Charlene M. Stubbs, Ph.D.

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Experience

- Clinical member of senior cross-functional strategy team (marketed products and new product development)
- Build positive relationships and work collaboratively with other functions within the organization (R&D, Marketing, Quality, Finance, etc.)
- Clinical representative for product safety review and quality trending
- Leadership for Global Clinical Affairs organizations
- Budget planning and management
- Design of clinical strategies and protocols for drugs and devices
- Clinical Operations (130+ successfully executed protocols); SOPs; process development and improvements (performance metrics)
- Multiple therapeutic areas: oncology, anti-inflammatory, cardiovascular, infectious diseases, CNS, GI. neurosurgery, diabetes, renal, cellular therapies, hematology, nutrition

Employment

7/12-Pres. **Self –Employed**
Position: Pharmaceutical Consultant
Provide consulting services to US and Global companies related to drug development strategies, regulatory strategies and protocol design/writing.

7/03 –6/12 **Baxter Healthcare Corporation, Medical Products Division**
Position: Vice President, Global Clinical Affairs
Responsible for global clinical development and operations for the Renal Division

Global responsibility for clinical research strategies, protocol design (Phase I-IV), clinical input for regulatory submissions and communications for renal drugs and devices, as well as clinical expertise and support for corporate projects. Strategic and administrative responsibilities for clinical staff and budget in US and in Brussels. Clinical representative to periodic product safety and quality reviews. Defined clinical strategies and operations for product Quality issues.

/02 - 7/03 **Employer: Takeda Pharmaceuticals North America, Inc.**
Position: Vice President, Clinical Research
Promoted to establish a CNS drug development venture

Established a CNS research strategy and therapeutic area. Lead the first NDA effort for TPNA; completed Phase II program and designed Phase III development program for a successful NDA submission for Ramelteon.. Designed development strategies for two Alzheimer's compounds; initiated Phase I trials. Clinical lead for a successful IND (infectious disease). Clinical representative to the Portfolio Review Committee and multiple task forces for process design and improvements.

11/99-/02 **Employer: Takeda Pharmaceuticals America, Inc.**
Position: Director, Clinical Development and Pharmacology
Established a clinical development and operations department; multiple successful INDs

Developed a clinical research and operations department: strategy, goals, function, personnel and budget (expanded from two employees to 65+). Defined other functional support groups, and hired personnel. Strategic planning and leadership for marketed product and new drug development. Protocol design, execution and oversight for Phase IV commitment studies for ACTOS and clinical development programs (Phases I-III). Clinical lead for five successful INDs (diabetes, GI, urology, CNS); initiated three Phase I studies. Clinical review of new product acquisitions. Clinical representative to the cross-functional team that determined the structure and organization of R & D.

7/98-11/99 **Employer: TAP Holdings, Inc.**
Position: Manager, Clinical Quality
Established a Clinical Quality Assurance Department; managed Regulatory investigation of Lupron and quality plans for research programs. Developed SOPs and processes.

1997-1998 **Employer: Pharmacia and Upjohn**
Product Manager, Marketing
Planned and executed strategic marketing objectives and related materials for prescription pharmaceutical products and one surgical device. Worked closely with KOLs, MSLs, Marketing, Sales, R&D and the medical community.

1996-1997 **Employer: Pharmacia and Upjohn**
Position: Senior Quality Assurance Manager
Developed quality assurance strategies and oversight for pivotal registration trials; GCP training for clinical development staff and investigator site staff. Upjohn lead on the team that accomplished integration of SOPs and processes for Pharmacia and Upjohn. Quality audits of investigator sites and

1992-1996 **Employer: The Upjohn Company**
Position: Senior Clinical Trials Specialist
Managed multiple worldwide clinical development programs for company top projects and product candidates: (Phases I-III), pharmacokinetics/pharmacodynamics and post-marketing (Phase IV) studies.

1984-1992 **Employer: The Upjohn Company**
Position: Senior Research Associate
Managed clinical development programs in multiple therapeutic areas.

Education

Ph.D., Pharmacology, Columbia Pacific University, San Rafael, CA
Master of Arts, (Major) **Administration and Management,** (Minors) **Science** and Communications, Columbia Pacific University, San Rafael, CA
Bachelor of Arts, (Major) **Administration and Management,** (Minor) Communications, Columbia Pacific University, San Rafael, CA
Registered Nurse, Associates Degree, Applied Sciences, Kellogg College, Battle Creek MI

Protocols and Technical Reports

1. High Dose Cytosine Arabinoside and m-AMSA in Refractory ANLL (February 5, 1985).

2. Acute Myelocytic Leukemia Study for First Relapse High Dose Cytosine Arabinoside plus m-AMSA (February 5, 1985).

3. Comparative Study of HiDAC Alone or Given Sequentially with L-ASP for Remission Induction (February 7, 1985).

4. Combination Intracavitary Chemotherapy with Cisplatin, Cytosine Arabinoside, and Duxorubicin (February 8, 1985).

5. Metastatic Breast Carcinoma: A Protocol for Combined Hormonal Chemotherapy (February 9, 1985).

6. Phase I Protocol: High Dose Cytosine Arabinoside in Solid Tumors (February 9, 1985).

7. High Dose Cytosine Arabinoside and m-AMSA Induction and Consolidation in Patients with Previously Untreated De Nova ANLL (March 22, 1985).

8. Pilot Protocol to Evaluate High Dose Cytosine Arabinoside and AMSA as Intensive Consolidation Therapy (March 22, 1985).

9. Multiple Dose MOTRIN® Suppository Tolerance Study (May, 1985).

10. Dose Response and Tolerance of Minoxidil in Normal Volunteers (June, 1985).

11. Cutaneous Tolerance of Topical Hydrocortisone Acetate and Other Corticosteroid Preparations (July, 1985).

12. Chronic Multiple-Dose Tolerance Study of MOTRIN-SR and ANSAID-SR® Tablets (August, 1985).

13. Tolerance of Ibuprofen 200-mg Capsules, NUPRIN® Tablets, Advil, and Placebo (October, 1985).

14. Tolerance of Colestipol Film-Coated Tablets, Colestipol Enteric-Coated Tablets, and Placebo in Normal Volunteers (December, 1985).

15. The Effects of MOTRIN® 800 mg Tablets, Naprosyn 500 Tablets, Aspirin and Placebo on the Gastric and Duodenal Mucosa of Normal Volunteers. An Endoscopic and Photographic Study (January, 1986).

16. The Effects of Aluminum Ibuprofen Tablets, MOTRIN® Tablets, and Aspirin Tablets on the Gastric and Duodenal Mucosa of Normal Volunteers. An Endoscopic and Photographic Study (January, 1986).

17. The Effects of Aluminum MOTRIN® Tablets, Aspirin and Placebo on the Gastric and Duodenal Mucosa of Normal Human Volunteers (February, 1986).

18. The Effects of ANSAID® Tablets, Aspirin, Cimetidine and Mylanta II on the Gastric and Duodenal Mucosa of Normal Volunteers. An Endoscopic and Photographic Study (February, 1986).

19. The Survival Following Cisplatin (DDP)-Based Intraperitoneal Chemotherapy for Refractory Ovarian Carcinoma (April, 1986).

20. Combination Intraperitoneal Chemotherapy of Previously Untreated Patients with State II and IV Ovarian Carcinoma (April, 1986).

21. Combination Intracavitary Chemotherapy with Cisplatin, Cytarabine, and Bleomycin (21.CABLEPLAT) (April, 1986).

22. Combination Intrapleural Chemotherapy with Cisplatin and Ara-C (PLURALPLAT) (May, 1986).

23. Pharmacokinetic Studies of Streptozocin (ZANOSAR®) by Continuous Infusion (May, 1986).

24. Phase II Trial of Streptozocin (ZANOSAR®) by Continuous Infusion in Metastatic Colorectal Cancer (May, 1986).

25. High-dose Cytosine Arabinoside in Previously Treated Patients with Poor Prognosis Non-Hodgkin's Lymphoma (May, 1986).

26. Treatment of Burkitt's Lymphoma and Undifferentiated Non-Burkitt's Lymphoma with Alternating Cycles of COMP and High-Dose CYTOSAR-U® (May, 1986).

27. High-Dose CYTOSAR-U® in Acute Non-Lymphocytic Leukemia (May, 1986).

28. High-Dose Cytosine Arabinoside Intensive Consolidation and Macho Consolidation in Adult ALL (May, 1986).

29. High-Dose CYTOSAR-U® with Autologous Transplantation in Recurrent Lymphoma in Adults (May, 1986).

30. High-Dose Cytosine Arabinoside and m-AMSA in Effective Treatment in Relapsed Acute Nonlymphocytic Leukemia (May, 1986).

31. Adult Acute Non-Lymphocytic Leukemia, A Randomized Trial of Post Remission Therapy (May, 1986).

32. Daily Intraperitoneal Administration of Cytarabine (May, 1986).

33. ANSAID-SR® ANSAID® Tablet, Aspirin and Placebo Chromium^{51} Tag and Tolerance Study (June, 1986).

34. Evaluation of Low-dose Ara-C in the Treatment of Myelodysplastic Syndrome (September, 1986).

35. Phase I Pilot Study for Treatment of Acute Non-lymphocytic Leukemia in the Elderly with Attenuated High-Dose CYTOSAR-U® (September, 1986).

36. High-Dose Cytosine Arabinoside and mAMSA Induction and Consolidation in Patients with Previously Untreated de novo Acute Non-lymphocytic Leukemia (September, 1986).

37. MOTRIN® and Feldene Platelet Aggregation Study (September, 1986).

38. Aluminum Ibuprofen Suspension Versus Aspirin in Osteoarthritis Patients Over 65 Years Old (October, 1986).

39. The Effects of MOTRIN® 400 mg Tablets, Rufen Tablets, Aspirin and Placebo Tablets on the Gastric and Duodenal Mucosa of Normal Volunteers. An Endoscopic and Photographic Study (November, 1986).

40. The Effects of MOTRIN® 600 mg Tablets, Rufen 600 mg Tablets, Aspirin and Placebo Tablets on the Gastric and Duodenal Mucosa of Normal Volunteers. An Endoscopic and Photographic Study (November, 1986).

41. MOTRIN®/Acetaminophen Endoscopic Study to Investigate Cytoprotection of the Gastric and Duodenal Mucosa in Normal Volunteers (November, 1986).

42. UNICAP M® Multivitamin Tolerance Study #2 (February, 1987).

43. Remission Induction Therapy in Relapsed Acute Myelocytic Leukemia (March, 1987).

44. Combination Chemotherapy (CHOP/AMA) for Patients with T-Cell Immunoblastic Sarcoma (March, 1987).

45. Continuous Infusion High Dose Ara-C (March, 1987).

46. Treatment of Patients in Blastic Phase of CML with Chemotherapy (Plus Autotransplantation) (March, 1987).

47. A Protocol for a Preliminary Trial of Cytarabine in Multiple Sclerosis (March, 1987).

48. High Dose Cytosine Arabinoside in the Treatment of Advance Non-Small Cell Lung Carcinoma (March, 1987).

49. MOTRIN®/Codeine Multiple Dose Tolerance Study (March, 1987).

50. Primary Treatment Protocol for Patients with Acute Myelocytic Leukemia and Its Variants (March, 1987).

51. Primary Treatment Protocol for Patients with Acute Myelocytic Leukemia and Its Variants. Adriamycin/Cytosine Arabinoside Induction with Intensive Consolidation Chemotherapy (March, 1987).

52. The Effects of MOTRIN® 800 mg Tablets, MOTRIN® 400 mg Tablets, Rufen 400 mg Tablets and Aspirin Tablets on the Gastric and Duodenal Mucosa of Normal Volunteers. An Endoscopic and Photographic Study (March, 1987).

53. Evaluation of the Safety of Co-administered Methotrexate and Ibuprofen/Flurbiprofen (July, 1987).

54. Effects of High Doses of MOTRIN-SR® Tablets on the Renal Function of Healthy Young and Elderly Subjects (July, 1987).

55. Systemic and Local Tolerance of Clindamycin Phosphate Cream (July, 1987).

56. Effects of High Doses of ANSAID® Tablets on the Renal Function of Healthy Young and Elderly Subjects (August, 1987).

57. Effects of High Doses of ANSAID-SR® Tablets on the Renal Function of Healthy Young and Elderly Subjects (September, 1987).

58. Evaluation of High Dose CYTOSAR-U® in the Treatment of AML (October, 1987).

59. Treatment of Relapsed or Treatment Refractory AML with a Combination of Daunorubicin, Cytosine Arabinoside (Constant Infusion) and Thioguanine Together with High-Dose Cytosine Arabinoside (October, 1987).

60. Sequential High Dose Arabinosyl Cytosine, Cyclophosphamide, Total Body Irradiation and Autologous Bone Marrow Transplant (October, 1987).

61. Bone Marrow Transplantation for Acute Leukemia and Lymphoma with High Dose Cytosine Arabinoside and Total Body Irradiation (October, 1987).

62. Clinical Pharmacology and Clinical Trials with Sequential High Dose Cytosine Arabinoside and Asparaginase in Acute Leukemia (October, 2987).

63. Cerebellar Toxicity with High Dose Cytosine Arabinoside (October, 1987).

64. CYTOSAR-U® Mega-dose Research Program in Italy (October, 1987).

65. High Dose Cytosine Arabinoside Therapy with and without Anthracycline Antibiotics for Remission Re-induction of Acute Nonlymphoblastic Leukemia (October, 1987).

66. A Phase II Trial of CYTOSAR-U® in Breast Cancer (November, 1987).

67. CYTOSAR-U® High Dose in the Treatment of Leukemia (November, 1987).

68. Phase II Trial of Low Dose 5-Azacytidine in ANLL (November, 1987).

69. Cell Recruitment of Synchronization after High Dose Ara-C Treatment in Adult Acute Leukemia Patients (November, 1987).

70. CYTOSAR-U® Mega-dose Therapy in Refractory AML (November, 1987).

71. CYSTOSAR-U® High Dose in Pretreated Relapsed Patients with Acute Leukemia (November, 1987).

72. CYTOSAR-U® Evaluation in Interstitial Pneumonitis. An Animal Study on the Influence of Ara-C on Lung Function (November, 1987).

73. Effect of Infusion Rate on the Kinetic-Dynamic Relationship for Intravenous Midazolam (December, 1988).

74. The Tolerance of IV Adinazolam Mesylate and N-Desmethyl Adinazolam Mesylate in Normal Healthy Volunteers (December, 1988).

75. Bioavailability Comparison of New and Established Formulations of LINCOCIN-SS® Each Delivering 1200 mg Lincomycin to Healthy Volunteers (February, 1989).

76. Single Dose Intramuscular Tolerance Study of the New Formulation of LINCOCIN® Sterile Solution 600mg/ml in Healthy Volunteers (March, 1989).

77. Multiple Dose Intramuscular Tolerance Study of the New Formulation of LINCOCIN® Sterile solution 600 mg/ml in Healthy Volunteers (March, 1989).

78. A Placebo Controlled Study in Normal Subjects Evaluating the Tolerance of Adinazolam Mesylate and N-Desmethyl Adinazolam Mesylate Administered as Oral Solutions (April, 1989).

79. Tolerance of Colestipol Film-Coated Tablets, Colestipol Enteric-coated Tablets, and Placebo in Normal Volunteers (February, 1990).

80. Single Dose Tolerance of Trospectomycin Vaginal Cream and Vaginal Suppositories (December, 1990).

81. Multiple Dose Tolerance and Pharmacokinetics of Trospectomycin Vaginal Cream and Vaginal Suppositories (April, 1991).

82. The Clinical Pharmacology of Single Doses of U-78875 as an Oral Suspension (April, 1991).

83. Comparative Bioavailability of U-78875 Given as an Aqueous Suspension of 10 mg or as a 10 mg Tablet with Either Fine, Medium or Course Particles (April, 1991).

84. Comparative Pharmacokinetics of U-78875, Given as a 10 mg Oral Tablet, in Normal Males and Surgically Sterile Females (April, 1991).

85. Multiple Dose Safety and Tolerance and Pharmacokinetics of U-78875 (June, 1991).

86. A Single Dose Response Study to Correlate Drug Levels of U-78875 and Diazepam with their Effects on EEG and Psychomotor/Performance Function of Healthy Volunteers (1991).

87. Flexible Dose Double-Blind Comparison of the Efficacy and Safety of U-78,875 vs Placebo in the Treatment of Generalized Anxiety (1991).

88. Flexible Dose Double-Blind Comparison of the Efficacy and Safety of U-78875 vs Placebo in the Treatment of Panic Disorder with Agoraphobia (1991).

89. Lincocin New Formulation Development: Single Dose Tolerance Study (1992).

90. Lincocin New Formulation Development: Multiple Dose Tolerance Study (1992).

91. Effect of Infusion Rate on Midazolam Pharmacokinetics (1992).

92. Phase I Study of the Safety, Tolerance, and Pharmacokinetics of Recombinant Soluble CD4-Pseudomonas Exotoxin (U-85,855) in HIV-Infected Individuals (1993).

93. Efficacy and Safety of Tirilazad Mesylate (U-74,006F) in Patients with Moderate and Severe Head Injury: North American Trial (1994-1996).

94. Efficacy and Safety of Tirilazad Mesylate (U-74,006F) in Patients with Moderate and Severe Head Injury: International Trial (1994-1996).

95. Vantin versus Biaxin in the Treatment of Chronic Bronchitis in Smokers (1996).

96. Vantin Once-a-Day Dosing versus Twice-a-Day Dosing in Otitis Media in Children (1996).

97. Vantin Suspension: Regular Flavor versus Modified Flavor versus Cefzil in Children with Otitis Media (1996).

98. Phase IV Study of Vantin in the Treatment of Sinusitis in Adult Smokers(1996)

99. Phase IV Study of Vantin in the Treatment of Sinusitis in Adult Non-Smokers (1996)

100. A Double-Blind, Randomized Study of the Safety and Efficacy of a Combination of Sulfonylurea and 45 mg of ACTOS™ (Pioglitazone HCl) Compared to a Combination of Sulfonylurea and 30 mg of ACTOS™ (Pioglitazone HCl) in the Treatment of Subjects with Type 2 (Non-Insulin Dependent) Diabetes Mellitus (1999)

101. A Double-Blind, Randomized Study of the Safety and Efficacy of a Combination of Metformin and 45 mg of ACTOS™ (Pioglitazone HCl) Compared to a Combination of Metformin and 30 mg of ACTOS™ (Pioglitazone HCl) in the Treatment of Subjects with Type 2 (Non-Insulin Dependent) Diabetes Mellitus (1999)

102. A Double-Blind, Randomized Study of the Safety and Efficacy of a Combination of Insulin and 45 mg of ACTOS™ (Pioglitazone HCl) Compared to a Combination of Insulin and 30 mg of ACTOS™ (Pioglitazone HCl) in the Treatment of Subjects with Type 2 (Non-Insulin Dependent) Diabetes Mellitus (2000)

103. A Double-Blind, Randomized Comparison Study of the Long Term (2-yr) Safety and Efficacy of Pioglitazone HCl or Glyburide In Subjects with Type 2 Diabetes Naïve to Pharmacologic Therapy (2000)

104. A Double-Blind, Randomized Comparison Study of the Safety and Efficacy of the Addition of Pioglitazone HCl or Placebo in Reducing or Eliminating Insulin Requirement in Subjects Controlled on Insulin and Metformin Who Have Previously Failed Combination Oral Therapy (2000)

105. A Double-Blind, Randomized Comparison Study of the Safety and Efficacy of Pioglitazone HCl or Glyburide in Subjects with Type 2 Diabetes Mellitus Post Acute Myocardial Infarction and/or Percutaneous Coronary Intervention (2001)

106. A Randomized, Double-Blind, Comparator-Controlled Study of Pioglitazone HCl vs Glyburide in the Treatment of Subjects with Type 2 (Non-Insulin Dependent) Diabetes and Mild to Moderate Congestive Heart Failure (2001)

107. A Randomized, Comparator Controlled, Double-Blind Study of the Liver Safety of Pioglitazone HCl Versus Glyburide With Metformin and Insulin as Part of Step Therapy in Subjects With Type 2 (Non-Insulin Dependent) Diabetes (2001)

108. A Single and Multiple Dose Pharmacokinetic and Safety Study of 15 mg, 30 mg and 45 mg ACTOS® (Pioglitazone HCl) Administered Orally to Adolescents with Type 2 (Non-Insulin Dependent) Diabetes Mellitus or Impaired Fasting Glucose (2001)

109. A Safety and Efficacy Study of Pioglitazone HCl in Adolescents with Type 2 (Non-Insulin Dependent) Diabetes (2001)

110. ACTOS®/ Theophylline Interaction Study (2001)

111. ACTOS®/ Ketoconazole Interaction Study (2001)

112. ACTOS®/Oral Contraceptive Interaction Study (2001)

113. Diabetes: Single Dose Safety, Tolerance and Pharmacokinetics (2002)

114. Diabetes: Multiple Dose Safety, Tolerance and Pharmacokinetics (2002)

115. Diabetes: Effects of Food on Pharmacokinetics (2002)

116. Diabetes: Effects of Age and Gender and Pharmacokinetics (2002)

117. Ramelteon: Efficacy and Safety in a Sleep Lab Model of Transient Insomnia (Phase II) (2002)

118. Ramelteon: Efficacy and Safety in Adult Subjects (Phase III) (2003)

119. Ramelteon: Efficacy and Safety in Adult Subjects (Phase III) (2003)

120. Ramelteon: Efficacy and Safety in Elderly Subjects (Phase III) (2003)

121. Ramelteon: Effects of Food on Pharmacokinetics (2003)

122. Ramelteon: Effects of Age and Gender on Pharmacokinetics and Pharmacodynamics (2003)

123. Ramelteon: Dose Ranging Study in Subjects with Chronic Insomnia (2003)

124. Ramelteon: Ketoconazole Interaction Study (2003)

125. Ramelteon: Fluvoxamine Interaction Study (2003)

126. Ramelteon: Fluconazole Interaction Study (2003)

127. Sepsis: Single Dose Safety, Tolerance and Pharmcokinetics (2003)

128. Diabetes: Single Dose Safety, Tolerance and Pharmacokinetics (2003)

129. Alzheimers: Single Dose Safety, Tolerance and Pharmacokinetics (2003)

130. Multiple renal solution and device studies in peritoneal dialysis subjects (2003-2012)