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## Summary

Physician with 20 years of full time experience in clinical pharmacology research as an Investigator (over 350 studies), Medical Director of clinical research units devoted to Phase I studies, and consultant. Consulting activities focus on clinical study design for first-in-human through proof of concept studies, protocol development and writing, and medical monitoring.

## Education

- 1984      Mayo Clinic, Rochester, MN  
Internal Medicine Residency
- 1980      Loma Linda University School of Medicine, Loma Linda, CA  
Medical School
- 1973      Pacific Union College, Angwin, CA  
BA

## Professional Experience

- 07/2008-present      Principal and Founder  
Pacific Pharma Group, LLC  
Kailua, HI and Tacoma, WA
- 08/11- 12/13      Assistant Clinical Professor  
John A. Burns School of Medicine, University of Hawaii, Honolulu, HI
- 07/11-07/13      Medical Director, Early Development  
Comprehensive Clinical Development Inc., Tacoma, WA
- 07/08-12/09      Senior Investigator  
Hawaii Clinical Research Center, Honolulu, HI
- 05/06-07/08      Medical Director  
Covance Clinical Research Unit, Honolulu, HI

08/00-05/06 Associate Medical Director and Medical Director  
Radiant Research Unit, Honolulu, HI

09/95-07/00 Medical Director and co-founder  
Northwest Kinetics, Tacoma, WA

06/91-08/95 Private Medical Practice and Teaching  
Tacoma Family Internal Medicine (UW Affiliation), Tacoma, WA

03/87-06/91 Private Medical Practice  
Western Clinic, Tacoma, WA

06/86-03/87 Associate Chief, Internal Medicine (Stanford Affiliation)  
Santa Clara Valley Medical Center, San Jose, CA

07/84-06/86 Private Medical Practice  
Bunn Community Health Center, Bunn, NC

**Licenses/Certifications**

Certified Physician Investigator	ACRP	09/13
MD24572 M.D.	WA, USA	04/17
MD11129 M.D.	HI, USA	01/16

DEA current, number available upon request

0907022 Diplomat in Internal Medicine, American Board of Internal Medicine	USA	no exp.
241738 Diplomat of the National Board of Medical Examiners	USA	no exp.

**Professional Memberships**

Drug Information Association (DIA)  
American College of Clinical Pharmacology (ACCP)

**Professional Presentations, Articles, Papers**

09/12	Antimicrob Agents Chemother. 2012	Chinsangaram J, Honeychurch KM, Tyavanagimatt SR, Leeds JM, Bolken TC, Jones
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	Sep;56(9):4900-5	KF, Jordan R, Marbury T, Ruckle J, Mee-Lee D, ross E, Lichtenstein I, Pickens M, Corrado M, Clarke JM, frimm AM, Hruby DE. "Safety and pharmacokinetics of the anti-orthopoxvirus compound ST-246 following a single daily oral dose for 14 days in human volunteers."
03/11	Br J Clin Pharmacol 71(3):429-36	Herman GA, Mistry GC, Yi B, Bergman AJ, Wang AQ, Zeng W, Chen L, Snyder K, Ruckle JL, Larson PJ, Davies MJ, Langdon RB, Gottesdiener KM, Wagner JA. "Evaluation of pharmacokinetic parameters and dipeptidyl peptidase-4 inhibition following single doses of sitagliptin in healthy, young Japanese males."
08/10	J Pain Symptom Manage 40(4):510-9 Epub	Masud S, Wasnich RD, Ruckle JL, Garland WT, Halpern SW, Mee-Lee D, Ashburn MA, Campbell JC. "Contribution of a heating element to topical anesthesia patch efficacy prior to vascular access: results from two randomized, double-blind studies."
4q/09	Cardiovasc Ther 27(4):239-45	Schwartz JI, Stroh M, Gao B, Liu F, Rosko K, Zajic S, Meehan AJ, Ruckle J, Lai E, Wagner JA. "Effects of laropiprant, a selective prostaglandin D(2) receptor 1 antagonist, on the pharmacokinetics of Rosiglitazone."
08/09	N Engl J Med. 361(8):756-65	Cummings SR, San Mart J, McClung MR, et al. FREEDOM Trial, "Denosumab for prevention of fractures in postmenopausal women with osteoporosis."
04/09	J Bone Miner Res. 24(4):744-52	Ruckle J., Jacobs M, Kramer W, Pearsall AE, Kumar R, Underwood KW, Seehra J, Yang Y, Condon CH, Sherman ML., "Single-dose, randomized, double-blind, placebo-controlled study of ACE-011 (ActRIIA-IgG1) in postmenopausal women."
06/08	Pediatr Int. 50(3):295-9	Scott D, Ruckle J, Dar M, Baker S, Kondoh H, Lockhard S. "Phase I trial of 13-valent pneumococcal conjugate vaccine in Japanese adults."
09/07	J Pharm Sci.	Vuong LT, Ruckle JL, Blood AB, Reid MJ, Wasnich RD, Synal HA, Dueker SR. "Use of accelerator mass spectrometry to measure the pharmacokinetics and peripheral blood

mononuclear cell concentrations of zidovudine.”

09/07	29 <sup>th</sup> annual meeting of American Society for Bone and Mineral Research	J. Ruckle, M. Jacobs, W. Kramer, R. Kumar, K. Underwood, R.S. Pearsall, A.E. Pearsall, J. Seehra, C. Condon, M.L. Sherman. “A Single Dose of ACE-011 is Associated with Increases in Bone Formation and Decreases in Bone Resorption Markers in Healthy, Postmenopausal Women.”
2005	Alzheimer Research 2, 483-492	Nigel H. Grieg, Jon Ruckle, Patrick Comer, Lidia Brownell, et al, “Anticholinesterase and Pharmacokinetic Profile of Phenserine in Healthy Elderly Human Subjects.”
06/05	Diabetes Technology & Therapeutics Vol 7, No. 3:467-477	Poon, Terri, Nelson Patric, Shen Larry, et al., “Exenatide Improves Glycemic Control and Reduces Body Weight in Subjects with Type 2 Diabetes: A Dose-Ranging Study.”
12/04	J Am Acad Child Adolesc Psychiatry 43(12):1497-505	Labellarte, Michael M.D.; Biederman, Joseph M.D., PH.D.; Emslie, Graham M.D.; Ferguson, James M.D.; Khan, Arifulla M.D.; Ruckle, Jon M.D.; Sallee, Randy M.D., PH.D.; Riddle, Mark M.D., “Multiple-dose pharmacokinetics of fluvoxamine in children and adolescents.”
01/03	Medicine Online	Richard Wasnich, Jon Ruckle. “High Fructose Diet Induces Hepatic Dysfunction in Healthy Men.”
2002	HIV Clinical Trials 3(6):435-450	Eiznhamer DA, Creagh T, Ruckle JL, Tolbert DT, Giltner J, Dutta B, Flavin MT, Jenta T, Xu Z-Q, “Safety and pharmacokinetic profile of multiple escalating doses of (+)-Calanalide A, a naturally occurring nonnucleoside reverse transcriptase inhibitor, in healthy HIV-negative volunteers.”
05/02	63 <sup>rd</sup> Annual Meeting of the Society for Investigative Dermatology P850	Richard Wasnich, Lily Li, Xiaoming Lin, Jon Ruckle, Christopher TenHoor, Daniel Freedman. “The Pharmacokinetic Properties of Alefacept Are Similar Among Caucasian and Japanese Healthy Volunteers.”
05/01	Antimicrob Agents Chemother 45(5):1379-1386	Creagh T, Ruckle JL, Tolbert DT, Giltner J, Eiznhamer DA, Dutta B. “Safety and pharmacokinetics of single doses of (+)-Calanalide A, a naturally occurring nonnucleoside reverse transcriptase inhibitor in healthy, human immunodeficiency virus-negative human subjects.”

11/00	Menopause 7(6):383-390	Sperof, Leon, Symons, James, Kempfert, Nona, et al., "The effect of varying low-dose combinations of norethindrone acetate and ethinyl estradiol (femhrt(R)) on the frequency and intensity of vasomotor symptoms."
11/00	AAPS	D.S. Tolbert, A. Karim, J. Nasafi, J.L. Ruckle, and J. Qian, "Effect of Double Strength Grapefruit Juice on the Pharmacokinetics of Eplerenone,"
03/00	Jpn J Clin Pharmacol Ther 31(2)	G. He, J. Massarella, J.L. Ruckle, Y. Ninomiya, A. Dorr, C. Woodruffe-Peacock, P. Ward, and A. Brown, "The Comparative Pharmacokinetics and Safety of the Oral Neuraminidase Inhibitor Oseltamivir when Given in Multiple Doses to Healthy Japanese and Caucasian Subjects."
01/00	Clin Pharmacol Ther 67(1):7-15	Marbury TC; Ruckle JL; Hatorp V; Andersen MP; Nielsen KK; Huange WC; Strange P, "Pharmacokinetics of Repaglinide in subjects with renal impairment,"
2000	J Clin Endocrinol Metab 85(4), 1518-1524	Clemmons DR, Moses AC, McKay MJ, Sommer A, Rosen DM, Ruckle J. "The Combination of Insulin-like Growth Factor-1 and Insulin-like Growth Factor Binding Protein-3 Reduces Insulin Requirements in Insulin-dependent Type 1 Diabetes: Evidence for <i>In Vivo</i> Biological Activity."
11/99	ACAAI	Glenn F. Carlson MD, A. Benjamin Suttle PH.D, Jon L. Ruckle MD, Bruce K. Birmingham PhD, "Lack of Interaction between Zafirlukast and Theophylline in Children."
09/99	39 <sup>th</sup> ICAAC	J. Ruckle, T. Creagh, D. Tolbert, J. Giltner, B. Dutta, C. Thomas, T. Wright, Z.-Q. XU, "Clinical Safety and Pharmacokinetic Profile of Single and Multiple Escalating Doses of (+)-Calanalide A, A Naturally Occurring NNRTI, in Healthy HIV-Negative Volunteers."
01/99	6 <sup>th</sup> Conference on Retroviruses and Opportunistic Infections	J. Ruckle, J. Giltner, T. Creagh, B. Dutta, D. Tolbert, Z-Q Xu, "Clinical Safety and Pharmacokinetics of (+)-Calanalide A, A Naturally Occurring NNRTI, in Normal Healthy and HIV-Infected Volunteers."

1999	J Child Adolesc Psychopharmacol 9(1):35-42	Dixon R; Engleman K; Kemp J; Ruckle JL, "A comparison of the pharmacokinetics and tolerability of the novel antimigraine compound zolmitriptan in adolescents and adults."
07/98	12 <sup>th</sup> Annual World AIDS Conference	Xu, Ze-Qi; Creagh, T.; Giltner, J.; Ruckle, J.; Frank, P.; Tolbert, D.; Flavin, M.T. "Preliminary Clinical Safety and Pharmacokinetics Profile of (+)-Calanalide A- A Naturally Occurring NNRTI."
02/98	5 <sup>th</sup> Conference on Retroviruses and Infectious Diseases	Creagh, T.; Xu, Ze-Qi; Ray, L.; Giltner, J.; Nayer, T.; Ruckle, J. "Preliminary Clinical Safety Profile of (+)-Calanolide A- A New Novel NNRTI."
1998	Diabetologia 41: [Suppl 1]/Issue 8	Ruckle, J.L. and Hatorp, V. "Repaglinide Pharmacokinetics in Patients with Renal Impairment Vs.. Healthy Volunteers."
12/96	Journal of Cardiovascular Pharmacology 28(6):769-773	Stimpel, Michael, Koch, Brigitte, Jansen, Thomas et al. "Moexipril Vs.. Captopril in Patients with Mild to Moderate Hypertension."
1996	Health Information: Management of a Strategic Resource	Ed. by Abdelhak, Mervat, et. al. "Computerized Patient Records, An Essential Technology
09/92	Proceedings of the Raima Technology Conference	Ruckle, JL. "IMIS: Use of object oriented programming techniques for physician workstations and computerized medical records."
03/89	Postgraduate Medicine 85(4):359-66	Silver FW, Ruckle JL., "Depression: Management Techniques in Primary Care

**Phase I Research Experience Summary as Investigator (1995-2013)**

Type of Study/Therapeutic Domain	# of Studies
Japanese Bridging	51
Ethnic Comparison (non-Japanese)	11
Large Molecule/Biologic	43
First Time In Human	12
Microdose	7
AME <sup>14</sup> C	13

PET scan	1
Medical Device	9
Diabetes	43
Osteoporosis	31
Hypertension/Cardiovascular	22
Elderly	14
Pediatrics	9
Asthma	9
Obesity/Weight Loss	12
Hyperlipidemia/Hypercholesterolemia	10
Osteoarthritis	7
Gastroenterology/Hepatic	6
Renal Insufficiency	6
Dermatology	7
Oncology	9
Vaccine	8
Women's Health	6
QTc intense/Cardiac Safety	8
CNS	9
Infectious Disease	9
BA/BE	26

Note: conventional Single Ascending Dose or Multiple Ascending Dose studies and PK/PD, safety & tolerability studies in normal healthy volunteers with a single formulation are not tabulated. Redacted Study List as Investigator (N = 353 studies): available upon request

## **Consulting/Medical Monitoring Experience since 2008**

Protocol design/product development strategy/protocol writing and/or medical monitoring for over 50 studies: Domains and indications include CNS, cardiovascular, pulmonary/asthma, nephrology, anti-inflammatory, antivirals, antibiotics, vaccines, diabetes, hyperlipidemia, dermatologics, human abuse liability, analgesia, amyloidosis, sleep disorders, and other niche indications.

Clinical trials include first-in-human studies for biologics and small molecules, <sup>14</sup>C labeled ADME and microdose studies, “bridging” studies for Japanese registration, Renal impaired and other special populations, and adaptive designs.