PMI RESEARCH & DEVELOPMENT

Study ZRHM-REXA-08-US
Clinical Study Report Appendix 16.1.4
List of Investigators and Other Important Participants and Descriptions of Qualifications and Research Facilities

Study Title:	A randomized, controlled, open-label, 3-arm parallel group, multi-center study to demonstrate reductions in exposure to selected smoke constituents in apparently healthy smokers switching to the Tobacco Heating System 2.2 Menthol (THS 2.2 Menthol) or observing smoking abstinence, compared to continuing to use menthol conventional cigarettes, for 5 days in confinement and prolonged by 86 days in an ambulatory setting
Study Number:	ZRHM-REXA-08-US
Product Name:	Tobacco Heating System 2.2 Menthol (THS 2.2 Menthol)
Study Initiated (first subject screened):	17 December 2013
Study Completed (last subject last visit):	12 October 2014
Principal Investigator and Affiliation:	Dr William Lewis, Covance Dallas Site 1341 W. Mockingbird Ln., Suite 400E Dallas, TX 75247 Dr H. Frank Farmer, Covance Daytona Beach Site 1900 Mason Ave., Suite 140 Daytona Beach, FL 32117
Sponsor:	Philip Morris Products S.A. PMI Research & Development Quai Jeanrenaud 5 2000 Neuchâtel, Switzerland
Sponsor Signatories:	Christelle Haziza, PhD, Manager P1 Clinical Program, Clinical Scientist Guillaume de La Bourdonnaye, MEng, MSc, Biostatistician Andrea Donelli, Clinical Scientist Ruben Rosoky, MD PhD MFPM, Medical Safety Officer
Version:	1.0
Date:	25 May 2016

This study was conducted in accordance with Good Clinical Practice.

Confidentiality Statement

This document is confidential. Disclosure of any of its contents to third parties is not permitted except by the prior written consent of Philip Morris Products S.A.

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16.1.4 LIST OF INVESTIGATORS AND OTHER IMPORTANT PARTICIPANTS AND DESCRIPTIONS OF QUALIFICATIONS AND RESEARCH FACILITIES

16.1.4.1 SITE 1

16.1.4.1.1 DESCRIPTION AND ADDRESS OF SITE 1

Site Name and Address	Description	Site Number
Covance CRU, Inc., 1900 Mason Ave, Suite 140 Daytona Beach, FL 32117	This is a Medical Research Clinic.	DAY

16.1.4.1.2 CV OF PERSONNEL OF SITE 1 (PI, SUB-PI, STUDY COORDINATOR)

The Principal Investigator for this study was H. Frank Farmer, MD.

H. Frank Farmer, Jr., MD, PhD, FACP, CPI

Covance Clinical Development Services
Medical Director

1900 Mason Ave, Suite 140, Daytona Beach, Florida
Tel: 386-366-6400

Employment History

Covance Clinical Development Services, Daytona Beach, Florida – Feb. 2004 – present
Medical Director/Principal Investigator – Feb. 2004 – present

- Provides supervision and direction to the physicians of the Covance Clinical Research Unit, as appropriate, and ensures that there is proper medical coverage from the physicians to cover the medical safety to the unit during all hours of operation.
- Involved with clients for medical consultation on study design and safety for early clinical phases of drug development and interfaces with the medical staff and clients to ensure proper study designs and notification of serious adverse events to the sponsors.
- Provides medical coverage for the Covance Clinical Research Unit, and as Principal Investigator/SubInvestigator, responsible for assuring the health and welfare of participants.
- Responsible for performing medical procedures, responsible for proper conduct of the study trial, and responsible for all trial related medical decisions.

Laboratory Director – Jan. 2013 – present

Laboratory Director – Feb. 2004 – Apr. 2011

Surgeon General, State of Florida, Tallahassee, Florida – Mar. 2011 – Mar. 2012
Surgeon General – Mar. 2011 – Mar. 2012

East Volusia Internal Medicine Associates, Ormond Beach, Florida – 1992 – 2004
Physician – 1992 – 2004

Endeavor Medical Group, Daytona Beach, Florida – 1996 – 2000
Physician/President – 1996 – 2000

Blue Cross/Blue Shield of Florida, Jacksonville, Florida – 1991 – 1992
Medical Director – 1991 – 1992

Private Practice Physician, New Smyrna Beach, Florida – 1980 – 1990
Physician – 1980 – 1990

Southwestern College, Georgia – 1971 – 1972
Professor of History – 1971 – 1972

COVANCE

Name: H. Frank Farmer, Jr. PhD, MD, FACP, CPI

Southwestern College, Georgia – 1968 – 1969
Professor of History – 1968 – 1969

Therapeutic Experience

- **Healthy Phase I Studies**
- **Cardiovascular:** hypertension, hypercholesterolemia
- **Dermatology:** psoriasis
- **Devices:** intradermal infusion, biomagnetic therapy
- **Endocrinology:** obesity, diabetes mellitus
- **Gastrointestinal:** GERD, h. pylori
- **Immunology:** rheumatoid arthritis, scleroderma, lupus
- **Infectious Disease:** flu vaccine, anthrax vaccine
- **Musculoskeletal:** osteoarthritis, pain – chronic, gout, fibromyalgia
- **Neurology:** pain – headache, migraine, chronic low back pain
- **Ophthalmology:** macular degeneration
- **Pulmonology:** smoking, asthma, allergic rhinitis
- **Women's Health:** hormone replacement therapy, oral contraceptives, osteoporosis, uterine fibroids

Language Capabilities

- English

Education

- Medical Doctor, Medical College of Georgia, Augusta, Georgia
- Doctor of Philosophy, History, University of Georgia, Athens, Georgia
- Master of Arts, History, University of Georgia, Athens, Georgia
- Bachelor of Arts, History, Stetson University, Deland, Florida

Memberships/Awards

- Board of Medicine, Member, State of Florida
- Editor, *The Internist*, American College of Physicians, Florida Chapter
- Board of Medicine, Chairman, State of Florida
- Board of Medicine, Member, State of Florida
- Military Service Academy Selection Advisory Committee – appointed by Representative John Mica
- Military Service Academy Selection Advisory Committee – appointed by Representative Andrew Crenshaw
- Judicial Nominating Committee – appointed by Governor Jeb Bush, Seventh Judicial Circuit
- Board of Governors, Florida Chapter, American College of Physicians, Florida Society of Internal Medicine
- Florida Medical Association, President
- Florida Medical Association, Historical Editor
- Florida Medical Association, Board of Governors
- Volusia County Medical Association, President

Name: H. Frank Farmer, Jr. PhD, MD, FACP, CPI

- Medical College of Georgia, Medical Class President

Other

- Medical Doctor, State of Florida, License No. ME30591
- Advanced Trauma Life Support, Shands Hospital, Jacksonville, Florida
- Advanced Cardiac Life Support, American Heart Association, Daytona Beach, Florida
- Diplomat, American Board of Internal Medicine
- Basic Life Support for Healthcare Providers, American Heart Association
- Military Decorations:
  - Bronze Star
  - Vietnamese Cross of Gallantry
  - Staff Honor Medal
  - Police Honor Medal
  - Vietnam Service Ribbon
  - Vietnam Campaign Ribbon
  - National Defense Ribbon
  - Meritorious Service Medal with 2 Clusters

Employee Signature: H. Farmer Jr

Date: 03 JAN 2014

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Hugh A. Coleman, DO

Covance Clinical Development Services
Associate Medical Director

1900 Mason Ave, Suite 140, Daytona Beach, Florida
Tel: 386-366-6400

Employment History

Covance Clinical Development Services, Daytona Beach, Florida – 2003 – present
Associate Medical Director – 2013 – present

- Provides medical coverage for the Covance Clinical Research Unit.
- As Principal Investigator/Sub Investigator, responsible for assuring the health and welfare of participants.
- Responsible for performing medical procedures, proper conduct of the study trial, and all trial related medical decisions.

Physician – 2003 – 2013

- Provides medical coverage for the Covance Clinical Research Unit.
- As Sub Investigator, responsible for assuring the health and welfare of participants.
- Responsible for performing medical procedures, proper conduct of the study trial, and all trial related medical decisions.

Florida Hospital Hospice, Ormond Beach, Florida – 2010 – present
Associate Medical Director – 2010 – present

Hugh A Coleman, DO PA, Ormond Beach, Florida – 2001 – Jun. 2013
Physician – 2001 – Jun. 2013

Oaktree Healthcare, South Daytona, Florida – 2001 – 2002
Medical Director – 2001 – 2002

Avante, Ormond Beach, Florida – 2001 – 2002
Assistant Medical Director – 2001 – 2002

Quick Care, Port Orange, Florida – 2001 – 2001
Physician – 2001 – 2001

Ormond Medical Arts, Ormond Beach, Florida – 1999 – 2001
Physician – 1999 – 2001

Physician's Walk-In-Medical Center, Delray Beach, Florida – 1998 – 1999
Physician – 1998 – 1999

COVANCE

Name: Hugh A. Coleman, DO

Healthfirst, Lake Worth, Florida – 1999 – 1999
Physician – 1999 – 1999

Family Practice Residency Clinic, Lake Worth, Florida – 1997 – 1999
Physician – 1997 – 1999

Therapeutic Experience

- **Healthy Phase 1 Studies**
- **Cardiovascular:** hypertension, hypercholesterolemia
- **Dermatology:** psoriasis
- **Devices:** intradermal infusion, biomagnetic therapy
- **Endocrinology:** obesity, diabetes mellitus
- **Gastrointestinal:** GERD, h. pylori
- **Immunology:** rheumatoid arthritis, scleroderma, lupus
- **Infections Diseases:** flu vaccine, anthrax vaccine
- **Musculoskeletal:** osteoarthritis, pain – chronic, gout, fibromyalgia
- **Neurology:** pain – headache, migraine, chronic low back pain
- **Ophthalmology:** macular degeneration
- **Pulmonology:** smoking, asthma, allergic rhinitis
- **Women's Health:** hormone replacement therapy, oral contraceptives, osteoporosis, uterine fibroids

Language Capabilities

- English

Education

- Doctor of Osteopathic Medicine, Western University of Health Sciences, College of Osteopathic Medicine of the Pacific (C.O.M.P), Pomona, CA
- Bachelor of Arts Degree, University of California, Santa Barbara, CA
- Bachelor of Arts Degree, University of British Columbia, Vancouver, BC, Canada

Memberships/Awards

- American Osteopathic Association (AOA)
- Florida Osteopathic Medical Association (FOMA)
- American Academy of Osteopathic Family Physicians (ACOFP)

Other

- Osteopathic Physician, State of Florida, License No OS 7503
- Advanced Cardiac Life Support, American Heart Association
- Basic Life Support Certification, American Heart Association
- Certified Clinical Densitometrist, ISCD

Name: Hugh A. Coleman, DO

- Board Certified in Family Practice, AOBFP
- Workman's Compensation Examiner Certification
- Board Certified in Hospice, AOBFP

Employee Signature: [signature]

Date: 06 Jan 2014

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William L. Gilmer, MD

Covance Clinical Development Services
Physician

1900 Mason Ave, Suite 140, Daytona Beach, Florida
Tel: 386-366-6400

Employment History

Covance Clinical Development Services, Daytona Beach, Florida – Oct. 2011 – present
Physician – May 2013– present

- Provides medical coverage for Covance Clinical Research Unit. As a Sub-Investigator, responsible for assuring the health and welfare of participants.
- Responsible for performing medical procedures, responsible for proper conduct of the study trial, and responsible for all trial related medical decisions.

Physician (On-call) – Oct. 2011– May 2013

- Provides medical coverage for Covance Clinical Research Unit. As a Sub-Investigator, responsible for assuring the health and welfare of participants.
- Responsible for performing medical procedures, responsible for proper conduct of the study trial, and responsible for all trial related medical decisions.

Emergency Room Group, Florida Hospital Ormond Emergency Room – 2001 – present
Physician – 2001 – present

Halifax Emergency Physicians, Ormond Urgent Care, Florida – 1996 – 2001
Physician – 1996 – 2001

Emergency Department, LRMC, Leesburg Florida – 1993 – 1995
Physician – 1993 – 1995

Solo Family Practice, Jacksonville Beach, Florida – 1969 – 1993
Physician – 1969 – 1993

United States Navy, Vietnam/Jacksonville, Florida – 1967 – 1969

Therapeutic Experience

- **Healthy Phase I Studies**

COVANCE

Name: William L. Gilmer, MD

Language Capabilities

- English

Education

- Confederate Memorial Medical Center, Shreveport, Louisiana, 1966-1967, Rotating Internship
- Louisiana State University, School of Medicine, New Orleans, Louisiana, 1962-1966
- Louisiana State University, Undergraduate, Baton Rouge, Louisiana, 1958-1962

Memberships/Awards

- American Academy of Family Practice
- Florida Academy of Family Practice

Other

- Board Certified, American Board of Family Practice, 1976
- Recertified – American Board of Family Practice, 1982, 1988, 1994, 2001, 2008
- BLS: ACLS Certified: 1993, 1995, 1997, 1999, 2003, 2005, 2007, 2009, 2011
- ATLS Certified: 2008

Employee Signature: W L Gilmer

Date: 07 May 2013

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Theresa M. Lessard, PA-C

Covance Clinical Development Services
Physician Assistant

1900 Mason Ave, Suite 1400, Daytona Beach, Florida
Tel: 386-366-6400

Employment History

Covance Clinical Development Services, Daytona Beach, Florida – Jan. 2013 – present
Physician Assistant – Jan. 2013 – present

- Provides medical coverage for the Covance Clinical Research Unit. As a Sub-Investigator, responsible for assuring the health and welfare of participants.
- Responsible for performing medical procedures, responsible for proper conduct of the study trial, and responsible for all trial related medical decisions.

Physician Assistants Inc, Ormond Beach/Daytona Beach, Florida – Oct. 2007 – present
Physician Assistant/Geriatrics – Oct. 2007 – present

- Independent contractor, providing acute and routine geriatric care in nursing homes and ALFs.
- Provides monthly Medicare mandated physical exams, reviews and monitors labs, medications, and diets.

Covance Clinical Development Services, Daytona Beach, Florida – 2007 – 2008
Physician Assistant, Clinical Operations– 2007 – 2008

- Provided information services and a knowledge base on the clinical aspects in clinical trials in Clinical Pharmacology.
- Responsible for performing clinical procedures and monitoring study participants' safety on an as needed basis in the Phase I Unit.
- Assisted laboratory staff and study coordinators in conducting clinical research trials for the pharmaceutical industry.

Florida Hospital Memorial, Ormond Beach/Palm Coast, Florida – Jul. 2001 – present
Physician Assistant/Emergency Department – Jul. 2001 – present

- Supervised by Board Certified Emergency Physicians in 32 bed, 50,000 visit/year ED.
- Responsible for full range of Emergency Department responsibilities, utilizing "next chart up" assignment of patients.

South Seminole Hospital, Longwood, Florida – Jan. 2001 – Jul. 2001
Physician Assistant/Emergency Department – Jan. 2001 – Jul. 2001

- Supervised by Board Certified Emergency Physicians in a 10 bed, 28,000 visit/year ED.
- Primary responsibility, but not limited to Urgent Care.

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Name: Theresa M. Lessard, PA-C

Winter Park Memorial Hospital, Winter Park, Florida – Sept. 1996 – Jan. 2001
Physician Assistant/Emergency Department – Sept. 1996 – Jan. 2001

- Supervised by Board Certified Emergency Physicians in a 23 bed, 36, 000 visit/year ED.
- Full range of Emergency Department responsibilities, utilizing "next chart up" assignment of patients.

Dr. Barbara Baldwin, Orlando, Florida – Jun. 1996 – Jul. 2001
Physician Assistant/Pediatrics – Jun. 1996 – Jul. 2001

- Full range of responsibilities in a private practice, including history and physicals, assessments, and treatment plans.
- Provided EPSDT, immunizations, counseling, referrals and Department of Disability evaluations.

Abbey Home Healthcare, Orlando, Florida – Sept. 1984 – May 1994
Senior Account Representative – Sept. 1984 – May 1994

- Sold medical equipment, respiratory therapy services, and IV services for patients cared for at home. Also responsible to prospect, negotiate, implement, and maintain joint ventures, sub-contracts and other general contracts.
- Provided CME lectures to nurses and therapists in hospitals and managed care corporations.
- Published two articles on Medicare regulations for Orange County Medical Society Journal.

Lucerne Hospital, Orlando, Florida – Sept. 1979 – Sept. 1984
Respiratory Therapy Department Manager – Sept. 1979 – Sept. 1984

- Responsible for the management of a thirty-member staff, including scheduling and performance reviews.
- Responsible to project, propose, and adhere to a yearly operation budget, and also created RT education programs for all hospital staff.

Orlando Regional Medical Center, Orlando, Florida – Jan. 1976 – Sept. 1979
Critical Care Respiratory Therapist – Jan. 1976 – Sept. 1979

- Performed all respiratory critical care functions in Intensive Care Units and Emergency Department.
- Proficient in BLS, ACLS, intubation, arterial blood gas draws and interpretation, A-line insertion, and ventilator set-up and management.
- Member of code team and proficient in all critical care equipment and monitors, including Intra-aortic balloon pump and cell-saver.

University of Central Florida, Orlando, Florida – 1978 – 1979
Adjunct Faculty Member – 1978 – 1979

- Provided didactic and practical clinical instruction to Respiratory Therapy students.

Therapeutic Experience

- **Healthy Phase I Studies**
- **Immunology:** Vaccines

Language Capabilities

- English

Education

- Master of Physician Assistant Studies in Emergency Medicine, University of Nebraska, Omaha, Nebraska

Name: Theresa M. Lessard, PA-C

- Bachelor of Science in Medicine Physician Assistant Program, University of Florida, Gainesville, Florida
- Master of Business Administration, University of Central Florida, Orlando, Florida
- Bachelor of Science in Respiratory Therapy, University of Central Florida, Orlando, Florida

Memberships/Awards

- American Academy of Physician Assistants
- Florida Academy of Physician Assistants

Other

- N/A

Employee Signature: _____

Date: 03 JAN 2014

Name: Albert J. Razzetti, MD

Therapeutic Experience

- **Healthy Phase I Studies**
- **Cardiovascular:** atherosclerosis, coronary heart disease, hypertension
- **Dermatology:** acne, dermatitis, eczema, psoriasis
- **Endocrine:** diabetes, obesity
- **GI/Hepatic:** colitis, constipation, diarrhea, dyspepsia, GERD, ulcer
- **Infectious Disease:** common cold, bacterial infection, influenza, pneumonia, cellulitis, sinusitis, UTI
- **Immunology:** seasonal allergies, autoimmune disease, rheumatoid arthritis
- **Hematology:** deep vein thrombosis, pulmonary embolism, venous thrombosis
- **Musculo-Skeletal:** degenerative joint disease, osteoarthritis, fibromyalgia, gout, pain
- **Nephrology/Urology:** benign prostate, hypertrophy, prostatitis, bladder disorder, urinary incontinence
- **Neurology:** addictive dependencies, alcoholism, anxiety, attention deficit disorders, depression, insomnia, peripheral neuropathy, migraine, chronic pain
- **Reproductive:** contraception, impotence, premenstrual syndrome disorder
- **Pulmonary :** acute laryngotracheobronchitis, allergic rhinits, asthma, bronchitis, dyspnea, COPD

Language Capabilities

- English - Fluent
- Italian - Fluent
- Spanish - Conversational

Education

- Medical Doctor, University of Turin Medical School, Torino, Italy
- Bachelors of Science Degree, Fordham University, Bronx, New York

Memberships/Awards

- American College of Physicians
- American College of Chest Physicians
- Florida Medical Association

Other

- Medical Doctor, State of Florida, License No ME 51441
- American Board of Pulmonary Medicine, 1992
- American Board of Internal Medicine, 1989

Employee Signature: _____

Date: 02 Jan 2014

Albert J. Razzetti, MD

Covance Clinical Development Services
Physician

1900 Mason Ave, Suite 140, Daytona Beach, Florida
Tel: 386-366-6400

Employment History

Covance Clinical Development Services, Daytona Beach, Florida – Jan. 2011 – present
Physician – Jan. 2011 – present

- Provides medical coverage for the Covance Clinical Research Unit. As a Sub-Investigator, responsible for assuring the health and welfare of the participants.
- Responsible for performing medical procedures, responsible for proper conduct of the study trial, and responsible for all trial related medical decisions.

West Volusia Medical Associates, P.A., Florida Hospital, Deland, Florida – 1991 – present
Physician – 1991 – present

Sleep Laboratory, Florida Hospital, Deland, Florida – 1991 – present
Physician – 1991 – present

Liberty IRB, Deland, Florida – 2007 – present
Board Member – 2007 – present

University Clinical Research, Deland, Florida – 1998 – 2008
Physician/Principal Investigator – 1998 – 2008

Florida Hospital, Deland, Florida – 1991 – 2000
Physician/Director of Pulmonary Services – 1991 – 2000

Jackson Memorial Hospital, Miami, Florida – 1988 – 1991
Physician, Pulmonary/Critical Care Fellowship – 1988 – 1991

Mount Sinai Hospital, Miami Beach, Florida – 1986 – 1989
Physician, Internal Medicine Residency – 1986 – 1989

St. Francis Hospital, Miami Beach, Florida – 1986 – 1991
ICU Physician – 1986 – 1991

COVANCE

16.1.4.2 SITE 2

16.1.4.2.1 DESCRIPTION AND ADDRESS OF SITE 2

Site Name and Address	Description	Site Number
Covance Clinical Research Unit Inc., 1341 W. Mockingbird Lane, Suite 300E & 400E Dallas, TX 75247	This is a Medical Research Clinic.	DAL

16.1.4.2.2 CV OF PERSONNEL OF SITE 2 (PI, SUB-PI, STUDY COORDINATOR)

The Principal Investigator for this study was William Lewis, MD.

William Lewis, M.D.

Covance Clinical Development Services
Physician

1341 W. Mockingbird Lane, Suite 400E, Dallas, TX
Tel: 214-647-9300

Employment History

Covance Clinical Development Services, DALLAS, TX – 2007– present
Physician/CPI – 2007 – present

- Provides medical coverage for the Covance Clinical Research Unit
- As Principal Investigator/Sub Investigator, responsible for assuring the health and welfare of participants
- Responsible for performing medical procedures
- Responsible for proper conduct of the study trial
- Responsible for all trial related medical decisions

PrimaCare- Urgent Care Center, DALLAS, TX – 2003 – 2007
Family Practice Physician – 2003 – 2007

- Responsible for evaluating and treating patients in an urgent care clinic; including interpreting X-rays and lab results and also supervising staff

CareNow- Urgent Care, DALLAS, TX – 2001 – 2003
Family Practice Physician – 2001 – 2003

- Responsible for evaluating and treating patients in an urgent care clinic; including interpreting X-rays and lab results and also supervising staff

Plano Medical Associates, PLANO, TX – 2000 – 2001
Family Practice Physician – 2000 – 2001

- Responsible for evaluating and treating patients in an office setting

Texas Healthcare, PLANO, TX – 1998 – 1999
Solo Practice Physician – 1998 – 1999

- Responsible for evaluating and treating patients in an office setting

Richardson Health Center- Urgent Care Center, RICHARDSON, TX – 1986 – 1998
Medical Director – 1986 – 1998

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Name: William Lewis, M.D.

- Responsible for evaluating and treating patients in an urgent care clinic; including interpreting X-rays and lab results and also supervising staff

Cigna Clinic, GARLAND, TX – 1985 – 1986
Family Practice Physician – 1985 – 1986

- Responsible for evaluating and treating patients in an office setting/HMO

Kaiser Clinic, LAHAINA, MAUI, HI – 1984 – 1985
Family Practice Physician – 1984 – 1985

- Responsible for evaluating and treating patients in an office setting/HMO

Farwell Clinic, FARWELL, TX – 1982 – 1984
Solo Practice Physician – 1982 – 1984

- Responsible for evaluating and treating patients in an office setting

Texas Tech Medical School, LUBBOCK, TX – 1980 – 1982
Family Practice Residency – 1980 – 1982

- Responsible for evaluating and treating patients while under supervision and receiving training

Lankenau Hospital, PHILADELPHIA, PA – 1979 – 1980
General Surgery Intern – 1979 – 1980

- Responsible for evaluating and treating patients while under supervision and receiving training

Therapeutic Experience

- **ENDOCRINE INDICATIONS:** Diabetes Mellitus/Hypoglycemia/Hyperglycemia, Hyperlipidemia/Hypercholesterolemia/Lipid Metabolism, Glucose Clamp
- **GI/HEPATIC INDICATIONS:** Ulcer-H-pylori, Other-Lactose Intolerance
- **MUSCULO-SKELETAL INDICATIONS:** Hyperurecemia (Gout)
- **SPECIAL SENSES INDICATIONS:** Ophthalmology (cataract, glaucoma, conjunctivitis, intraocular pressure, macular degeneration)/ retinal diseases

Language Capabilities

- English

Education

- Master of Medical Management, University of Texas-UT Southwestern, DALLAS, TX
- Doctor of Medicine, UT Southwestern Medical School, DALLAS, TX
- Bachelor of Arts, Southern Methodist University, DALLAS, TX

Memberships/Awards

- Academy of Pharmaceutical Physicians and Investigators, 2010-2014
- American Academy of Urgent Care Medicine, 2006–2014

Name: William Lewis, M.D.

- American Board of Family Practice, 1983–1990, 1990–1997, 1998–2005

Other

- Medical License, State of Texas, License # F4212
- Certified Physician Investigator, 2014
- BLS-2014
- ACLS-2014

Employee Signature: [illegible]

Date: 10 Jan 2014

Neha Ghael, D.O.

Covance Clinical Development Services

Physician- PRN Contracted

1341 W. Mockingbird Lane, Suite 400E, Dallas, TX
Tel: 214-647-9300

Employment History

Covance Clinical Development Services, DALLAS, TX – Jun. 2006 – present
Physician – Jun. 2006 – present

- Provides medical coverage for the Covance Clinical Research Unit
- Principal Investigator/Sub Investigator, responsible for assuring the health and welfare of participants. Responsible for performing medical procedures, responsible for proper conduct of the study trial, and responsible for all trial related medical decisions

Prima Care, CEDAR HILL, TX – 2003 – present
Medical Director – Jan.2008 – present

- responsibilities include evaluating and treating patients in an urgent care setting, evaluating/interpreting lab results, X-rays and ECGs
- supervises staff, attends monthly meetings to evaluate the performance of the center, and scheduling
- audits charts and other administrative duties

Physician, DALLAS TX – 2003 – present

- works in an outpatient setting where she treats both acute and chronic conditions, ranging from upper respiratory illness to orthopaedic injuries to diabetes mellitus to preventative medicine
- procedures include removing ingrown nails, electrocautery of papillomas, pap smears, incision and drainage of abscesses, in-office treatment of verruca, removal of IUD's, suturing lacerations, interpreting electrocardiograms and radiographs, splinting and casting orthopaedic injuries, and performing osteopathic manipulative treatment
- Averages between 25-35 patients per day

NOVA Southeastern University College, FT. LAUDERDALE, FL – 2000 – 2003
Family Practice Residency – 2000 – 2003

- residency experience included rotations at Broward General Medical Center
- rotations included six months of Internal Medicine and additional months in various areas such as Ob-Gyn, Pediatrics, Emergency Medicine, Cardiology, Gastroenterology and General Surgery
- duties also included performing up to 20+ admissions per shift, including obtaining complete medical histories, physicals, writing admission orders, and managing the patients care until discharged from the hospital

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Name: Neha Ghael, D.O.

- spent 1-2 days per week in the family practice continuity care clinic where I managed a wide variety of medical diagnoses and performed procedures such as shave biopsies, trigger point injections, endometrial biopsies, incision and drainage of abscesses

University of Texas, SAN ANTONIO, TX – 1995 – 1996
Research Assistant – 1995 – 1996

- Research assistant, Division of Life Sciences, under the supervision of Dr. Paul H Rodriguez, Ph.D
- Studied the effects of the chemical mutagen ethyl methanesulfate (EMS) on populations of *Aedes aegypti* mosquitoes in terms of egg production, percent hatchability and F1 progeny viability

Therapeutic Experience

- N/A

Language Capabilities

- English
- Gujarati
- Spanish

Education

- Master of Public Health, NOVA Southeastern University College of Osteopathic Medicine, FT. LAUDERDALE, FL
- Doctor of Osteopathic Medicine, University of North Texas Health Science Center, FT. WORTH, TX
- Master of Science, University of Texas, SAN ANTONIO, TX
- Bachelor of Science, University of Alabama, HUNTSVILLE, AL

Memberships/Awards

- American Osteopathic Association
- Texas Osteopathic Association
- American Academy of Family Physicians
- American College of Osteopathic Family Physicians
- American Association of Physicians of Indian Origin

Other

- Texas Medical License: L6907
- Board Certified in Family Practice
- ACLS

Employee Signature: Neha Ghael DO

Date: 21 JAN 2014

Wendy Joseph, RPA-C

Covance Clinical Development Services
Physician Assistant

1341 W. Mockingbird Lane, Suite 400E, Dallas, TX 75247
Tel: 214-647-9300

Employment History

Covance Clinical Development Services, DALLAS, TX – Jul. 2013 – present
Physician Assistant – Jul. 2013 – present

- The Physician Assistant will provide an information service and knowledge base on the clinical aspects of clinical trials in Clinical Pharmacology. In addition, he/she may act as a sub-investigator.

Benedict Olusola, Dallas, TX – Dec. 2005 – Jun 2013
PT- Physician Assistant – Dec. 2005 – present

- Under direct supervision of a physician, perform medical assessments/histories and physicals.
- Order and interpret labs and diagnostic tests.
- Formulate appropriate diagnoses and the appropriate management.
- Conduct health education and counseling.

Parkland Hospitals, Dallas, TX – Aug. 2005 – present
Physician Assistant – Aug. 2005 – present

- Under direct supervision of a physician, perform medical assessments/histories and physicals.
- Order and interpret labs and diagnostic tests.
- Formulate appropriate diagnoses and the appropriate management.
- Conduct health education and counseling.

St. Peters Hospital, Albany, NY – Oct. 2004 – Jul. 2005
Physician Assistant – Oct. 2004 – Jul. 2005

- Under direct supervision of a physician, perform medical assessments/histories and physicals.
- Order and interpret labs and diagnostic tests.
- Formulate appropriate diagnoses and the appropriate management.
- Admission and management of pts from ER to Cardiology Dept./ Cardiac Unit.
- Conduct health education and counseling.

COVANCE

Name: Wendy Joseph, RPA-C

North Central Hospital, Bronx, NY – Jul. 2004 – Aug. 2005
PT. Physician Assistant – Jul. 2004 – Aug. 2005

- Under direct supervision of a physician, perform medical assessments/histories and physicals.
- Order and interpret labs and diagnostic tests.
- Formulate appropriate diagnoses and the appropriate management.
- Conduct health education and counseling.

Health Star Plus-Juvenile Detention, Bronx, NY – Jul. 2003 – Aug. 2005
Physician Assistant – Jul. 2003 – Aug. 2005

- Under direct supervision of a physician, perform medical assessments/histories and physicals.
- Order and interpret labs and diagnostic tests.
- Formulate appropriate diagnoses and the appropriate management.
- Conduct health education and counseling.

Montefiore Medical Center, Bronx, NY – Oct. 2002 – Oct. 2003
Physician Assistant – Oct. 2002 – Oct. 2003

- Administer and Monitor Cardiac Stress Testing: EKG, Echo and Pharmacological.

Therapeutic Experience

- **Neurology/Psychiatric Indications:** Addictive/withdrawal/cessation/dependencies- drug, nicotine, alcohol

Language Capabilities

- English

Education

- BS Physician Assistant Studies, Harlem Hospital Physician Assistant Program, CCNY-CUNY, New York, NY

Memberships/Awards

- Harlem Hospital Physician Assistant Program- Class of 2002 Professional Service Award

Other

- NCCPA certified
- ACLS/BCL Certified
- DEA Registration
- TX DPS Registered
- Texas State PA Registered/License
- New York State Registered/License

Employee Signature: _____

Date: 14 Jan 2014

Laura Garcia Kakar, MS, PA-C

Covance Clinical Development Services
Physician Assistant

1341 W. Mockingbird Lane, Suite 400E, Dallas, TX 75247
Tel: 214-647-9300

Employment History

Covance Clinical Development Services, DALLAS, TX – Jul. 2013 – present
Physician Assistant – Jul. 2013 – present

- The Physician Assistant will provide an information service and knowledge base on the clinical aspects of clinical trials in Clinical Pharmacology. In addition, he/she may act as a sub-investigator.

Dallas Sleep, Dallas, TX – Dec. 2006 – present
Physician Assistant/ Office manager – Dec. 2006 – present

- Co-Founder
- Physician Assistant
- Office Manager, from Dec. 2006 till Dec. 2010

Texas Medical Board, Dallas, TX – May 2012 – present
Expert Consultant – May 2012 – present

- Review cases from TMB and give recommendations as to whether standard of care was met.

Dr. Jessie Doyal, Mesquite, TX – Dec. 2006 – Dec. 2007
Physician Assistant – Dec. 2006 – Dec. 2007

- Associate: Under supervision of Physician, saw patients in private family practice clinic.

Dr. Roberto Lopez, Rowlett, TX – Dec. 2005 – Dec. 2006
Physician Assistant – Dec. 2005 – Dec. 2006

- Associate: Under supervision of Physician, saw patients in private internal medicine clinic.

San Jose Medical Group, San Jose, CA – Sep. 2003 – Oct. 2004
Physician Assistant – Sep. 2003 – Oct. 2004

- Physician Assistant in Primary Care clinic, full time.

Audie L Murphy VA Hospital, San Antonio, TX – Jan. 1998 – Jul. 2003
Physician Assistant – Jan. 1998 – Jul. 2003

- Actively involved in evaluating and treating patients in Internal Medicine clinic.

COVANCE

Name: Laura Garcia Kakar, MS, PA-C

VA Hospital, San Antonio, TX – Mar. 2001 – Jul. 2003
Physician Assistant – Mar. 2001 – Jul. 2003

- Evaluated and treated patients in Endocrinology Outpatient clinic, part time.

Wilford Hall Medical Center, Lackland Air Force Base, TX – Jan. 2000 – Jan. 2002
Physician Assistant – Jan. 2000 – Jan. 2002

- Evaluated and treated patients in the Fast Track (Urgent Care Center) of the Emergency department.

Therapeutic Experience

- **N/A**

Language Capabilities

- English
- Spanish

Education

- MS, Physician Assistant Studies, University of Texas Pan American, Edinburg, TX
- BS, Physician Assistant Studies, University of Texas Medical Branch, Galveston, TX

Memberships/Awards

- American Academy of Physician Assistants
- Texas Association of Physician Assistant

Other

- National Commission of Certification Certified Physician Assistant
- Texas State Physician Assistant License
- BLS
- ACLS

Employee Signature: Laura Kakar

Date: 22 Aug 2013

Name: Laura Garcia Kakar, MS, PA-C

Appendix I

Masters Thesis: A Review of the Literature on Cardiovascular Outcomes of Various Treatment Options in Adults with Obstructive Sleep Apnea. 2008, Laura Kakar

Jeanelle L. Kam, MD, CPI

Covance Clinical Development Services
Physician

1341 W. Mockingbird Lane, Suite 400E, Dallas, TX 75247
Tel: 214-647-9300

Employment History

Covance Clinical Development Services, DALLAS, TX – Jun 2013 – present
Physician – Jun 2013 – present

- Provides medical coverage for the Covance Clinical Research Unit. As Principal Investigator/SubInvestigator, responsible for assuring the health and welfare of participants. Responsible for performing medical procedures, responsible for proper conduct of the study trial, and responsible for all trial related medical decisions.

Covance Clinical Development Services, Honolulu, HI – Nov 2008 – Dec 2013
Physician – Nov 2008 – Dec 2013

- Provides medical coverage for the Covance Clinical Research Unit.
- Responsible for assuring the health and welfare of participants.
- Responsible for performing medical procedures, for proper conduct of clinical trials and for trial related medical decisions.
- Involved with clients for medical consultations on study design and safety for early clinical phases of drug development.
- Interfaced with medical staff and clients to ensure proper study designs and notification of serious adverse events to the sponsor.

Kaiser Permanente, San Francisco, CA – Jun 2005 – Dec 2007
Physician, Obstetrics and Gynecology – Jun 2005 – Dec 2007

- Provided diagnosis, treatment, and management of patients in the Obstetrics and Gynecology Department.
- Responsible for providing outpatient medical histories and physical exams for the well being of patients and managing long term obstetrical and gynecological care.
- Responsible for assuring the proper management of laboring patients in inpatient post-op gynecological patients.

Cedars-Sinai Medical Center, Los Angeles, CA – Jun 2004 – May 2005
Physician Internship in Obstetrics and Gynecology – Jun 2004 – May 2005

- Provided medical care to patients in the Obstetrics and Gynecology Department.
- Responsible for providing outpatient medical histories and physical exams for the well being of patients and managing long term obstetrical and gynecological care
- Responsible for assuring the proper management of laboring patients in inpatient post-op gynecological patients.
- Diagnosis, treatment, and care of patients assigned in her care.

COVANCE

Name: Jeanelle L. Kam, MD

Department of Biological Sciences, NIH Bethesda, MD – Sep 1996 – May 1999
Pre-Doctoral Intramural Research Training Award Fellowship – Sep 1996 – May 1999

- Conducted basic science research on the ADP-ribosylation factor directed ATPase-activating proteins.
- Responsible for performing the experimental procedures including the preparation of protein purification, conducting the enzyme assays, with interpretation of data with mentor.

Therapeutic Experience

- **Phase I Health**
- **Cardiovascular:** Hypertension
- **Dermatology**: Acne/Acne Vulgaris, Dermatitis, Eczema, Urticaria
- **Endocrine:** Diabetes Mellitus
- **GI/Hepatic:** Constipation, Other-Lactase Intolerance
- **Infectious Disease:** Genital tract Infection: Sexually Trans Diseases, yeast, Herpes Simplex, Urinary Tract Infections
- **Musculo-Skeletal:** Osteoporosis, Gout
- **Reproductive/Gender Based:** Contraception/Birth Control, Endometriosis/ Endometrial Protection/Hyperplasia/Cerv, Dysplasia/Uterine fibroids/, Ovarian cysts, Hormone replacements for deficiencies/menopausal syndromes, Impotence/Erectile, Dysfunction/Penile Implant, Infertility/Conception/In Vitro fertilization/Ovarian Hyperstimulation, Labor and Deliver (prevention/supportive), Menorrhagia/Dysmenorrhea, Pelvic Pain/Pelvic Inflammatory Disease (PID), Premenstrual Syndrome/Dysphoric Disorder (PMDD), Sexual Dysfunction-Female, Surgery on reproductive system, Diagnostics of Reproductive system-non-specified, Devises for Reproductive system

Language Capabilities

- English

Education

- M.D., University of Hawaii, John A. Burns School of Medicine, Honolulu, HI
- B.A. Liberal Studies, Pre-medicine, University of Hawaii, Honolulu, HI

Memberships/Awards

- Association of Clinical Research Professionals

Other

- M.D. License, State of Texas, License No. P7790
- M.D. License, State of Hawaii, License No. MD-14684
- M.D. License, State of California, License No. A95484
- M.D. License, State of Washington, License No. MD60327434
- Certified Physician Investigator 2012
- Advanced Cardiac Life Support Certification, 2008, 2010, 2012

Name: Jeanelle L. Kam, MD

Employee Signature: _____

Date: 09 Jan 2014

Name: Jeanelle L. Kam, MD

Appendix I

PUBLICATIONS:

Beal, A.C., Co, J.P.T., Dougherty, D., Jorsling, T, Kam, J.L., Perrin, J., and Palmer, R.H., "Quality Measures for Children's Health Cure," Pediatrics. Vol. I13. No. 1: pp. 199-209, January 2004.

Kam, J. L., Hu, M., Peiler, L.L., and Yamamoto, L.G, "Acute Comportment Syndrome Signs and Symptoms Described In Medico! Textbooks," Hawaii Medical Journal, .Yol. 62: pp. 142·143, July 20, 2003.

Kam, J.L., Miura, K., Jackson, T.R., Gruschus, J., Roller, P., Stouffer, S., Clark, J., Anega, R. and Randazzo, P.A., "Phosphoinositide-dependent Activation of the ADP-ribosylation Factor GTPase-activating Protein ASAP I," Journal of Biological Chemistry, Vol. 275. No. 13: pp. 9653-9663, March 31, 2000.

Andreev, J., Simon, J.P., Sabatini, D., Kam, J.L., Randazzo, P.A., and Schlessinger, J., "identification of a New Pky2 'Target Protein with ARF·OAP Activity," Molecular and Cellular Biology, Vol 19, No. 3: pp. 2338-2350, March 1999.

Kam, J.L., "The University of Hawaii Manoa-John A. Burns School of Medicine: Commemorative Service to Loved Ones Who Shored Their Bodies for Medicine," Journal for Minority Medical Students,

PRESENTATIONS

Martenyl, F., Lowe, S., Dean, R.A., Moog, S.A., Gonzales, C.R., Freidrich, S., May, P.C., Audio,

J.E., Citron, M., Labell, E.S., Moran, S., Yen, M., Jhee, S, Kam, J., and Ereshefsky, L., "Central and Peripheral PK and PD Effects of
the Beta Site APP Cleavage (BACE·I) Inhibitor LY28811376 in Humans, international Conference of Alzheimer's Disease, Honolulu,
HI 2010.

Kam, J.L., Co, J.P., and Beal A, "Measures for Health Core Quality for Children," Pacific Region nod Indigenous Doctor's Congress, Honolulu, HI, 2002

Kam, J.L., "Textbook Misinformation of the Significance of Pulselessness and Pallor in Acute Compartment Syndrome," American Academy of Pediatrics National Conference, Son Francisco, CA, 2001

Kam, J.L., Andrade, J., Gntschus, J., Stauffer, S., Aneja, R., Ferriti, J. and Randazzo, P., "Phosphoinositide- Dependent Regulation of ADP-Ribosylation Factor," National Institutes of Health Research Festival Poster· Session, Bethesda, MD, October 1998

T. Alex King, M.D.

Covance Clinical Development Services
Physician

1341 W. Mockingbird Lane, Suite 400E, Dallas, TX
Tel: 214-647-9300

Employment History

Covance Clinical Development Services, DALLAS, TX – Jul. 2010 – present
Physician – Jul. 2010 – present

- Provides medical coverage for the Covance Clinical Research Unit
- As Principal Investigator/Sub Investigator, responsible for assuring the health and welfare of participants
- Responsible for performing medical procedures
- Responsible for proper conduct of the study trial
- Responsible for all trial related medical decisions

Physician, AUSTIN, TX – 2008 – Jun. 2010

- Provides medical coverage for the Covance Clinical Research Unit
- As Principal Investigator/Sub Investigator, responsible for assuring the health and welfare of participants
- Responsible for performing medical procedures
- Responsible for proper conduct of the study trial
- Responsible for all trial related medical decisions

UT Southwestern Medical Center, DALLAS, TX – 1999 – 2008
Assistant Professor – 1999 – 2008

- Provided support in the Department of Family Medicine and Community Health

Therapeutic Experience

- **ENDOCRINE INDICATIONS:** Diabetes Mellitus/Hypoglycemia/Hyperglycemia, Glucose Clamp
- **GI/HEPATIC INDICATIONS: Ulcer:** H. Pylori
- **INFECTIOUS DISEASE INDICATIONS:** Vaccines for infectious diseases
- **MUSCULO-SKELETAL INDICATIONS:** Pain-chronic
- **NEUROLOGY/PSYCHIATRIC INDICATIONS (INCLUDES CNS):** Insomnia/sleep disorder, Pain-Head (Headache), migraine
- **REPRODUCTIVE/GENDER-BASED INDICATIONS:** Hormone replacements for deficiencies/menopausal syndromes

COVANCE

Name: T. Alexander King, M.D.

- **SPECIAL SENSES INDICATIONS:** Ophthalmology (cataract, glaucoma, conjunctivitis, intraocular pressure, macular degeneration)/retinal diseases

Language Capabilities

- English

Education

- Doctor of Medicine, University of Texas Southwestern Medical School, DALLAS, TX
- Bachelor of Arts-Biology, Austin College, SHERMAN, TX
- Liberal Arts Program (Plan II), University of Texas, AUSTIN ,TX

Memberships/Awards

- Academy of Pharmaceutical Physicians and Investigators, 2012-2014
- American Academy of Family Physicians
- Texas Academy of Family Physicians

Other

- Certified Physician Investigator, 2012
- Medical Doctor, State of Texas, License No. K7176
- American Board of Family Medicine, 2006 – 2016
- Human Participants Protection Education for Research Teams, Austin, TX, 2008
- ACLS and BLS, 2012-2014

Employee Signature:_____

Date:_____09 JAN 2014_____

A list of publications, manuscripts, abstracts, and presentations is available upon request.

Name: T. Alexander King, M.D.

Appendix I

Publications, manuscripts, abstracts, and/ or presentations

King TA. Skin Papule (Basal Cell Carcinoma). In: Rakel (ed). Essential Family Medicine, 3rd edition, Saunders Elsevier, Philadelphia, PA: 2006

Matthew M. Medlock, MD

Covance Clinical Development Services
Medical Director

1341 W. Mockingbird Lane, Suite 400E, Dallas, TX 75247
Tel: 214-647-9300

Employment History

Covance Clinical Development Services, DALLAS, TX – Oct. 2013 – present
Medical Director – Oct. 2013 – present

- Provides supervision and direction to the physicians of the Covance Clinical Research Unit, as appropriate.
- Ensures that there is proper medical coverage from the physicians to cover the medical safety to the unit during all hours of operation.
- Involved with clients for medical consultation on study design and safety for early clinical phases of drug development.
- Interfaces with the medical staff and clients to ensure proper study designs and notification of serious adverse events to the sponsors.
- Provides medical coverage for the Covance Clinical Research Unit.
- As Principle Investigator/SubInvestigator, responsible for assuring the health and welfare of participants. Responsible for performing medical procedures, responsible for proper conduct of the study trial, and responsible for all trial related medical decisions.

PPD Phase I Clinical Research Unit, Austin, TX – Oct. 2006 – Oct. 2013
Principal Investigator and Associate Medical Director – Oct. 2006 – Oct. 2013

- Principal Investigator for 160 Phase I studies
- Sub-investigator on most other studies conducted at the Phase I CRU (over 100 studies/year)
- With the Medical Director, primary medical feasibility (safety/ethics) review of proposed studies for the unit
- Extensive experience with protocol development and writing including statistical and pharmacokinetic analysis plans, study planning and conduction, and final study CSR review and completion

Eisai Medical Research, Inc, Ridgefield Park, NJ – Jul. 2004 – Sep. 2006
Director, Clinical Pharmacology – Jul. 2006 – Sep. 2006
Associate Director, Clinical Pharmacology – Jul. 2004 – Jul. 2006

- Project Team member representing Clinical Pharmacology and Internal Medicine for numerous investigational products covering various medical conditions including diabetes, dyslipidemia, Alzheimer's disease, psoriasis, atopic dermatitis, rheumatoid arthritis, SLE, sepsis, GERD, and epilepsy.
- Responsible for the creation and review of investigator brochures, clinical study protocols and reports, product development plans, informed consents, FDA meetings and letters, due diligence for in-licensing of products, and meetings with key opinion leaders.
- Study director for several Phase 1 studies, including a first-in-human study.

COVANCE

Name: Matthew Medlock, MD

Uniformed Services University of the Health Sciences, and National Institute of Drug Abuse, Bethesda, MD – Jun. 2002 – Jun. 2004
Fellowship, Clinical Pharmacology – Jun. 2002 – Jun. 2004

- Sub-Investigator for several studies conducted in the CPU at NNMC under NIDA and the Army
- 3 month externship at the FDA as an acting Medical Officer (Cardio-Renal Division) primarily reviewing several IND's, including the Medical Officer section for a pre-IND meeting
- Assisted the teaching of the Clinical Pharmacology series for the USUHS fourth-year medical students
- Clinical Pharmacology consultation service for NNMC and WRAMC

Hawaii Permanente, Honolulu, HI – Feb. 2001 – Dec. 2001
Staff Physician – Feb. 2001 – Dec. 2001

- General Internal Medicine practice covering outpatients.

Northwest Permanente, Portland, OR – Jul. 1998 – Dec. 2000
Staff Physician – Jul. 1998 – Dec. 2000

- General Internal Medicine practice covering outpatients and inpatients.
- Several clinical committees at KPNW including the Asthma/COPD steering committee.
- Supervision of Internal Medicine residents from OSHU

Legacy Portland Hospital, Portland, OR – Jul. 1997 – Jun. 1998
Chief Medical Resident – Jul. 1997 – Jun. 1998

- Responsible for the 50+ internal medicine residents.
- Member of several residency and hospital committees.

Therapeutic Experience

- **CARDIOVASCULAR INDICATIONS:** Atherosclerosis, arteriosclerosis, coronary, artery disease, coronary heart disease, Congestive Heart Failure/Cardiac Edema/Cardiomyopathy, Hypertension-systolic or diastolic, Myocardial Infarctions (Q-wave, non Q wave)
- **DERMATOLOGY INDICATIONS:** Dermatitis, Eczema, Psoriasis
- **ENDOCRINE INDICATIONS:** Diabetes Mellitus/Hypoglycemia/Hyperglycemia, Hyperlipidemia/Hypercholesterolemia/Lipid Metabolism, Hypothyroidism
- **GI/HEPATIC INDICATIONS:** Crohn's disease, Dyspepsia/Gastritis/Esophagitis/GERD, Hepatitis- A, B, C, D or E, Ulcerative colitis
- **INFECTIOUS DISEASE INDICATIONS:** Acquired Immune Deficiency/AIDS/HIV, Infection-bacterial, non-specified, Infection-fungal, non-specified, Tuberculosis-typical (MTB) or atypical (MAI)
- **IMMUNOLOGY INDICATIONS:** Autoimmune disease- non-specified, Lupus, Rheumatoid Arthritis
- **MUSCULO-SKELETAL INDICATIONS:** Gout, Multiple Sclerosis, Pain- acute
- **NEUROLOGY/PSYCHIATRIC INDICATIONS (includes CNS):** Addictive/withdrawal/cessation/dependencies- drug, nicotine, alcohol, Alzheimer's disease/dementia/memory disorders/cognitive disorders, Bipolar Disorder (manic-depressive), Depression, Insomnia/sleep disorder
- **PULMONARY/RESPIRATORY INDICATIONS:** Asthma, Chronic obstructive pulmonary disorder/emphysema, Pulmonary hypertension

Name: Matthew Medlock, MD

Language Capabilities

- English

Education

- M.D., University of Texas Southwestern Medical School, Dallas, TX
- B.A. Biology, University of Texas, Austin, TX

Memberships/Awards

- American Society of Clinical Pharmacology and Therapeutics
- American College of Clinical Pharmacology
- Drug Information Association
- Texas Medical Association

Other

- M.D. License, State of Texas, License No. M5373
- Controlled Substance Registration Certificate, DEA Registration
- Texas Controlled Substances Registration Certificate, DPS Registration
- Advanced Cardiac Life Support Certification, 2012

Employee Signature: MMedlock

Date: 9 dec 2014

Name: Matthew Medlock, MD

Appendix I

DIA 2011 Annual Meeting. SIAC Showcase: Biologics--Changing the Phase I Clinical Landscape: Practical Implications in the CPU. (panel speaker)

Gopal K, Vickery D, Ma L, Yu X, Noren C, Power E, Beresford E, Medlock M. Lack of Pharmacokinetic Drug Interaction Between Oral Posaconazole and Caspofungin or Micafungin. J Clin Pharmacol. 2011 Jan;51(1):84-92.

O'Mara E, Kasserra C, Huddlestone JR, Wan Y, Soni P, Caceres M, Medlock M, Morrison R, Devinsky O. Effect of Vicriviroc on the QT/corrected QT Interval and Central Nervous System in Healthy Subjects. Antimicrob Agents Chemother. 2010 Jun;54(6):2448-54.

Gopal K, Moton A, Ma L, Medlock MM, McLeod J. Pharmacokinetics and Absorption of Posaconazole Oral Suspension under Various Gastric Conditions in Healthy Volunteers. Antimicrobial Agents and Chemotherapy; 2009 Mar; 53(3):958-66.

Medlock MM, Cantilena LR, Riel MA. Comment on: Adverse events following discharge from the hospital. Ann Intern Med. 2004 Feb 3;140(3):231-2.

Medlock MM, Cantilena LC, Haigney M, Riel MA, Kahn R, Elkashef A, Chiang CN. Cardiovascular Effects of Intravenous Cocaine in Human Volunteers. Clin Pharmacol Ther 2003;73(2):P31.(abstract)

16.1.4.3 CV OF KEY CRO STAFF

16.1.4.3.1 LIST OF KEY CRO STAFF (PROJECT MANAGER, STATISTICIAN, DATA MANAGER, MEDICAL WRITER, LEAD CRA, MEDICAL MONITOR)

- Covance Clinical Development Services :

Medical Monitor	Katerina Bovtenko, MD, MSc
Clinical Project Manager	Jasmine Ropers
Lead Clinical Research Associate	Ann Hintz (until 20 June 2014)
	Mary Martinez (from 20 June 2014 until 05 November 2014)
	Esther Clements (as of 05 November 2014)

Covance Clinical Data, Analysis and Reporting Organization (CDARO, Leeds, UK):

CDARO Project Manager:	Jo Taylor, BSc, PhD
CDARO Data Manager	Mary Russo, BSc
CDARO Pharmacokineticist	Stuart Hossack, BSc
CDARO Statistician	John Hunter, BSc, MSc Andrew Hedge, BSc, MSc
CDARO Medical Writer (CDARO)	Andrew Senior Louise Wakenshaw, BSc, PhD

16.1.4.3.2 CV OF KEY CRO STAFF

Katerina Bovtenko, MD

Covance Clinical Development Services
Medical Director

Covance Maidenhead, Berks, Osprey House, Maidenhead Office Park, Westacott Way, SL63QH, UK
Tel: 01628548000

Employment History

Covance Clinical Development Services, Maidenhead, United Kingdom – Sep 2008 – present

Medical Director – March 2013 – **present**

- Project physician on global clinical trial programs
- Medical input in the company improvement initiative processes
- Therapeutic area and protocol training for the project teams
- Providing medical input into the projects feasibility, proposals and bid defense meetings
- Identification and work with the consultant experts in IBD and IBS
- Investigators' Meeting participation

Associate Medical Director – Jun 2011 – Feb 2013

- Lead and back up project physician on clinical trial projects
- Medical and safety monitoring, Medical review of the study documents and plans
- Participation in the bid defense, audits and client partnership meetings

On assignment as a Medical Monitor – May 2010 – May 2011

- Dual role between Medical and Scientific Affairs Department and Clinical Operations Department
- Medical review of clinical trial and safety data including immediately reportable events

Senior Clinical Research Associate – Sep 2008 – May 2011

- Site management including regular contacts with investigators for patient recruitment discussions
- Maintaining the communication between the investigative sites and Medical Monitor
- Conducting site motivational visits to improve the enrolment
- Assisting sites in safety reporting and safety query resolution
- Handling the regulatory authority inspection; post audits follow-up action
- Communication with vendors; Contract negotiations with sites and budget review
- Conducting routine monitoring visits, pre-study visits, site initiation and close-out visits

COVANCE.

- Study feasibility
- Ethics Committee local and central submissions
- Involvement in the company improvement processes
- Mentoring junior staff

PSI Co Ltd, Kiev. Ukraine – Dec 2003 – Sep 2008
Medical Monitor / Safety Officer – May 2008 – Sep 2008

- Primary and secondary contact for the sponsor, the project team and investigative sites; Primary contact for all project-specific medical issues
- Development of the study-specific medical documents including safety plan, medical monitoring plan
- Study protocol medical review
- Medical review of safety events including safety narratives, CIOMS
- Medical input into study feasibility
- Support in the preparation of the periodic safety reports

Co-Project Manager – Sep 2007 – Apr 2008

- Responsible for all project activities in Russia & Ukraine
- Serving as a contact for all sites regarding the study procedural concerns\protocol interpretation including medical queries
- Supporting ongoing study-specific internal and external communication medical issues
- Review of incoming safety reports including review for medical consistency
- Participation in study feasibility (gastroenterology; cardiology; oncology; infectious diseases; haematology)
- Generation and review of the project specific documents (including monitoring plan, drug management plan, communication plan, etc), newsletters, weekly activity reports; progress reports
- Presenting at Investigator's Meetings, Audits
- Supervision the project teams in Russia & Ukraine; Switzerland; Trainings of CRAs and Project Coordinators
- Review of monitoring/initiation/selection/close-out reports
- Performed site initiation, close-out, site evaluation visits; Co-monitoring of investigational sites for quality control purposes
- Handling of contractual issues; Central EC and Regulatory authorities submissions
- Mentoring of junior staff; line management responsibilities

Senior / Lead Clinical Research Associate – Nov 2006 – Sep 2007

- Focal communication point for investigational sites, project staff, primary and secondary communication line for vendors, customer
- Onsite training of investigators and staff; Site Management
- Supervision of project teams in Switzerland, Russia, Ukraine
- Feasibility, selection, initiation of sites, routine monitoring and close out visits, Audits
- Review of incoming safety events, including review for medical consistency
- Delivery of the presentation on safety events at the investigator's meetings and CRA training
- Involved in all aspects of study from feasibility and set-up till the study closure

Clinical Research Associate – Dec 2003– Nov 2006

- Site management and monitoring, audits

CORIS (private medical insurance company), Kiev. Ukraine – Jul 2003 –Nov 2003
Medical Coordinator (Physician)

Clinic of Medicine and Hepatology, Kiev. Ukraine – Mar 2003 –May 2003
Physician (General Medicine)

"Basseinova" Central Hospital of Kiev. Ukraine – Jun 2002– Aug 2003
Physician (Gastroenterology)

Therapeutic Experience

- **GI/HEPATIC: CROHN'S DISEASE, ULCERATIVE COLITIS, DYSPEPSIA/GASTRITIS/GERD, PHASE II-III**
- **NEPHROLOGY/UROLOGY: OVERACTIVE BLADDER/URINARY INCONTINENCE, CHRONIC KIDNEY DISEASE, ANEMIA, GLOMERULOSCLEROSIS, PHASE II-III**
- **ONCOLOGY: NON-SMALL CELL LUNG CANCER, KIDNEY CANCER, HEMATOLOGICAL MALIGNANCIES, PHASE II-III**
- **ENDOCRINOLOGY: HYPERTHYROIDISM/GRAVE'S DISEASE, PHASE I**
- **RESPIRATORY & INFECTIOUS DISEASES: PNEUMONIA – COMMUNITY ACQUIRED, HEPATITIS B/C, HPV VACCINE, PHASE II-III**
- **NEUROSCIENCE: SCHIZOPHRENIA, PHASE III**

Language Capabilities

- English, French, Ukrainian and Russian

Education

Postgraduate Course in Pharmaceutical Medicine (Ongoing), Welsh School of Pharmacy, Cardiff University, United Kingdom

MSc Program (Gastroenterology), Diploma with distinction, Bogomolets National Medical University, Department of Hospital Therapy #2, Kiev, Ukraine

MD (MBBS equivalent), Diploma with distinction, Bogomolets National Medical University, Kiev, Ukraine

Memberships/Awards

- British Association of Pharmaceutical Physicians, UK since 2010
- Ukrainian Medical Society, Kiev, Ukraine since 2002

Other

Computer literacy: Word, Excel, Power Point, Outlook, Lotus Notes, Phase Forward/Inform, ClinTrace, MedDRA, ClinPhone, Almac.
Excellent communication skills; quick learner, dedicated and organized
Literature, theatre, travelling

A list of abstracts and presentations is available upon request.

Employee Signature: _____

Date: 1 Apr 2014

Appendix I

1. MSc dissertation "Psychological and autonomic nervous system parameters in patients with stomach ulcer" (2003);
2. Research Conference, department of infectious diseases: "New methods of diagnostic of viral hepatitis" (2001), presentation;
3. 54th scientific conference of students and young researches, Department of Pharmacology "Hypotension medications. Angiotensin-converting enzyme inhibitors" (2000), presentation;
4. Research Conference, department of hygiene, "Chemical pollution of environment, its resources, influence on health, ways of prevention". Diploma of 2d degree (1999), presentation;
5. Research Conference. Department of foreign languages. "Cocaine abuse and dependence", "Depression and the dynamics of smoking" (1998), presentation.

COVANCE
SOLUTIONS MADE REAL

Jasmine Ropers

Covance Clinical Development Services
Project Manager, Project Management – CardioMedPharm

3402 Kinsman Blvd., Madison, Wisconsin

Tel: 1-608-442-8200

Employment History

Covance Clinical Development Services, Madison, Wisconsin, USA – Aug 2000 – Present
Project Manager, Project Management, CardioMedPharm, Early Clinical Development – Jun 2011 – Present

- To ensure that all allocated projects are carried out in accordance with relevant protocols, SOPs (Covance and Sponsor), and specified GCP and FDA requirements as applicable
- Initiate improvements to enhance the efficiency and the quality of the work performed on assigned projects
- Providing operational strategies to clients and internal functional teams and responsible for on time, on-budget provision of client deliverables for assigned projects
- Establish excellent working relationships with client project teams to ensure client satisfaction and operational excellence
- Proactively engage in both quality assurance and risk management activities to ensure project deliverables are met according to both Covance and client requirements
- Resolve conflicts as needed

Project Manager III, Early Clinical Development – Dec 2010 – Jun 2011

- Primary client contact who managed studies from initiation through the transfer of final deliverables
- Managed clinical trial activities in accordance with GCP and ICH standards, the protocol, SOP's, and study management plans
- Managed all activities involving the case report form (CRF), study Monitors, and issues related to data management
- Evaluated progress of designed projects against quality, budget, and timeline expectations
- Ensured timely communication, escalation and resolution of all issues

Project Manager I, Early Clinical Development – Jun 2008 – Dec 2010

- Assessed key operational and safety information from protocols and investigator brochures of assigned studies
- Evaluated progress of designed projects against timelines, budget and client satisfaction surveys and recommended and/or implemented appropriate actions

COVANCE
SOLUTIONS MADE REAL

Jasmine Ropers

- Ensured that all allocated projects were carried out in strict accordance with the relevant protocols, SOPs, and specified GCP and ICH standards
- Communicated on a regular basis with assigned clients regarding questions, concerns, and project status

Supervisor, Data Management, Pharmacometrics – 2005 - 2008

- Supervised the Data Entry, Data Management, and Quality Control Staff
- Duties included: scheduling, training, appraisal of staff members, assignment of staff to specific studies, ensuring adequate staff were available to meet workload demands, and monitoring study progress to verify client deadlines were met

Oracle Clinical Specialist, Pharmacometrics – 2004 - 2005

- Main resource for the Pharmacometrics department for issues and questions related to Oracle Clinical Data Management System (OCDMS)
- Served as the Global Librarian for Madison and was in charge of training new data management staff in OCDMS related materials

Data Coordinator, Pharmacometrics – 2001 - 2004

- Involved with the acquisition, uploading, and clean up of laboratory data
- Provided support to research assistants/associates and QC auditors within the department, and provided back up for data entry during times of peak workflow
- Main contact for Madison in the implementation of OCDMS

Data Services/ Staff Assistant III, Pharmacometrics – 2000 - 2001

- Entered data from Case Report Forms (CRFs) electronically using specifically designed software
- Reviewed the CRFs for errors and notified appropriate staff by way of database edit forms
- Entered the completed edits when they were returned to the data department
- Reviewed data entries based on results of a double data entry comparison and completed database audits after final comparisons were performed

Fennimore Community School District, Fennimore, Wisconsin – Aug 1999 – Aug 2000
Data Specialist – Aug 1999 – Aug 2000

- Created databases with MS Access, input grades and attendance information into a student records database
- Prepared budget reports using MS Excel
- Installed and implemented photo ID hardware and software
- Answered telephones and assisted students and parents with questions

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Jasmine Ropers

Therapeutic Experience

- **Immune Mediated Inflammatory Disease (IMID):**
  - **Inflammatory Bowel** – Irritable Bowel (Phase I)
- **CardioMetabolic:**
  - **Metabolic and Cardiovascular Risk** – Type II Diabetes (Phase I)
- **Neuroscience:**
  - **Psychiatry** – Addiction (Phase I-III)
  - **Pain** – Musculoskeletal/Arthritic Pain (Phase IV)
- **Other:**
  - **Phase I** – Normal Healthy, Single Ascending Dose (SAD), Multiple Asceding Dose (MAD), PK/PD, Renal Deficiency, Hepatic Deficiency

Language Capabilities

- English

Education

- Associate Degree – Microcomputers, Southwest Wisconsin Technical College, Fennimore, Wisconsin, USA

Memberships/Awards

- Not Applicable

Other

- Certified Project Manager certification
- Greenbelt training and completion of project entitled, "Reduction in Time and Labor to Create Pharmacometrics Datasets" June 2008
- Trained in Targeted Selection interviewing June 2005

Employee Signature: Jasmine Ropers

Date: 13 May 2015

Covance is an independent, publicly held company with headquarters in Princeton, New Jersey, USA.
Covance is the marketing name for Covance Inc. and its subsidiaries around the world.

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Ann Hintz

Covance Clinical Development Services
Senior Clinical Research Associate – Clinical Operations (Regionally Based, Florida, USA)

206 Carnegie Center, Princeton, New Jersey

Tel: 1-609-452-8550

Employment History

Covance Clinical Development Services, Princeton, New Jersey, USA – Nov 2014 – Present
Senior Clinical Research Associate, Clinical Operations, Early Clinical Development – Nov 2014 – Present

- Manages all aspects of site monitoring responsibilities for clinical trials, according to Covance standard operations procedures, ICH guidelines and GCP, including pre-study qualification, initiation, routine/interim monitoring and close-out visits
- May serves as lead CRA for a protocol or project – which includes training other CRAs on study specifics, ensuring consistency at study sites, responsibility for overseeing CRA performance, reviewing trip reports for content and timelines, and leveraging best practices, writing Monitoring Plan
- Generates and assures implementation of Project Plans related to the Clinical Monitoring responsibilities
- Tracks progress of projects and initiates appropriate actions to achieve target objectives, including fiscal responsibility for tracking monitoring expenses against the project budget
- Mentoring and activities to junior CRA
- Participate in identification/feasibility and recruitment of investigator sites, collection of investigator pre-study visits and site management responsibilities

From Jun 2014 to Nov 2014 was continuing her education towards her Bachelor's Degree

Senior Clinical Research Associate, Clinical Operations, Early Clinical Development – Jun 2013 – Jun 2014

- Manages all aspects of site monitoring responsibilities for clinical trials, according to Covance standard operating procedures, ICH guidelines and GCP, including pre-study qualification, initiation, routine/interim monitoring and close-out visits
- Generates and assures implementation of Project Plans related to the Clinical Monitoring responsibilities

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Ann Hintz

- Tracks progress of projects and initiates appropriate actions to achieve target objectives, including fiscal responsibility for tracking monitoring expenses against the project budget
- Participate in identification/feasibility and recruitment of investigator sites, collection of investigator pre-study visits and site management responsibilities
- Served as a Lead CRA for a protocol or project – which includes training other CRAs on study specifics, ensuring consistency at study sites, responsibility for overseeing CRA performance, reviewing trip reports for content and timelines, and leveraging best practices, writing Monitoring Plan

DOCS Global, a Division of ICON Research, New York, New York, USA – May 2012 – Jun 2013
Clinical Research Associate – May 2012 – Jun 2013

- Regional CRA responsible for field monitoring, remote data collection, monitoring of adverse events exclusively for the Medtronic Corevalve trial
- Reviewed site progress and conduct of the Medtronic clinical study, ensured the accuracy of data collection, provided site guidance and ensured site compliance to the protocol, compliance to CFRs, GCPs and site IRB policies
- Trained and mentored new contract CRAs to the Medtronic Corevalve project and completed training and observational reports
- Performed Device Accountability for implanted experimental devices and all related delivery systems
- Continuous and ongoing written communication via Pre and Post Visit Letters and ongoing verbal communication with all Principle Investigators and Clinical Research Coordinators

Reata Pharmaceuticals, Irving, Texas, USA – Apr 2012 – Jun 2012
Independent Contract Clinical Research Associate – Apr 2012 – Jun 2012

- Regional CRA responsible for field monitoring, remote data collection, monitoring of adverse events exclusively for the BEACON trial
- Reviewed site progress and conduct of sponsor clinical study, ensured the accuracy of data collection, provided site guidance and ensured site compliance to the protocol, compliance to CFRs, GCPs and site IRB policies
- Continuous and ongoing written communication via Pre and Post Visit Letters and ongoing verbal communication with all Principle Investigators and Clinical Research Coordinators
- Completion of Monitoring Visit Reports (Trip Reports) per sponsor SOP timelines
- Ensured all Adverse Events, Protocol Deviations, IND Safety Reports or Non-compliance has been promptly reported to sponsor and site IRB as per sponsor and IRB written policies as well as per the CFR guidelines

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- Primary CRA for Puerto Rico and Miami area sites

Edwards Lifesciences, Irvine, California, USA – Dec 2008 - Apr 2012
Clinical Research Associate II – Dec 2008 – Apr 2012

- Regional CRA responsible for field monitoring, remote data collection, monitoring of adverse events for the Transcather Heart Valve Program-Aortic and Pulmonic
- Reviewed site progress and conduct of sponsor clinical study, ensured the accuracy of data collection, provided site guidance and ensured site compliance to the protocol, compliance to CFRs, GCPs and site IRB policies
- Lead CRA for Duke University Medical Center, Emory University Medical Center, University of Miami Medical Center, Ochsner Clinic Foundation, Rush University Medical Center and University of Texas-Houston
- Trained and mentored new CRAs
- Conducted Study Initiation Visits – trained investigative staff to the intricacies and logistics of conducting the clinical trial including training to protocol, regulatory and investigator responsibility, device accountability and electronic data capture system (EDC)
- Responsible for communicating weekly follow up compliance to assigned sites and formulating a corrective action plan (CAPA) in cases of site non-compliance

Tampa General Hospital, Tampa, Florida, USA – Feb 2008 – Dec 2008
Certified Clinical Research Coordinator – Feb 2008 – Dec 2008

- Coordinated all aspects of inpatient clinical trials among a full spectrum of ages and disease processes including Pediatric drug studies, Infectious Disease drug studies including HIV as well as Cardiovascular drug and device trials
- Non-voting member of the Tampa General Hospital Research Committee which reviewed all clinical research protocols conducted at Tampa General Hospital thru the University of Florida
- Responsible for maintaining all site essential regulatory documents, subject recruitment and enrollment, completion of paper and electronic Case Report Forms, Adverse Event reporting in collaboration with the Principle Investigator and scheduling and ensuring compliance with study visits per protocol
- Administration of investigational drug
- Collaborated with site research pharmacist on investigational drug accountability and maintenance of investigational device accountability

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CrossCountry Travcorp / Strategic Nurse Staffing, Boca Raton, Florida/Melville, New York, USA – Aug 2007 – Feb 2008

Travel Registered Nurse – Cardiac Catheterization Lab – Aug 2007 – Feb 2008

- Contracted travel RN for the cardiac catheterization lab with 13 week assignments in both Austin, Texas and Clermont, Florida

St. Luke's Medical Center, Milwaukee, Wisconsin, USA – Feb 2002 – Aug 2007

Certified Clinical Research Coordinator (CCRC) – Aug 2004 – Aug 2007

- Performed and coordinated patient identification for trial enrollment, data collection, Case Report Form completion, regulatory compliance and completion of subject follow up visits
- Implemented all aspects of Cardiovascular therapeutic trials from both small early development trials to large international studies with the ability to prioritize work in order to meet trial deadlines
- Experience extends to all major classes of Cardiovascular drugs, devices and procedures and performed cross-disciplinary studies of the Cardiovascular effects of treatments for other therapeutic areas including renal, hepatic, neurovascular and diabetic disorders
- Collaborative involvement for formulating a study budget, ensuring appropriateness of research billing practices, communicating with local Medicare Intermediary for compliance in research billing and ensured timely negotiations for contract completion

Registered Nurse – Circulatory Dynamics Lab – Feb 2002 – Aug 2004

- Provided nursing care to patients undergoing peripheral and/or cardiovascular procedures
- Assisted with unit based orientation program
- Participated and supported shared governance activities
- Assisted staff with the application and integration of nursing research in the cardiac catheterization laboratory
- Participation in the preparation for the JCAHO survey process and accompanied the JCAHO surveyors during site review
- Functioned as a Stage IV staff nurse providing clinical leadership through advanced practice role modeling

All Saints Medical Center, Racine, Wisconsin, USA – Jan 1994 – Feb 2002

Registered Nurse III - CCU – Jul 2001 – Feb 2002

- Functioned as charge nurse for a cardiac step-down unit specializing in care of the post cardiac invasive procedure patient as well as the post operative coronary artery bypass patients (open heart)
- Served as committee chair and unit representative for the Educational Advisory Committee
- Preceptor for new staff nurses
- Completed daily staffing levels, staff0patient assignments and shift change reports

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- Hospital response nurse for house-wide Code Blue events and functioned as a unit based BLS/CPR instructor

Utilization Review/Quality Management Nurse – Oct 1998 – Jul 2001

- Provided third-party payers, Medicare and Medicaid providers with continued medical reviews to support and certify hospital days for reimbursement
- Collaborated with the Chief of Staff regarding physicians quality of care deviations
- Reviewed patient medical records for adherence to hospital's Standards of Care
- Completed hospital Quality Assurance data collection

Registered Nurse - CCU – Jan 1994 – Oct 1998

Staff nurse providing full range of nursing care to pre and post-operative cardiac patients

Therapeutic Experience

- **Immune Mediated Inflammatory Disease (IMID):**
  - **Inflammatory Respiratory** – Smoking Alternative (Phase I)
- **CardioMetabolic:**
  - **Metabolic and Cardiovascular Risk –** Type II Diabetes, Dyslipidemia, Hypertension, Cardiovascular Outcomes Studies (Phase III)
  - **Cardiovascular Disease** – Atherosclerosis; Peripheral Artery Disease, PAD, PAOD; Acute Coronary Syndrome, Acute Myocardial Infarction, Unstable Angina, Angina, coronary thrombosis; Heart Failure, LV dysfunction; Diabetic nephropathy, renal vascular disease (Phase III)
- **Neuroscience:**
  - **Neurology –** Carotid Artery Disease (Phase III)
- **Infectious Disease:**
  - **Bacterial Disease Therapy** – Skin Infection/cSSSI, Sepsis (Phase III)
  - **Anti-Viral Therapy** – HIV/AIDS (Phase III)
- **Other:**
  - **Phase I** – Normal Healthy, PK/PD

Language Capabilities

- English

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Education

- Associate Degree – Nursing, Gateway Technical College, Kenosha, Wisconsin, USA
- Bachelor of Science in Health Sciences-Clinical Research Administration, The George Washington University, Washington, DC, USA

Memberships/Awards

- Certified Clinical Research Associate (CCRA) through Association of Clinical Research Professionals (ACRP)
- Current unrestricted Registered Nurse licensure in Wisconsin (Compact state) and Florida
- Member of the Association of Clinical Research Professionals
- Member of the Regulatory Affairs Professional Society

Other

- Not Applicable

Employee Signature: Ann Hintz

Date: 07 MAR 2016

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Mary Martinez, BA

Covance Clinical Development Services
Senior Clinical Research Associate (Regionally Based, Florida, USA)

3402 Kinsman Blvd., Madison, Wisconsin
Tel: 1-608-442-8200

Employment History

Covance Clinical Development Services, Madison, Wisconsin – Oct 2013 – present
Senior Clinical Research Associate, Early Clinical Development – Oct 2013 – present

- Manages all aspects of site monitoring responsibilities for clinical trials, according to Covance standard operating procedures, ICH guidelines and GCP, including pre-study qualification, initiation, routine/interim monitoring and close-out visits
- May serve as lead CRA for a protocol or project – which includes training other CRAs on study specifics, ensuring consistency at study sites, responsibility for overseeing CRA performance, reviewing trip reports for content and timeliness, and leveraging best practices
- Generates and assures implementation of Project Plans related to the Clinical Monitoring responsibilities
- Tracks progress of projects and initiates appropriate actions to achieve target objectives, including fiscal responsibility for tracking monitoring expenses against the project budget

ICON PLC, Dublin, Ireland– Jun 2013 – Oct 2013
Contract Clinical Research Associate – Jun 2013 - Oct-2013

- Monitoring to include: Pre-study, initiation and routine monitoring of clinical sites under appropriate SOP and ICH/GCP guidelines
- Ensured the protection of study patients by verifying that informed consent procedures, protocol requirements and adverse event reporting requirements were adhered to according to the applicable regulatory requirements
- Ensured the integrity of the data submitted on Case Report Forms (CRFs) or other data collection tolls by source document review

Quintiles, Raleigh, North Carolina – Jul 2010 – Jun 2013
Contract Clinical Research Associate – Jul 2010 – Jun 2013

- Responsible for all aspects of study site monitoring including pre-study, initiation, routine monitoring and close-out of clinical sites under appropriate SOP and ICH/GCP guidelines
- Ensured the protection of study patients by verifying that informed consent procedures, protocol requirements and adverse event reporting requirements are adhered to according to the applicable regulatory requirements
- Ensured the integrity of the data submitted on Case Report Forms (CRFs) or other data collection tools by source document review

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Name: Mary Martinez

Novelia Clinical, Morrisville, North Carolina – May 2008 – Jul 2010
Contract Clinical Research Associate – May 2008 – Jul 2010

- Multi-study monitoring to include: initiation, routine monitoring and closeout of clinical sites under appropriate SOP and ICH/GCP guidelines
- Ensured the protection of study patients by verifying that informed consent procedures, protocol requirements and adverse event reporting requirements were adhered to according to the applicable regulatory requirements
- Ensured the integrity of the data submitted on Case Report Forms (CRFs) or other data collection tools by source document review
- InForm (eCRF) trainer

Covance Inc., Madison, Wisconsin – May 2007 – May 2008
Contract Clinical Research Associate – May 2007 – May 2008

- Responsible for all aspects of study site monitoring including pre-study, initiation, routine monitoring and close-out of clinical sites under appropriate SOP and ICH/GCP guidelines
- Ensured the protection of study patients by verifying that informed consent procedures, protocol requirements and adverse event reporting requirements were adhered to according to the applicable regulatory requirements
- Ensured the integrity of the data submitted on Case Report Forms (CRFs) or other data collection tools by source document review

i3 Research, Princeton, New Jersey – Dec 2006 – May 2007
Contract Clinical Research Associate – Dec 2006 – May 2007

- Monitored all phases of clinical activity: potential site evaluation and selection, pre-study site visits, site initiation, interim site visit and closeout visits
- Responsible for monitoring multi-protocol clinical trials; assure adherence to Good Clinical Practices, investigator integrity and compliance with all study procedures
- Responsible for ensuring patient safety, clean data, and target enrollment as well as meeting or exceeding established timelines

Sanofi-Aventis Pharmaceuticals, Bridgewater, New Jersey – Oct 2002 – Nov 2006
Regional Senior Clinical Research Associate, Project Manager for outsourced studies – Oct 2002 – Nov 2006

- Provided management and oversight of the monitoring/site component for Sanofi-Aventis Cardiovascular outsourced trials
- Responsible for ensuring patient safety, clean data, and target enrolment as well as meeting or exceeding established timelines
- Active team member of Priority Projects Task Forces: Outsourcing Group
- Responsible for monitoring multi-protocol, multi-therapeutic clinical trials; assured adherence to Good Clinical Practices, investigator integrity and compliance with all study procedures
- Performed 'Total Site Management' for all studies, including study start-up activities, all regulatory document collection, clinical supply shipments and investigational product shipment
- Trained and mentored CRA level I personnel
- Monitored all phases of clinical activity: potential site evaluation and selection, pre-study site visits, site initiation, interim site monitoring and site close-out
- Developed monitoring plans and source documentation forms
- Responsible for all aspects of study site enrollment and tracking
- Responsible for all informed Consent/HIPAA review prior to IRB submission

Name: Mary Martinez

INC Research, Inc., Raleigh, North Carolina – Mar 2001 – Oct 2002
Clinical Research Specialist (Sr. CRA) – Mar 2001 – Oct 2002

- Responsible for monitoring multi-protocol clinical trials; assure adherences to Good Clinical Practices, investigator integrity and compliance with all study procedures
- Investigator site evaluation, site initiation, interim site monitoring, site close-out and regulatory document collection and maintenance
- Experienced in DEA Schedule II compounds, DEA requirements including procedures for drug order and shipment, drug storage, drug dispensation, drug accountability and FDA procedures for drug return
- Trained and mentored CRA level I personnel

ClinTrials Research Inc., Cary, North Carolina – Oct 2000 – Mar 2001
Clinical Research Associate – Oct 2000 – Mar 2001

- Responsibilities include: Investigator site evaluation, site initiations, interim site monitoring and regulatory document collection and maintenance
- Liaison between the sponsor, Investigator sites and Jr. CRAs
- Case Report Forms (CRF), Pharmacy and Study Reference Manual design, including all study tools and forms
- Clinical trial monitoring by GCP/ICH and FDA requirements
- Responsible for Adverse Event and SAE reporting to the sponsor

Quintiles CVA, San Antonio, Texas – Jul 1999 – Oct 2000
Clinical Research Associate – Jul 1999 – Oct 2000

- Conducted routine monitoring visits to access site's compliance with protocol, federal regulations, Good Clinical Practice, an pertinent standard operating procedures
- Lead CRA and solely responsible for 17 sites nationwide
- Organize and presented at Investigator meetings
- Responsible for Clinical Trials budgeting, Letters of Indemnification (LOIs), Clinical Trial Agreements (CTAs) assistance, and Informed Consent forms design
- Liaison between the sponsor, Investigator sites and CRAs
- Protocol development and review
- Case Report Form (CRF), Pharmacy and Study Reference Manual design
- Independent and organized in the responsibilities associated with project management and lead CRA roles

Schering-Plough Research Institute, Kenilworth, New Jersey – Sep 1997 – Jul 1999
Scientist I – Sep 1997 – Jul 1999

- Scientist and Monitor in Department of Drug Metabolism and Pharmacokinetics pre-clinical contract studies and Phase I and IIb clinical studies
- Monitored studies at contract laboratories (CROs): pharmacokinetic and toxicokinetics studies
- Designed and written protocols for contract laboratory studies (CROs)
- Performed site evaluations and verified adherence to protocols, SOPs an FDA guidelines
- Prepared and submitted written reports detailing study actions and findings
- Written, reviewed, validated and edited various reports for NDA/IND submissions

Trega Biosciences, La Jolla, California – Jun 1994 – Sep 1997
Research Associate II: Drug Development/Pharmacology – Jun 1994 – Sep 1997

- Performed quantitative and qualitative analysis of new investigational drugs

Name: Mary Martinez

- Developed protocols and assays for pharmacology and pharmacokinetic analysis
- Written and validated various reports for the FDA submissions

Therapeutic Experience

- **Cardiovascular:** Acute Coronary Syndrome/Angina (acute or unstable/Ischemia, Arrythmia/Fibrillations (ventricular/atrial)/cardiac arrest/heart block, Atherosclerosis/arteriosclerosis/coronary artery disease/coronary heart disease, Congestive Heart Failure/Cardiac Edema/Cardiomyopathy, Hypertension – systolic or diastolic (Phase III)
- **Endocrine:** Diabetes Mellitus/Hypoglycemia/Hyperglycemia, Obesity, Adjustable lap-band for weight loss (Phase III)
- **GI/Hepatic:** Crohn's disease, Irritable colon/Irritable bowel/spastic colon, Constipation/Intestinal Obstruction, Ulcerative colitis (Phase III)
- **Infectious Disease:** Infection-fungal, non specified (Phase III)
- **Immunology:** Vaccines/Immunotherapy/Monoclonal Antibody (Phase III); Allergy – seasonal, perineal, peanut (Phase IV)
- **Hematology:** Deep Vein Thrombosis/Pulmonary Embolism/Venous Thrombosis/Thromboembolism (Phase III)
- **Musculo-Skeletal:** Degenerative Joint Disease/Osteoarthritis, Pain – chronic, Surgery/Devices/Implants on musculoskeletal system, bones or joints, Total Hip replacement/ Total Knee replacement (Phase III); Pain – acute (Phase IIb, III)
- **Neurology/Psychiatric:** Depression, Pain – chronic, back, muscle strain, sciatica, sickle cell, other etc. (Phase III); Stroke – ischemic/Stroke – hemorrhagic/ TIA/cerebrovascular disease (Phase IIb, III)
- **Reproductive/Gender-based:** Hormone replacements for deficiencies/menopausal syndromes, Sexual Dysfunction – Female, Sexual Dysfunction – Males (Phase III)
- **Pulmonary/Respiratory:** Asthma (Phase III, IV)

Language Capabilities

- English

Education

- Bachelor of Arts – Botany, Miami University, Oxford, Ohio

Memberships/Awards

- ACRP
- DIA

Other

- NA

Employee Signature: _____

Date: 30 Oct 2013

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Esther Clements

Covance Clinical Development Services
Senior Clinical Research Associate – Clinical Operations (Regionally Based, USA)

206 Carnegie Center, Princeton, New Jersey

Tel: 1-609-452-8550

Employment History

Covance Clinical Development Services, Princeton, New Jersey, USA – Sep 2009 – Present
Senior Clinical Research Associate, Clinical Operations, Early Clinical Development – Oct 2014 – Present

- Manages all aspects of site monitoring responsibilities for clinical trials, according to Covance standard operations procedures, ICH guidelines and GCP, including pre-study qualification, initiation, routine/interim monitoring and close-out visits
- Serves as lead CRA for a protocol or project – which includes training other CRAs on study specifics, ensuring consistency at study sites, responsibility for overseeing CRA performance, reviewing trip reports for content and timelines, and leveraging best practices, writing Monitoring Plan
- Generates and assures implementation of Project Plans related to the Clinical Monitoring responsibilities
- Tracks progress of projects and initiates appropriate actions to achieve target objectives, including fiscal responsibility for tracking monitoring expenses against the project budget
- Mentoring and supervisory activities to junior CRA
- Participate in identification/feasibility and recruitment of investigator sites, collection of investigator pre-study visits and site management responsibilities

Project Manager, Early Clinical Development – Jan 2014 – Oct 2014

- Serve as Project Manager for domestic and/or international projects for one or more clients, according to Covance Standard Operating Procedures, ICH Guidelines and GCP and Project Plans
- Serve as Project Manager for assigned business development opportunities and key client contact for assigned projects
- Establish excellent working relationship with client project teams to ensure client satisfaction, operational excellence and successful conduct of assigned projects
- Responsible for on time, on-budget provision of client deliverables for assigned projects
- Define and manage project resource needs, liaising with senior management in Project Management and Clinical Operations, establishing a contingency plan for key resources

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- Promote effective teamwork among project team members within Covance departments and offices; resolve conflicts as needed and ensure all staff adhere to professional standards and SOP's established for clinical research

Clinical Team Lead – Apr 2013 – Jan2014

- Responsible for ensuring appropriate resources, coordinating and managing the clinical operations team, and providing operational leadership and expertise to ensure successful execution of the clinical operations deliverables (quality, timeline, budget and scope)
- Ensure all clinical operations staff adheres to professional standards, ICH/GCP guideliens, SOPs and clinical operations training plans for assigned projects
- Develops risk contingency plans for key clinical operations activities in collaboration with the core team and reviews progress of the clinical operations aspect of projects and initiate appropriate actions to achieve target objectives
- Owns the development of training material and tools (project-specific & site monitoring) as well as training specific to the clinical operations team
- Develops and maintains relationships with assigned clients and serves as the client interface for all clinical operations matters
- Oversight of the Trial Master File (TMF), ensuring documents are filed as per the TMF plan and complete TMF provided to the client at the end of the study

Associate Project Manager – Mar 2012 – Apr 2013

- Reported to Project Manager/Senior Project Manager/Project Director, ensured adequate resources are available for assigned project, assisted to achieve on time, on budget provision for client deliverables for assigned projects/clients according to Covance Standard Operating Procedures, ICH Guidelines and GCP
- Assisted in the leadership of the core project team as directed by Project Manager/Senior Project Manager/Project Director facilitating their ability to lead extended/complete project team, contributing to effective team work and providing performance feedback to respective supervisors
- Ensured that all staff allocated to assigned projects adheres to professional standards and SOPs established for clinical research
- Coordinated internal and external team members, track study progress and contribute to contingency planning for key resources
- Client primary contact for areas assigned by the Project Manager/ Project Director and delivered Client satisfaction
- Contributed to and participate in the delivery of presentations for new business in collaboration with business development

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Esther Clements
Senior Clinical Research Associate – Sep 2010 – Mar 2012

- Acted in the project role as Lead Clinical Research Associate and managed additional projects under the direction of a Project Manager as assigned including internal group interactions to evaluate study needs and resources required to achieve target objectives
- Organized and conducted Clinical Research Associate project meetings; trained new monitors on study protocol and study plans; ensured monitors adhere to Covance SOPs; reviewed trip reports; assisted in monitor site allocation; contributed to development of trip report templates; updated to PD process templates; and met with line managers to discuss monitor issues
- Assisted with the Investigator Meetings as needed, including presenting to sites and staff.

Clinical Research Associate II – Sep 2009 – Sep 2010

- Previously responsible for all aspects of study site monitoring including site selection, close-out of clinical sites, maintenance of study files, review of AEs and SAEs; conduct of pre-study and initiation visits; liaise with vendors; and other duties, as assigned
- Assured the implementation of project plans as assigned
- Site administration and site monitoring responsibility for clinical studies according to Covance Standard Operating Procedures, ICH Guidelines and GCP

INC Research Inc., Mississauga, Ontario, Canada – Sep 2006 – Sep 2009
Lead Clinical Research Associate – Mar 2009 – Sep 2009

- Managed study Clinical Research Associate, conducted weekly meetings with study Clinical Research Associate; created monitoring tools/templates for the study (Annotated trip report, Site visit letters and Frequently Asked Question Log); and developed the Clinical Monitoring Plan, CRF completion guidelines, Site Reference Manual and monthly newsletters
- Worked closely with Project Managers to meet study timelines and adjust to changing project requirements

Clinical Research Associate – Sep 2006 – Mar 2009

- Monitored Central Nervous System (CNS) related clinical research studies in the areas of Multiple Sclerosis, Diabetic Peripheral Neuropathy and Social Anxiety Disorder, ensuring compliance with ICH/GCP guidelines
- Worked closely with the Project Manager on a Phase II study to create an improved real time monitoring summary ("Dashboard") that consolidated existing trackers to effectively monitor key timelines in the study, analyzed risks relating to study completion, aided with data-lock and study closeout

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- Trained and signed off Clinical Research Associates on Close Out Visit (COV) procedures, which encompassed creation of COV study documents, annotated trip report in ProjecTrend and visit letter templates
- Aided the Project Manager in study closeout: created monthly reports for the Project Manager analyzing subject status and queries in Electronic Data Capture (EDC) systems; developed a weekly Dashboard that provided status on active subjects, closed out visit status at each site; helped with backend checks in ECD systems and reviewed study visit trip reports in study system (ProjecTrend)

Bayer Inc., Toronto, Ontario, Canada – Oct 2005 – Aug 2006
Health Economics Analyst / Public Policy and Communications – Oct 2005 – Aug 2006

- Participated in internal project review/management of several studies, presentation of findings, assisting in manuscript and poster submission of results
- Proposal request, Selection, management, review of deliverables and payment of vendors
- Pricing analysis of Bayer Inc. products within Canadian market
- Preparation of documents for CDR submission taking into account new CADTH guidelines for economic analysis

Jansen Ortho (Johnson & Johnson), Toronto, Ontario, Canada – Apr 2004 – Dec 2004
Financial Analyst, Co-op / Sales and Marketing Finance – Apr 2004 – Dec 2004

- Performed revenue reconciliation, investment portfolio allocation, active budget recording, and franchise P&L updating to support team objectives for marketing divisions
- Monitored project costs and resource usage for marketing managers using excel spreadsheets, presented with PowerPoint
- Generated month-end analysis for Directors Report, interpreted company expense policy, which examined actual vs. budget
- Revised SAP training manual and incorporated changes in the updated system
- Submitted Pharma and Biotech division's 2005 Business Plan within strict deadline compliance
- Modified macros and updated SAP system, increasing MS Excel-based month-end report efficiency

Bayer Inc., Toronto, Ontario, Canada – Sep 2003 – Dec 2003
Health Economics and Policy Analyst, Co-op / Public Policy and Communications – Sep 2003 – Dec 2003

- Analyzed pricing scenarios and discrepancies within public and private markets to hypothesize future new product sales
- Developed MS Excel-based pricing model to forecast new product sales in the Canadian marketplace

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- Worked with regional Public Policy directors to create an Environment Assessment document for management's future decision making process
- Collected and analyzed Program (IMS database) data and prepared new product submission documents for the Health Economics and Outcome Research regarding drug approval

Eli Lilly Canada Inc., Toronto, Ontario, Canada – Jan 2003 – Apr 2003
Clinical Trial Performance Metrics / Documentation of Business Processes Project, Co-op / Research And Development – Jan 2003 – Apr 2003

- Created MS Excel template to calculate the ROI and breakeven point for prospective clinical trials
- Consulted with Project Managers, Clinical Research Associates and marketing to develop a standard Dashboard, which decreased time required by Clinical Research Associates to update R&D management and marketers regarding clinical trial progress for all future updates; trained staff on Dashboard roll-out
- Evaluated staff responsibilities and updated processes for R&D business office

St. Michael's Hospital, MS Clinic, Toronto, Ontario, Canada – 1994 – Aug 2002
Lead Clinical Study Coordinator, MS Clinic – 2000 – Aug 2002

- Previously responsible for scheduling twelve clinical trials encompassing 280 patients and five physicians
- Booked MRIs and other procedures as necessary
- Previously responsible for communicating updates with REB, preparing submission for new studies, updating protocol changes, implementing updated consent forms and completed clinical research forms (CRFs) for four studies
- Initiated and conducted weekly staff meetings coordinating study tasks and establishing clinic priorities
- Selected by Aventis Pharma to present and train coordinators in Montreal, Canada and Paris, France on the administration of Multiple Sclerosis Functional Composite in clinical trials

Research Technician (Infectious Disease, Pathology) – 1994 - 2000

- Performed animal procedures for joint research with Aventis-Pasteur, and hospitals, to examine effects of Chlamydia Pneumonia on development of atherosclerotic plaques
- Worked independently to complete procedures and meet deadlines in combined and overlapping studies with Pfizer, Bayer, Abbott, Aventis-Pasteur and St. Joseph's Hospital (Hamilton)
- Created Laboratory Manual of Standard Operating Procedures documenting surgical techniques, project observations, and experimental results used

Therapeutic Experience

- **CardioMetabolic:**

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Esther Clements

- **Metabolic and Cardiovascular Risk** – Dyslipidemia, Hypertension (Phase III)
- **Cardiovascular Disease** – Diabetic nephropathy, renal vascular disease (Phase III)

- **Neuroscience:**
  - **Neurology** – Multiple Sclerosis (Phase II-IV)
  - **Psychiatry** – Anxiety, Schizophrenia (Phase II), Bi-Polar (Phase III), Fibromyalgia (Phase II, III)
- **Infectious Disease:**
  - **Bacterial Disease Therapy** – Skin Infection/cSSSI (Phase III)
- **Other:**
  - **Genito-Urinary – Women's Health** – Contraception (Phase III)

Language Capabilities

- English

Education

- Master of Business Administration (MBA), McMaster University, DeGroote School of Business, Hamilton, Ontario, Canada
- Bachelor of Science (Toxicology), University of Toronto, Toronto, Ontario, Canada

Memberships/Awards

- Association of Clinical Research (ACRP) and Canadian Chapter ACRP

Other

- Covance ACE Award Recipient

Employee Signature: G Clements

Date: 14 May 2015

A list of publications, manuscripts, abstracts, and presentations is available in Appendix 1.

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Esther Clements

Appendix 1

Publications, manuscripts, abstracts, and/ or presentations

Publications

- Note: E. Viira is Esther Clements
- Fong, I.W., Chiu, B., **Viira, E.**, Fong, M.W., Jang, D., and Mahoney, J.B., Influence of Clarithromycin on Early Atherosclerotic Lesions after Chlamydia pneumoniae Infection in a Rabbit Model. Antimicrobial agents and Chemotherapy, Aug 2002, 46(8): 2321-2326
- Fong, I.W., Chiu, B., **Viira, E.**, Fong, M.W., Jang, D., and Mahoney, J.B., De Novo Induction of Atherosclerosis by Chlamydia pneumoniae in a Rabbit Model. Infection and Immunity, Nov 1999 67(11): 6048-6055
- Fong, I.W., Chiu, B., **Viira,** E., Jang, D., Fong, M.W., Peeling, R., and Mahoney, J.B., Can an Antibiotic (Macrolide) Prevent Chlamydia pneumoniae - Induced Atherosclerosis in a Rabbit Model. Clinical and Diagnostic Laboratory Immunology, Nov 1999, 6(6): 891-894
- Chiu, B., **Viira, E.**, Tucker, W., and Fong, I.W., Chlamydia pneumoniae, cytomegalovirus and Herpes Simplex Virus in atherosclerosis of the carotid artery. Circulation, April 1997, 26:29-31
- Fong, I.W., Chiu, B., **Viira, E.**, Fong, M.W., Jang, D., and Mahoney, J.B., Rabbit Model for Chlamydia pneumoniae infection. J. Clin. Microbiol. Jan 1997, 35:48-52

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Jo Taylor

Covance Clinical Development Services
Senior Manager, Project Integration

Osprey House, Maidenhead Office Park, Westacott Way, Maidenhead, SL6 3QH
Tel: +44 (0)1628 548000

Employment History

Covance Clinical Development Services, Maidenhead, Berkshire, U.K – Jan. 2012 – Present
Senior Manager, Project Integration – Jan. 2012 – Present

- Project manager for local and international projects
- Responsible for timely production of deliverables
- Negotiate and update timelines across CDARO
- Liaise with clients, vendors and Covance departments regarding conduct of study

Quest Diagnostics Clinical Trials, Heston, Middlesex, U.K. – Jan. 2006 – Jun. 2011
Senior Project Manager – Apr. 2008 – Jun. 2011

- Dedicated senior project manager for main strategic client account; responsible for delivering key programs of work in high profile therapeutic areas.
- Early interaction with client at study design stage to ensure in-built cost containment strategy.
- Present and provide training at international monitor/investigator meetings.
- Support internal and external/client audits.
- Participate in 6 Sigma process improvement projects.

Project Manager – Jan. 2006 – Mar. 2008

- Primary point of contact for numerous study teams across a range of international clients from niche Biotechs to Top 5 Pharma.
- Overall responsibility for timely study start-up, maintenance and close-out of all assigned projects.
- Matrix-manage effective inter-departmental study team.
- Proactively facilitate internal communication and problem resolution to achieve high levels of client satisfaction.

Pfizer Ltd., Sandwich, Kent, U.K – Aug. 2001 – Aug. 2002
Research Associate, Pharmaceutical R&D – Aug. 2001 – Aug. 2002

- Conduct solubility/stability/dissolution profiling studies for molecules in early development to aid selection of candidate drugs.
- Assist in the development of novel, fully automated, high throughput drug screening techniques.
- Prepare and present data at senior management review meetings.

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Name: Jo Taylor

Therapeutic Experience

- **Cardiovascular:** Acute & Chronic Coronary Heart Disease / Myocardial Infarctions (Phases I, II & III)
- **Gastro-Intestinal:** Functional Dyspepsia (Phase III)
- **Immunology:** Rheumatoid Arthritis (Phases II-III)
- **Infectious Diseases:** HIV (Phases II-IV)
- **Musculo-Skeletal:** Multiple Sclerosis (Phase II)
- **Oncology:** NSCLC (Phase I), Ovarian (Phase II), Breast (Phase III)
- **Other:** Major Depressive Disorder (Phase II), Fragile-X Syndrome (Phase II)

Language Capabilities

- English

Education

- Doctor of Philosophy degree in Neuroscience, Imperial College London, U.K.
- Bachelor of Science with Honors (2:1) degree in Applied Psychology, University of Durham, U.K.

Memberships/Awards

- Project Management Institute – Certified Project Manager

Other

- Not Applicable

Employee Signature: Taylor

Date: 17-APR-2014

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Mary Russo

Covance Clinical Development Services
Senior Clinical Data Coordinator Princeton USA

210 Carnegie Center, Princeton, NJ 08540
Tel: (800) 621-8901

Employment History

Covance Clinical Development Services, Princeton, NJ **October 1995 – Present**

Senior Clinical Data Coordinator (June 2007 – Present)

- Member of the Data Management leadership team responsible for the Medial Validation review process directed from the sponsor's Medical Monitor for a global Cardiovascular Outcome study.
- Responsible for the creation of SAS edit checks for the programmers to ensure the reconciliation of the Adjudication Results Plan.
- Perform successful UAT testing for Change Controls and Amendment updates for multiple studies.
- Responsible for the Un-blinded reconciliation of study medication between the clinical database and IVRS for three phase 3 studies.
- Identify technical database problems within the Electronic Data Capture system and work with the EDC Project Manager to re-configure the datasets to alleviate the issues.
- Successfully locked the database for a large global four year Multiple Myeloma study on time and under budget.
- Provide the development of the project Data Management Plan, including the creation of data acquisition conventions and data review guidelines/ diagnostics specification; and set up the data management systems according to project requirements.
- Serve as the technical data management leader on small to moderate project with technical oversight of data management activities for the delivery of clinical data according to client quality and integrity specifications, and project timelines and budgets.

COVANCE

Name: Mary Russo

.Clinical Data Coordinator II (Aug 2002 – Jun 2007)

- Serve as a member of the project team with primary responsibility for clinical data review, query generation / resolution and reconciliation activities to support the delivery of clinical data according to client quality and integrity specifications, and project timelines and productivity targets.
- Potential to assist in the development of the project Data Management Plan, including the creation of data acquisition conventions and data review guidelines / diagnostics specification; and set-up of the data management systems according to project requirements.
- Potential to serve as the technical data management leader on small projects with technical oversight of data management activities for the delivery of clinical data according to client quality and integrity specifications, and project timelines and budgets.

Clinical Data Coordinator (Jul 1999 – Aug 2002)

- Serve as a member of the project team with primary responsibility for clinical data review, query generation /resolution and reconciliation activities to support the delivery of clinical data according to client quality and integrity specifications, and project timelines productivity targets.

Users Inc. Hightstown, NJ (Dec 1986 – Sep 1995)
Assistant Supervisor of Data Center

- Oversee the data services provided to Credit Unions

Therapeutic Experience

- **Cardiology/Vascular : Atrial Fibrillation: Phase 3, CV Outcome Study Phase 3, Dyslipidemia**
- **Musculoskeletal; Osteoporosis: Phase 3 and 3b**
- **Endocrine: Diabetes Mellitus: Phase 3**
- **Oncology: Soft Tissue Sarcoma, Multiple Myeloma Phase 3**
- **Pulmonary/Respiratory: Chronic Obstructive Pulmonary Disease: Phase 3, Asthma Phase 1 and 3**
- **Hematology: Anemia in patients with CKD: Phase 3**

Language Capabilities

- Not Applicable

Education

- High School Diploma, Saint Raymond Academy, Bronx, NY
- Business Certification, The Assisium, NY, NY

Memberships/Awards

- Not Applicable

Name: Mary Russo

Other

- EMT and Paramedic Assistant Certifications

Employee Signature: Mary Russo

Date: 01 April 2014

STUART HOSSACK

Covance Clinical Development Services
MANAGER, PHARMACOKINETICS

SPRINGFIELD HOUSE, HYDE STREET, LEEDS, LS2 9LH, UK
Tel: 0113 237 3500

Employment History

COVANCE CLINICAL DEVELOPMENT SERVICES, LEEDS, UK – Aug. 2008 - Present
MANAGER, PHARMACOKINETICS – Mar. 2012 - Present

- Accountable for the supervision, appraisal, training and coaching of the PK group.
- Provide business development support for CDARO
- Perform scientific review of PK contributions prepared by reportees.
- Assume the role of Pharmacokineticist for allocated studies.

TEAM LEADER, PHARMACOKINETICS – Aug. 2009 – Mar. 2012

- Responsible for the supervision, appraisal, training and coaching of a team of Pharmacokinetic (PK) Data Coordinators.
- Role of Pharmacokineticist for allocated clinical studies and Responsible Scientist/Principal Investigator for toxicokinetic (TK) studies.
- Provide PK training to Covance CDARO employees and act as source of expertise on all PK processes.
- Support business development and strategy of PK group

PHARMACOKINETICIST II – Aug. 2008 - Aug. 2009

- Conduct interim PK and Pharmacodynamic (PD) analyses, interpret and present data at dose escalation teleconferences to support dose progression.
- Review draft protocols for allocated studies and provide input into study design based upon available TK/PK data.
- Compile standalone PK, PD and or PK/PD reports or prepare interpretative text for inclusion within CSR body.
- Conduct non-compartmental GLP TK analyses, prepare TK reports or scientifically review TK appendices.

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Name: STUART HOSSACK

APTUIT, EDINBURGH, UK– Sep. 2005 - Aug. 2008
SENIOR PHARMACOKINETICIST – Feb. 2007 - Aug. 2008

- Primary PK contact within company, providing inter-departmental PK advice/training and consultancy to external clients.
- Provide input into study design and PK methods for preclinical and clinical studies.
- Responsible for business activities of PK/PD group, preparing quotes and managing studies to agreed timeline, budget and resource.
- Line manager to 2 Associate Pharmacokineticists, providing in-depth training and performance review

PHARMACOKINETICIST – Sep. 2005 - Jan. 2007

- Conduct interim PK analyses, interpret and present data at dose escalation teleconferences to support dose progression.
- Perform non-compartmental and compartmental PK modelling/simulations to aid selection for study design discussions.
- Deputise for Senior Manager of PK/PD group during absences.
- Improve efficiencies in PK processes

QUINTILES LTD, EDINBURGH, UK – Feb. 2002 - Aug. 2005
PHARMACOKINETICIST II – Nov. 2003 - Aug. 2005

- Responsible Scientist/Principal Investigator for PK/TK studies.
- Prepare TK and clinical PK study phase reports.
- Fast turnaround interim PK analysis for Phase 1 dose escalation studies

PHARMACOKINETICIST I – Feb. 2002 - May. 2003

- Non-compartmental analysis and QC of TK and clinical for PK data.
- Prepare TK study phase reports.

Therapeutic Experience

- **N/A**

Language Capabilities

- ENGLISH - MOTHER TONGUE

Education

- BACEHLOR of SCIENCE (HONS) in MEDICAL MICROBIOLOGY, UNIVERSITY OF EDINBURGH, EDINBURGH, UK

Memberships/Awards

- N/A

Other

- N/A

Employee Signature: _____

Date: 14 APR 2014

Name: STUART HOSSACK

Appendix I

Lecturer

2010 Assessment of Pharmacokinetics and Pharmacodynamics in Man, Clinical Pharmacology Module, University of Leeds, Leeds, UK

Publications

Pierce D, Hossack S, Poole L, et al. 2011, The effect of sevelamer carbonate and lanthanum carbonate on the pharmacokinetics of oral calcitriol. Nephrol Dial Transplant. 26:1615–1621.

Pierce D, Hossack S, Robinson A, et al. 2012, Assessment of Pharmacodynamic Equivalence and Tolerability of Lanthanum Carbonate Oral Powder and Tablet Formulations: A Single-Center, Randomized, Open-Label, 2-Period Crossover Study in Healthy Subjects. Clinical Therapeutics, 34 (6): 1290-1300.

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John A. Hunter

Covance Clinical Development Services
Statistical Fellow, Biostatistics and Statistical Programming (USA)

3402 Kinsman Blvd, Madison, WI
Tel: 608-442-8200

Employment History

COVANCE CLINICAL DEVELOPMENT SERVICES, MADISON, WI – Jan 2013 – present
STATISTICAL FELLOW – Jan 2013 – present

- Provide statistical guidance in development of clinical research program and in design of individual studies.
- Responsible for development of statistical analysis plans as well as production of associated tables, figures, and listings.
- Lead statistician on clinical study teams.

GENZYME CORPORATION, MIDDLETON, WI – Jul 2005 – Dec 2012
DIRECTOR, BIOSTATISTICS – Aug 2008 – Dec 2012
ASSOCIATE DIRECTOR, BIOSTATISTICS – Jul 2005 – Jul 2008

- Lead statistician in renal and cardiovascular portfolios.
- Provided statistical sections for protocols, performed sample size calculations, developed randomization specifications, prepared statistical analysis plans, developed dataset specifications, and interpreted statistical results.
- Reviewed tables, figures, and listings for study reports, and contributed statistical results for NDAs, MAAs, IBs, core dossiers, and other regulatory documents.

BONE CARE INTERNATIONAL, MIDDLETON, WI – Oct 2002 – Jun 2005
SENIOR MANAGER, BIOMETRICS – Oct 2002 – Jun 2005

- Served as statistician supporting clinical trials, including design and analysis. Also, provided statistical support to marketing and pre-clinical departments.
- Performed statistical duties, including development of statistical sections for protocols, sample size calculations, randomizations, and statistical analysis plans.
- Reviewed tables, figures, and listings for study reports, and contributed statistical results for INDs, sNDA, IBs, and other regulatory documents.
- Developed all statistical/programming SOPs, maintained department budget, and provided monthly updates to senior management.

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Name: JOHN A. HUNTER

COVANCE CLINICAL RESEARCH UNIT, MADISON, WI – Sep 1995 – Oct 2002
MANAGER, BIOSTATISTICS & PROGRAMMING – Jun 2000 – Oct 2002
SUPERVISOR, BIOSTATISTICS – Jun 1998 – May 2000
BIOSTATISTICIAN – Sep 1995 – May 1998

- Created statistical SOPs and developed more efficient and effective procedures as staff increased.
- Performed statistical duties, including development of statistical sections for protocols, sample size calculations, randomizations, and statistical analysis plans.
- Analyzed data and oversaw production of tables, figures, and listings for clinical study reports from Phase 1 and Phase 2a clinical trials, primarily pharmacokinetic data from rising-dose, bioequivalence, food-effect and drug-drug interaction studies.

Therapeutic Experience

- **ONCOLOGY:** Solid Tumors (Phases 1, 4)
- **DERMATOLOGY:** Psoriasis (Phase 2)
- **ENDOCRINE:** Hypercholesterolemia (Phases 1-3), Hyperphosphatemia (Phases 2-4), Secondary Hyperparathyroidism (Phase 4)
- **NEPHROLOGY:** Hemodialysis (Phases 2-4), Chronic Kidney Disease (Phases 2-4)
- **PULMONARY:** Idiopathic Pulmonary Fibrosis (Phase 2)

Language Capabilities

- English

Education

- Master of Science, Statistics, University of Wisconsin-Madison, Madison, Wisconsin
- Bachelor of Science, Electrical Engineering, Calvin College, Grand Rapids, Michigan

Memberships/Awards

- American Statistical Association, Ordinary Member
- Covance Way Award, 1998
- Genzyme Vice President's Award, 2011

Employee Signature: John Hunter

Date: 20 Jan 2014

A list of publications, manuscripts, abstracts, and presentations is available in Appendix I.

Name: JOHN A. HUNTER

Appendix I

Kant KS, Gonzalez AR, Hariachar S, Bernardo M, Duggal A, Engstrand S, Hunter J, Plone M, Hertel J. "Converting to doxercalciferol capsules from intravenous paricalcitol or doxercalciferol." *J Ren Nutr* 2012; 22(1): 34-40.

Patel A, Robertson J, Darwin C, Locay H, Añel R, Engstrand S, Hunter J, Plone M, Cangiano J. "Double-blind study comparing doxercalciferol and placebo in vitamin D-replete CKD patients." *Dial Transplant* 2011; 40(6): 252–257.

Moustafa M, Lehrner L, Al-Saghir F, Smith M, Goyal S, Dillon M, Hunter J, Block G. "A randomized, double-blind, placebo-controlled, dose-ranging study using Genz-644470 and sevelamer carbonate in hyperphosphatemic chronic kidney disease patients on hemodialysis." *NDT Plus* 2010;3(suppl 3):iii236.

Fan S, Ross C, Mitra S, Kalra P, Heaton J, Hunter J, Plone M, Pritchard N. "A randomized, crossover design study of sevelamer carbonate powder and sevelamer hydrochloride tablets in chronic kidney disease patients on haemodialysis." *Nephrol Dial Transplant* 2009; 24:3794-3799.

Mason, BJ, AM Goodman, RM Dixon, MHA Hameed, T Hulot, K Wesnes, JA Hunter, and MG Boyeson. "A Pharmacokinetic and Pharmacodynamic Drug Interaction Study of Acamprosate and Naltrexone." *Neuropsychopharmacology*, Vol. 27, 4:596-606 (Oct 2002).

AbdelHameed, MH, G Balan, J Hunter, P Teitelbaum, S Skettino, and M Jerling. "Investigation of the Potential Pharmacokinetic (PK) Interaction Between Ranolazine SR and Digoxin in Healthy Volunteers." Presented at the 2001 AAPS Annual Meeting and Exposition. Denver, CO.

AbdelHameed, MH, G Balan, J Hunter, P Teitelbaum, and D Wells. "Pharmacokinetics (PK) of NPS 1776 after Multiple Oral Doses in Normal Healthy Subjects." Presented at the 2001 AAPS Annual Meeting and Exposition. Denver, CO.

Name: JOHN A. HUNTER

AbdelHameed, MH, G Balan, J Hunter, P Teitelbaum, and D Wells. "Pharmacokinetics (PK) of NPS 1776 in Normal Healthy Subjects." Presented at the 2000 AAPS Annual Meeting and Exposition. Indianapolis, IN.

Jung, D, MH Abdelhameed, J Hunter, P Teitelbaum, A Dorr and K Griffy. "The Pharmacokinetics and Safety Profile of Oral Ganciclovir in Combination with Trimethoprim in HIV- and CMV-Seropositive Patients." *Brit. J. of Clin. Pharm.*, Vol. 47, 3:255-259 (1999).

AbdelHameed, MH, JA Hunter, P Teitelbaum, DL Coggin, J Girault, T Hulot and A Goodman. "Evaluation of the Pharmacokinetic (PK) Drug Interaction Between Acamprosate (ACAMP) and Naltrexone (NAL) in Normal Healthy Adult Volunteers." Presented at the 1999 AAPS Annual Meeting and Exposition. New Orleans, LA.

AbdelHameed, MH, J Hunter, D Coggin, P Teitelbaum, A Dorr, K Griffy and D Jung. "Effect of Gender on the Pharmacokinetics (PK) of Oral Ganciclovir (GCV) in HIV- and Cytomegalovirus (CMV)- Seropositive Adult Volunteers." Presented at the 1997 AAPS Annual Meeting and Exposition. Boston, MA.

AbdelHameed, MH, J Hunter, P Teitelbaum, A Dorr, K Griffy and D Jung. "Evaluation of Pharmacokinetic (PK) Interaction Between Oral Ganciclovir (GCV) and Trimethoprim (TMP) in HIV- and Cytomegalovirus (CMV)- Seropositive Adult Volunteers". Presented at the 1997 AAPS Annual Meeting and Exposition. Boston, MA.

ANDREW HEDGE

Covance Clinical Development Services
PRINCIPAL STATISTICIAN

SPRINGFIELD HOUSE, HYDE STREET, LEEDS, LS2 9LH, UK
Tel: 0113 237 3500

Employment History

COVANCE CLINICAL DEVELOPMENT SERVICES, LEEDS, UK – Aug. 1989 – Present
PRINCIPAL STATISTICIAN – Mar. 2013 – Present

- Input into study design, including sample size calculation
- Produce and check randomizations
- Writing statistical analysis plans, analyzing and QCing of clinical trial data, including creating TFLs.
- Training of statistical and non-statistical staff and providing general statistical advice to clients

BIOSTATISTICIAN III – Mar. 1997– Mar. 2013

- Input into study design, including sample size calculation
- Produce and check randomizations
- Writing statistical analysis plans, analyzing and QCing of clinical trial data, including creating tables, figures and listings.
- Training of statistical and non-statistical staff and providing general statistical advice to clients

SENIOR STATISTICIAN – Mar.1993 – Mar. 1997

- Study statistician responsibility for phase I clinical trials.
- Statistical analysis of phase I clinical trials, including generation and checking of tables, figures and listings.
- Derivation of pharmacokinetic non-compartmental parameters.
- Produce and check randomizations

STATISTICIAN – Mar. 1990 – Mar. 1993

- Study statistician responsibility for pre-clinical trials.
- Statistical analysis of phase I clinical trials.
- Derivation of pharmacokinetic non-compartmental parameters.
- Generation of tables, figures and listings.

TRAINEE STATISTICIAN – Aug. 1989 – Mar. 1990

- Produce randomizations
- Analysis of pre-clinical trial data

COVANCE

Name: ANDREW HEDGE

LEEDS GENERAL INFIRMARY, LEEDS, UK– Apr. 1986 – Dec. 1988
RESEARCH ASSITANT – Apr. 1986 – Dec. 1988

- Responsible for research into using new methodology to analyze data collected on a previous study
- Write up results for an MSc Thesis
- Provide general statistical advice to members of the department

MILDON & COMPANY, LEEDS, UK – Aug. 1985 – Dec. 1985
INSURANCE SALESMAN – Aug. 1985 – Dec. 1985

- Sell insurance to the general public

Therapeutic Experience

- N/A

Language Capabilities

- ENGLISH - MOTHER TONGUE

Education

- BACHELOR of SCIENCE in OPERATIONAL RESEARCH with STATISTICS, UNIVERSITY OF LEEDS, UK
- MASTER of SCIENCE in MEDICAL PHYSICS, UNIVERSITY OF LEEDS, UK

Memberships/Awards

- STATISTICIANS IN THE PHARMACEUTICAL INDUSTRY (PSI)

Other

- PSI CONFERENCE, CHESTER, UK 2007
- PSI CONFERENCE, CHESTER, UK 2001
- PSI CONFERENCE, HARROGATE, UK 1998
- PSI CONFERENCE, STRATFORD, UK 1997
- PSI CONFERENCE, BOURNEMOUTH, UK 1996
- PSI CONFERENCE, BLACKPOOL, UK 1995
- PSI CONFERENCE, COVENTRY, UK 1994
- PSI CONFERENCE, BRISTOL, UK 1993
- PSI CONFERENCE, BRIGHTON, UK 1992
- PSI CONFERENCE, YORK, UK 1994

Employee Signature: Andrew Hedge

Date: 04 JUN 2014

Name: ANDREW HEDGE

Appendix I

Presentations/Teaching Courses

PSI Conference 1992 (Parallel session) Talk on "Pre-clinical studies: An introduction and some of the problems"

Publications

Models of the Distribution of Protein, Water and Electrolytes in the Human Body. Infusiontherapie 1990; 17 (Suppl 3): 21-25

ANDREW SENIOR

Covance Clinical Development Services
MEDICAL WRITER II

SPRINGFIELD HOUSE, HYDE STREET, LEEDS, UK
Tel: 0113 237 3500

Employment History

COVANCE CLINICAL RESEARCH UNIT, LEEDS, UK – Mar 2010 – present
MEDICAL WRITER II - Jun 2012 - Present

- Responsible for the production of study protocols, clinical study reports (CSRs), Investigator Brochures and other documents needed.
- Provide guidance and leadership to ensure successful project completion
- Prepare and coordinate the development of draft and final protocols and protocol amendments for Phase I/II studies.
- Interpret clinical, pharmacokinetic, pharmacodynamic and statistical results as appropriate for Phase I/II studies.
- Provide training of Associate Medical Writers and Editors, as appropriate.

MEDICAL WRITER I - Mar 2010 - Jun 2012

- Responsible for the production of study protocols, clinical study reports (CSRs), Investigator Brochures and other documents needed.
- Provide guidance and leadership to ensure successful project completion
- Prepare and coordinate the development of draft and final protocols and protocol amendments for Phase I/II studies.
- Interpret clinical, pharmacokinetic, pharmacodynamic and statistical results as appropriate for Phase I/II studies.
- Provide training of Associate Medical Writers and Editors, as appropriate.

PRISM IDEAS, CHESHIRE, UK - May 2009 - Feb 2010
MEDICAL WRITER – May 2009 – Feb 2010

- Promote new pharmaceutical products and diagnostic equipment by composing manuscripts for medical journals and producing new promotional material;
- Prepare slide presentations for investigator meetings and posters for symposia;
- Analyse clinical trial results; write clinical study reports and protocols;
- Develop relationships with clients such as clinical project managers at pharmaceutical companies, key opinion leaders, doctors and academics. Give suggestions on how to communicate their messages or promote their product;
- Analyse published literature and rapidly gain expertise of a particular clinical area to provide objective opinions and produce publications quickly.

COVANCE

Name: ANDREW SENIOR

CHROMA THERAPEUTICS, OXFORDSHIRE, UK - Jan 2006 - Jan 2009
SENIOR DEVELOPMENT CHEMIST – Jan 2006 – Jan 2009

- Develop and optimise chemical processes for the synthesis of novel pharmaceutical products.
- Manage the technology transfer of chemical processes to external manufacturers for GMP synthesis of material for clinical trials
- Management of junior members of laboratory staff.
- Review GMP documentation.
- Write chemistry sections of Investigational Medicinal Product Documents.
- Manage internal project meetings for every compound in development.

RHODIA PHARMA SOLUTIONS, NEWCASTLE, UK – Aug 2005 -Dec 2005
DEVELOPMENT CHEMIST – Aug 2005 -Dec 2005

- Process development, validation and GMP synthesis of commercially viable synthetic organic processes for pharmaceutical intermediates and final drug products.

IMS HEALTH, LONDON, UK - Jan 2005 - Jul 2005
PATENT ANALYST - Jan 2005 - Jul 2005

- Search for newly published pharmaceutical patents and analyse the chemistry for drug structures and synthetic methods. Provide market information to pharmaceutical companies.
- Maintain a database of chemistry and patent information on drug compounds in development and on the market.
- Provide patent status information for the generic pharmaceutical market.

OSI PHARMACEUTICALS, OXFORDSHIRE, UK – Jun 2004 - Dec 2004
DEVELOPMENT CHEMIST – Jun 2004 – Dec 2004

- Process development, validation and GMP synthesis of commercially viable synthetic organic processes for pharmaceutical intermediates and final drug products.

AVECIA PHARMACEUTICALS, YORKSHIRE, UK - Mar 2001- Jun 2004
DEVELOPMENT CHEMIST – Mar 2001 – Jun 2004

- Process development, validation and GMP synthesis of commercially viable synthetic organic processes for pharmaceutical intermediates and final drug products.

Name: ANDREW SENIOR

Therapeutic Experience

- ONCOLOGY (BREAST, LUNG AND PROSTATE CANCER, AND LEUKEMIA)
- HEPATITIS
- ANTI OBESITY
- GOUT
- ALLERGIC RHINITIS
- ANTIFUNGALS
- ANTIBIOTICS
- CORONARY DISEASE
- CYSTIC FIBROSIS
- COPD
- ARTHRITIS
- BIOMARKERS FOR HEART DISEASE
- BIOMARKERS FOR PREECLAMPSIA

Language Capabilities

- ENGLISH – MOTHER TONGUE

Education

- DOCTOR OF PHILOSOPHY in ORGANIC CHEMISTRY, LEEDS UNIVERSITY, LEEDS, UK
- BATCHELOR OF SCIENCE with HONOURS in CHEMISTRY WITH MEDICINAL CHEMISTRY, UNIVERSITY OF HUDDERSFIELD, HUDDERSFIELD, UK

Memberships/Awards

- N/A

Employee Signature: A. Senior

Date: 11 April 2014

A list of publications, manuscripts, abstracts, and presentations is available upon request.

Name: ANDREW SENIOR

Appendix I

MEDICAL WRITER OF THE FOLLOWING MANUSCRIPTS:

- Should progression-free survival be the primary measure of efficacy for advanced NSCLC therapy?
  Soria JC, Massard C, Le Chevalier T. Ann. Oncol. 2010 Dec;21(12):2324-32.
- The preeclampsia biomarkers soluble fms-like tyrosine kinase-1 and placental growth factor: current knowledge, clinical implications and future application.
  Lapaire O, Shennan A, Stepan H. Eur. J. Obstet. Gynecol. Reprod. Biol. 2010 Aug;151(2):122-9.

LOUISE WAKENSHAW

Covance Clinical Development Services
MEDICAL WRITER

SPRINGFIELD HOUSE, HYDE STREET, LEEDS, UK
Tel: 0113 237 3500

Employment History

COVANCE CLINICAL DEVELOPMENT SERVICES, LEEDS, UK – Jul. 2012 – Present
MEDICAL WRITER – Jul. 2012 – Present

- Responsible for production of study protocols and clinical study reports (CSRs) for Phase I clinical trials.
- Interpretation of clinical, pharmacokinetic, pharmacodynamic and statistical results.
- Involvement in the review of draft and final statistical analysis plan (SAP).
- Communication with internal staff and external clients to obtain information for the completion of above protocols and reports for within required timeframe.

INSTITUTE OF FOOD RESEARCH, NORWICH, UK– Jun. 2008 - Jul. 2012
RESEARCH SCIENTIST – Jun. 2008 - Jun. 2012

- Project management of research projects.
- Individual and team-led research, implementing various scientific techniques to answer key research questions.
- Project and experimental design, developing standard operating procedures and H&S forms, literature reviews, sample and data collection, analysis of data including statistical analysis, writing of report and publication manuscripts.

UNIVERSITY OF LEEDS, IMCB DEPARTMENT, LEEDS, UK – Oct. 2007 - Jun. 2008
RESEARCH SCIENTIST – Oct. 2007 - Jun. 2008

- Individual and team-led research, implementing various scientific techniques to answer key research questions.
- Developing standard operating procedures and COSHH forms
- In charge of lab budget for purchase of consumables.

Therapeutic Experience

- N/A

Language Capabilities

- ENGLISH - MOTHER TONGUE

COVANCE

Name: LOUISE WAKENSHAW

Education

- DOCTOR of PHILOSOPHY in MOLECULAR & CELLULAR IMMUNOLOGY, UNIVERSITY of LEEDS, LEEDS, UK
- BACHELOR of SCIENCE in BIOCHEMISTRY, UNIVERSITY of SHEFFIELD, SHEFFIELD, UK
- 4 A LEVELS, RICKMANSWORTH SCHOOL, WATFORD, HERTS, UK

Memberships/Awards

- N/A

Other

- N/A

Employee Signature: LWakenshaw

Date: 26 Feb 2014

Name: LOUISE WAKENSHAW

Appendix I

2012 Manuscript in preparation, Wakenshaw L, Sarafian M, Le Gall G, Rabot S, and SR. Carding, The influence of host immunity, gut microbiota and diet in the development of obesity and metabolic syndrome.

Mar 2012 Volunteer, The Big Bang Fair, NEC, Birmingham, UK, *IFR stand Food for sport.*

Feb 2012 Submitted, L Wakenshaw and SR Carding. The Immunology behind Obesity. *British Society of Immunology "Bite size" educational online feature.* L.Wakenshaw 26.03.12

Dec 2011 British Society of Immunology's monthly magazine, front cover scientific image and conference report.

Sept 2011 Oral presentation, Wakenshaw L, Sarafian M, Le Gall G, and SR Carding., The influence of host immunity, gut microbiota and diet in the development of obesity and metabolic syndrome, *1st International conference on ImmunoMetabolism, Crete, Greece.*

May 2011 Volunteer, The Big Bang Fair, ExCel, London, UK, *IFR stand Taste and Flavour.*

Oct 2008 Publication, Cruickshank S, Wakenshaw L, Cardone J, Howdle P, Murray PJ, and S Carding (work equal between 1st two authors), Evidence for the involvement of NOD2 in colonic epithelial cell growth and survival (*World Journal of Gastroenterology* 14(38): 5834-5841.).

2005 Publication, Wakenshaw L, Walters M and A.Whitehouse (work equal between 1st two authors) - The Herpesvirus Saimiri replication and transcription activator acts synergistically with CCAAT enhancer binding protein alpha to activate the DNA polymerase promoter. *(Journal of Virology 79(21): 13548-60).*

2005 Publication, Singh J, Cruickshank S, Newton D, Wakenshaw L *et al.*, Toll like receptor-mediated responses of primary intestinal epithelial cells during the development of colitis. *(Am J Physiol Gastrointest Liver 288:G514-24)*