
Research and Education Fund 1999-2002; Annual Meeting Planning Committee 2000-3;
Abstract Selection Committee 2000-2, 2007—
- Member, International League of Associations for Rheumatology
- Member, PANLAR Epidemiology Sub-Committee 1993-1994
- Member, American Association for the Advancement of Science
- Member, Clinical Immunology Society; Meeting Planning Committee, FOCIS: 2001-3
- Co-chair: Fellows' Spring School in Autoimmune Diseases: 2004—; Membership committee: 2006—
- Member, American Society for Clinical Pharmacology and Therapeutics
- Member, American Women in Science

BOARDS

- 2005-** Board of Directors, Arthritis Foundation, Northern California Chapter; member Medical and Scientific Committee
- 2004-2008** Board of Directors, Consortium of Rheumatology Researchers of North America: CORRONA
- 1998-2004** Board of Directors, Executive Committee Member at Large, Djerassi Resident Artists Program

PUBLICATIONS

1. Glas-Greenwalt P, Strand V, Astrup: Fibrinolytic Activity in the Closed Ductus Arteriosus. *Experientia* 1972; 28:448-9.
2. Glas-Greenwalt P, Strand V, Astrup T: Plasminogen Activator and Alkaline Phosphatase in Guinea Pig Vessels. *Arch Path Lab Med* 1974.
3. Gossain T, Kinzel T, Strand V, Rovner D: Essential Hyponatremia. *Am.J.Med.Sci* 1978; 8:353-8.
4. Strand V, Talal N: Advances in the Diagnosis and Concept of Sjogren's Syndrome. *Bull Rheum Ds* 1980; 30:1046-52.
5. Strand V, Mayor G, Ristow G, Greenbaum D, Mayle J, Rosenbaum R: Concomitant Renal and Hepatic Failure Treated by Polyacrylonitrile Membrane Hemodialysis. *Inter. J Artif Organs* 1981; 3:136-9.
6. Shillitoe EJ, Daniels TE, Whitcher JP, Strand V, Talal N, Greenspan JS: Antibody to Cytomegalovirus in Patients with Sjogren's Syndrome. *Arth Rheum* 1982; 25:260-5.
7. Bakhshi A, Miyasaka N, Kavathas P, Daniels TE, Strand V, Herzenberg LA, Talal N: Lymphocyte Subsets in Sjogren's Syndrome: A Quantitative Analysis Using Monoclonal Antibodies and the Fluorescence-Activated Cell Sorter. *J Clin Lab Immunol* 1983; 10:63-9.
8. Miyasaka N, Seaman W, Bakhshi A, Sauvezie B, Strand V, Pope R, Talal N: Natural Killing Activity in Sjogren's Syndrome. *Arth Rheum* 1983; 26:954-60.
9. Strand CV, Clark SR: Adult Arthritis: Drugs and Remedies. *American Journal of Nursing* 1983; 83:266-270. (Editor of entire section: For CE Credit: Adult Arthritis), *Am J Nursing* 1983; 83:253-78.
10. Contributor, *Saunders Dictionary and Encyclopedia of Laboratory Medicine and Technology*, Ed. Bennington JL, Saunders WB (several entries: e.g. Beta 2 Microglobulin).
11. Alger W, Strand V: Non-Steroidal Anti-Inflammatory Drugs. *St. Luke's Hospital Drug and Therapeutics Bulletin*, Feb. 1984.
12. Buhles W, Koretz S, Mastre B, Strand V: Ganciclovir Treatment of Life-or-Sight-Threatening Cytomegalovirus Infection: Experience in 314 Immuno-Compromised Patients. *Rev Infect Dis* 1988; 10:S490-94.
13. Strand V: "Trial Design and Concepts Specific to Biologic Agents" in *Proceedings: Early Decisions in DMARD Development II: Biologic Agents in Autoimmune Disease*, Strand V. Ed. Amento E, Scribner C. Assoc Eds. Arthritis Foundation, 1991.
14. Ackerman S, Strand V: "Use of an Anti-CD5 Immunoconjugate in Rheumatoid Arthritis" in *Proceedings: Early Decisions in DMARD Development II: Biologic Agents in Autoimmune Disease*, Strand, V. Ed. Amento E, Scribner C. Assoc Eds. Arthritis Foundation, 1991.
15. Strand V: The Emerging Role of Biologics in Rheumatic Diseases, in "Perspectives in Pediatric Rheumatology". *J Rheum* 1992; 19: 40-5.
16. Olsen N, Teal G, Strand V: In Vivo T Cell Depletion in Rheumatoid Arthritis is Associated with Increased In Vitro IgM Rheumatoid Factor Synthesis. *Clin Immunol Immunopath* 1993; 67:124-9.
17. Strand V, Lipsky P, Cannon G, Calabrese L, Wiesenhutter C, Cohen S, Olsen N: and the CD5 Plus RA Investigators Group: Effects of Administration of an Anti-CD5 Immunoconjugate in Rheumatoid Arthritis: Results of Two Phase II Studies. *Arth Rheum* 1993; 36:620-30.
18. Strand V, Lee ML: CD5 Plus RA Investigators Group: Differential Patterns of Response to Treatment with an Anti-CD5 Immunoconjugate in Patients with Rheumatoid Arthritis. *Clin Exper Rheum* 1993; 11:161-3.
19. Bell RE, Wilke WS, Strand V, et al: Treatment of Rheumatoid Arthritis with Anti-CD5: Possible Synergism between Biologic and Traditional Immunosuppressive Therapy; Submitted.
20. Strand V, for the OMERACT Committee: OMERACT and the Clinical Evaluation of New Therapeutic Agents: A Bird's Eye View. *J Rheum* 1993; 20:588-9.
21. Fishwild D, Strand V: Treatment with an Anti-CD5 Immunoconjugate: Effect on Peripheral T cells and in vitro Assays of Immune Function in Patients with Rheumatoid Arthritis. *J Rheum* 1994; 21:596-604.
22. Stafford FJ, Fleisher TA, Lee G, Brown M, Strand V, Austin III H, Balow JE, Klippel JH: A pilot study of anti CD5 Ricin A chain immunconjugate in Systemic Lupus Erythematosus. *J Rheum* 1994; 21:2068-70.
23. Strand V: Are There Special Considerations Relevant to Trials of Biologic Agents? *J Rheum* 1994; 21: 41-5.
24. Strand V, Scott DL, Panayi GS: Evaluating Biologic Agents in Rheumatoid Arthritis: A Framework for Clinical Trials. Editorial. *J Rheum* 1994; 21:1390-2.

25. Fishwild, D.M.; Strand, V. Administration of an anti-CD5 immunoconjugate to patients with rheumatoid arthritis. Selective decrease in synovial collagenase gene expression. *Arth Rheum* 1994; 37:193-200.
26. Strand V, Keystone E: Biologic Interventions in Rheumatoid Arthritis. *J Biotechnology in Health Care* 1994-5; 1: 283-302 and 1: 377-95.
27. Cannon GW, Marble DW, Griffiths MM, Cole BC, McCall S, Schulman S, Strand V: Immunologic Assessment during Treatment of Rheumatoid Arthritis with Anti-CD5 Immunoconjugate. *J Rheum* 1995; 22:207-13.
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33. Strand V: Conference Summary and Final Comments pp. 233-236. Strand V Ed. Johnson K, Pillemer S. Assoc Eds. Proceedings: Biologic Agents in Autoimmune Disease IV, Arthritis Foundation, Atlanta, GA, 1996.
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35. Strand V: Meeting Report: Innovative Therapies in Autoimmune Diseases. ID Research Alert, Weekly Highlights June 11, 1997:20-25.
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38. Simon L, Strand V: Clinical response to nonsteroidal antiinflammatory drugs. Editorial. *Arth Rheum* 1997; 40: 1940-43.
39. Strand V: Future use of biologic agents alone and in combination for the treatment of rheumatoid arthritis. *J Rheum* 1997; 57:17-49.
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44. Strand V, Gladman D, Isenberg D, Petri M, Smolen J, Tugwell P: Outcome Measures in Clinical Trials in Systemic Lupus Erythematosus. *J Rheum* 1999; 26: 490-7.
45. Smolen J, Strand V, Cardiel M, Edworthy S, Furst D, Gladman D, Gordon C, Isenberg DA, Klippel J, Petri M, Simon L, Tugwell P, Wolfe F: Randomized Clinical Trials and Longitudinal Observational Studies in SLE: Consensus on a Preliminary Core Set of Outcome Domains. *J Rheum* 1999; 26: 504-7.
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47. Strand V, Cohen S, Schiff M, Weaver A, Fleischmann R, Cannon GW, Fox R, Moreland L, Olsen N, Furst D, Sharp J, Loew-Friedrich I, for the Leflunomide RA Investigators Group: Treatment of Active Rheumatoid Arthritis with Leflunomide Compared to Placebo and Methotrexate. *Archives Int Med* 1999; 159:2542-50.

48. Strand V, Tugwell P, Bombardier C, Maetzel A, Crawford B, Dorrier C, Thompson A, Wells G: Function and health related quality of life—results from a randomized controlled trial of leflunomide versus methotrexate or placebo in patients with active rheumatoid arthritis. *Arth Rheum* 1999; 42:1870-8.
49. Strand, V: Biologic Agents and Innovative Interventional Approaches in the Management of SLE. *Curr Opin Rheum* 1999; 11:330-40.
50. Strand V: Advances in the Treatment of Rheumatoid Arthritis. *Clinical Cornerstone* 1999; 2:38-47.
51. Fox RI, Harrmann ML, Grangou CG, Wahl GM, Morris RE, Strand V, Kirschbaum B: Mechanism of Action for Leflunomide in Rheumatoid Arthritis. *Clinical Immunology* 1999; 93:198-208.
52. Isaacs JD, Morgan AW, Strand V: Combination biologic therapy. *Clinical Exper Rheum* 1999; 17:S21-4.
53. Strand V: Comment: Steroid withdrawal favours joint erosion in rheumatoid arthritis. *Clin Exper Rheum* 1999; 17:519-20.
54. Olsen NJ, Strand V, Kremer JM: Leflunomide for the treatment of rheumatoid arthritis. *Bull Rheum Ds* 1999; 48:8.
55. Molenaar ETH, Boers M, van der Heijde DMFM, Alarcon G, Bresnihan B, Cardiel M, Edmonds J, Felson D, Furst D, Kirwan J, Lassere M, Paulus H, Rau R, van Riel PLCM, Scott D, Simon L, Strand V: Imaging in Rheumatoid Arthritis: Results of Group Discussions. *J Rheum* 1999; 26:749-51.
56. Scott DL, Strand V, Hermann ML, Schleyerback R, Kirschbaum BJ: Leflunomide, an immunomodulatory drug for the treatment of rheumatoid arthritis and other autoimmune disease. *Immunopharmacology* 2000; 47:273-89.
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58. Sharp JT, Strand V, Leung H, Hurley F, Loew Friedrich, on behalf of the Leflunomide Rheumatoid Arthritis Investigators Group: Treatment with Leflunomide Slows Radiographic Progression of RA – Results from 3 Randomized Controlled Trials of Leflunomide in Patients with Active Rheumatoid Arthritis. *Arth Rheum* 2000; 43:495-505.
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60. Leung H, Hurley F, Strand V: Issues Involved in a Metaanalysis of RA Radiographic Progression. *J Rheum* 2000; 27: 544-8.
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63. Lipani JA, Strand V, Johnson K, Woodworth T, Furst D, Singh G, Day R, Brooks P For the OMERACT Drug Safety Working Party Editorial: A proposal for developing a large patient population cohort for long-term safety monitoring in rheumatoid arthritis. *J Rheum* 2000; 27:827-30.
64. Molenaar ETM, Boers M, Brooks PM, Simon L, Strand V, Tugwell P: Recent developments for optimal end-points in rheumatoid arthritis clinical studies. *Ds Manage Health Outcomes* 2000; 8:87-97.
65. Haraoui B, Strand V, Keystone E: Biologic Agents in the treatment of rheumatoid arthritis. *Current Pharmaceutical Biotechnology* 2000; 1:217-33.
66. Strand V, Lassere M, van der Heijde D, Johnson K, Boers M: Recent Rheumatoid Arthritis Clinical Trials Using Radiographic Endpoints – Updated research agenda. *J Rheum* 2001; 28:887-9.
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68. Wolfe F, Strand V: Radiography of rheumatoid arthritis in the time of increasing drug effectiveness. *Curr Rheum Reports* 2001; 3:46-52.
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71. Woodworth T, Furst D, Strand V, Kempeni J, Fenner H, Lau CS, Miller F, Day R, Lipani J, Brooks P: Standardizing Assessment of

Adverse Effects in Rheumatology Clinical Trials. Status of OMERACT Toxicity Working Group March 2000: Towards a Common Understanding of Comparative Toxicity/Safety Profiles for Antirheumatic Therapies. *J Rheum* 2001; 28:1163-69.

72. Lipani JA, Strand V, Johnson K, Woodworth T, Furst D, Singh G, Day R, Brooks P and the OMERACT Drug Safety Working Party: A proposal for developing a large patient population cohort for longterm safety monitoring in rheumatoid arthritis. *J Rheum* 2001; 28:1170-3.
73. Welch V, Singh G, Strand V, Fries J, Boers M, Ramey D, Day R, Brooks P, Tugwell P, Clinch J, Kristjansson: Patient based method of assessing adverse events in clinical trials in rheumatology: the revised Stanford Toxicity Index. *J Rheum* 2001; 28:1188-91.
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77. Maetzel A, Strand V, Tugwell P, Wells G, Bombardier C: Economic comparison of leflunomide and methotrexate in patients with active rheumatoid arthritis. *Pharmacoeconomics* 2002; 20:61-70.
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79. Strand V, Hochberg M: The Risk of Cardiovascular Thrombotic events with selective Cyclooxygenase-2 Inhibitors. *Arth Rheum* 2002; 47:349-55.
80. Scott DL, Strand V: The effects of disease modifying anti-rheumatic drugs on the HAQ score. Lessons from the leflunomide clinical trials database. *Rheumatology* 2002; 41: 899-909.
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82. Strand V, Landewe R, van der Heijde D: Using estimated yearly progression rates to compare radiographic data across recent randomized controlled trials in rheumatoid arthritis. *Ann Rheum Ds* 2002; 61: ii64-ii66.
83. Strand V: Invited Editorial: Predictors and outcomes of scleroderma renal crisis: data from the high dose vs low dose D-penicillamine in early diffuse systemic sclerosis trial, *Arth Rheum* 2002; 46:2836-7.
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85. Strand V, Sharp J: Radiographic Data from recent randomized controlled trials in rheumatoid arthritis: what have we learned? *Arth Rheum* 2003; 48:21-34.
86. Alarcon-Segovia D, Tumlin J, Furie RA, McKay J, Cardiel MH, Strand V, Bagin RG, Linnik MD, Hepburn B and the LJP 394 investigator Consortium: LJP 394 for the prevention of renal flare in patients with systemic lupus erythematosus: results from a randomized, double blind, placebo controlled study. *Arth Rheum* 2003; 48: 442-54.
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88. Pincus T, Strand V, Koch G, Amara I, Crawford B, Wolfe F, Cohen S, Felson D: An index of the three core data set patient questionnaire measures distinguishes efficacy of active treatment from that of placebo as effectively as the ACR 20% response criteria (ACR20) or the disease activity score (DAS) in a RA clinical Trial. *Arth Rheum* 2003; 48: 625-30.
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91. Strand V, Simon LS: Use of low dose glucocorticoid therapy in early rheumatoid arthritis. *Clin Exp Rheum* 2003; 21:S186-90.
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