PMI RESEARCH & DEVELOPMENT

Study ZRHM-REXA-07-JP

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 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 85 days in an ambulatory setting
Study Number:	ZRHM-REXA-07-JP
Product Name:	Tobacco Heating System 2.2 Menthol (THS 2.2 Menthol)
Study Initiated (first subject screened):	01 August 2013
Study Completed (last subject last visit):	03 July 2014
Principal Investigator and Affiliation:	Mamoru Oki, MD, PhD, Seishukai Clinic 3-18-5, Matsugaya, Taitou-ku Tokyo 111-0036, Japan Professor Masahiro Endo, MD, Tokyo Heart Center Osaki Hospital, 5-4-12, Kita-Shinagawa, Shinagawa-ku, Tokyo 141-0001, Japan
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 Nicola Lama, PhD, Biostatistician Andrea Donelli, Clinical Scientist Patrick Picavet, MD, Medical Safety Officer
Version:	1.0
Date:	24 February 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.

TABLE OF CONTENTS

16.1.4 List of Investigators and Other Important Participants and Descriptions of Qualifications and Research Facilities 3

16.1.4.1 Site 1 3

16.1.4.2 Site 2 9

16.1.4.3 CV of Key CRO Staff 15

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
Seishukai Clinic 3-18-5, Matsugaya, Taitou-ku Tokyo 111-0036, Japan	This is a Medical Research Clinic.	SEI

16.1.4.1.2 CV of Personnel of Site 1 (PI, Sub-PI, Study Coordinator)

The Principal Investigator for this study was Mamoru Oki, MD, PhD.

The Sub-Investigators were:

Ritsuko Oki

Hiroyuki Shimizu

Jun Hasegawa

Form 1

Reference number	

As of 5, July, 2013

Curriculum Vitae
(■Principal Investigator □ Sub-investigator)

Name	Mamoru Oki				
Affiliated institution	Seishukai Clinic				
Department/ position	Department of Urology /President & CEO				
Education	Graduated from Dokkyo Medical university Faculty of Medicine in 1982				
Medical licensure	■ Full Medical License (Japan) no. (267320), obtained in (1982) □ Full Dental License no. ( ), obtained in ( )				
Board certification	• Board Certified Member of The Japanese Urological Association • Board Certified Member of The Japanese Society for Dialysis Therapy				
Professional experience (approx. for last five years)	Apr 1982	-	Mar 1997	:	Department of Urology, Nippon Medical School Hospital
	Apr 1997	-	Mar 2001	:	Department of Urology, Hasegawa Hospital
	Apr 2001	-	Mar 2005	:	Department of Urology, Hasegawa Hospital
	Apr 2005	-	Present	:	Department of Urology, Seishukai Clinic
Area of expertise	Urology				
Professional memberships	• The Japanese Urological Association • The Japanese Society for Dialysis Therapy • Japanese Society of Endourology				
Main researches, authorship, research papers, etc. (at most 10 most recent works related to clinical studies, etc.)	• Research about calculus fragmentation, Nephrology Key Notes, and treatment of bladder tumor • Bioequivalent examination in the healthy male adult of Risperidone tab 3mg • Bioequivalent examination in the healthy male adult of Meloxicam tab 10mg • Pharmacologic examination in the healthy male adult of Ecabet NA • Bioequivalent examination in the healthy adult of Saprogrelat Hydrochloride tab 50mg • Bioequivalent examination in the healthy adult of Saprogrelat Hydrochloride tab 100mg • Bioequivalent examination in the healthy adult of Levofloxacin Oral Solution 25mg/mL				
Experiences in clinical researches and post-market clinical studies (approx. for the last two years)	Item		Pharmaceutical product		Medical devices
	Number of studies conducted (brackets show studies in progress)		19 studies (4 studies)		0 studies (0studies)
	Main indications				
	Experience as principle investigator (no. of studies): ■ Yes (19 studies) □ No				
	Experience as sub-investigator (no. of studies):□ Yes (studies) ■ No				
Remarks*					

*If there has been no experience in clinical studies or post-market clinical studies in approximately the last two years but there was experience in the past, provide a brief explanation of the experience.

Signature: Mamoru Oki Date: 5. July, 2013

Note) (When the hospital director is not equal to the principal investigator): The principal investigator should prepare 2 original copies of this form (affixed the names and seals or signed), one copy is submitted to the hospital director and one copy to the sponsor, respectively.
(When the hospital director is equal to the principal investigator): The principal investigator should prepare 1 original copy of this form (affixed the names and seals or signed), the original copy is submitted to the sponsor.

Form 1

Reference number	

As of 5, July, 2013

Curriculum Vitae
(□Principal Investigator ■ Sub-investigator)

Name	Ritsuko Oki				
Affiliated institution	Seishukai Clinic				
Department/ position	Dialysis Center / Physician				
Education	Graduated from Nippon Medical School Faculty of Medicine in 1995				
Medical licensure	■ Full Medical License (Japan) no. (373947), obtained in (1995) □ Full Dental License no. ( ), obtained in ( )				
Board certification					
Professional experience (approx. for last five years)	1995	-	1997	:	Resident, Nippon Medical School Hospital
	1995	-	Present	:	Department of Ophthalmology, Nippon Medical School Hospital
	2007	-	Present	:	Dialysis Center, Seishukai Clinic
Area of expertise	Ophthalmology				
Professional memberships	• Japanese Ophthalmological Society				
Main researches, authorship, research papers, etc. (at most 10 most recent works related to clinical studies, etc.)	• Research about surgery for cataract				
Experiences in clinical researches and post-market clinical studies (approx. for the last two years)	Item		Pharmaceutical product		Medical devices
	Number of studies conducted (brackets show studies in progress)		19studies (4studies)		0study (0studies)
	Main indications				
	Experience as principle investigator (no. of studies): □ Yes (studies) ■ No				
	Experience as sub-investigator (no. of studies):■ Yes (19studies) □ No				
Remarks*					

*If there has been no experience in clinical studies or post-market clinical studies in approximately the last two years but there was experience in the past, provide a brief explanation of the experience.

Signature: Ritsuko Oki Date: 5. July. 2013

Note) (When the hospital director is not equal to the principal investigator): The principal investigator should prepare 2 original copies of this form (affixed the names and seals or signed), one copy is submitted to the hospital director and one copy to the sponsor, respectively.
(When the hospital director is equal to the principal investigator): The principal investigator should prepare 1 original copy of this form (affixed the names and seals or signed), the original copy is submitted to the sponsor.

Form 1

Reference number	

As of 30 Nov 2013

Curriculum Vitae
(□Principal Investigator ■ Sub-investigator)

Name	Hiroyuki Shimizu				
Affiliated institution	Seishukai Clinic				
Department/ position	Dialysis Center / Physician				
Education	Graduated from Nippon Medical School Faculty of Medicine in 1991				
Medical licensure	■ Full Medical License (Japan) no. (343435), obtained in (1991) □ Full Dental License no. ( ), obtained in ( )				
Board certification					
Professional experience (approx. for last five years)	2004	-	Present	:	Urology department, Nippon Medical School Hospital
	2005	-	Present	:	Dialysis Center, Seishukai Clinic
		-		:	
Area of expertise	Urology				
Professional memberships	• The Japanese Urological Association • The Japanese Society for Dialysis Therapy • Japanese Society of Endourology • Japan Society of Clinical Oncology • Japan Endoscopy Society				
Main researches, authorship, research papers, etc. (at most 10 most recent works related to clinical studies, etc.)					

	Item	Pharmaceutical product	Medical devices
Experiences in clinical researches and post-market clinical studies (approx. for the last two years)	Number of studies conducted (brackets show studies in progress)	0studies (0studies)	0study (0studies)
	Main indications		
	Experience as principle investigator (no. of studies): □ Yes (studies) ■ No		
	Experience as sub-investigator (no. of studies): □ Yes (studies) ■ No		
Remarks*			

*If there has been no experience in clinical studies or post-market clinical studies in approximately the last two years but there was experience in the past, provide a brief explanation of the experience.

Signature: Hiroyuki Shimizu Date: 30 / Nov / 2013

Note) (When the hospital director is not equal to the principal investigator): The principal investigator should prepare 2 original copies of this form (affixed the names and seals or signed), one copy is submitted to the hospital director and one copy to the sponsor, respectively.
(When the hospital director is equal to the principal investigator): The principal investigator should prepare 1 original copy of this form (affixed the names and seals or signed), the original copy is submitted to the sponsor.

Form 1

Reference number	

As of 28/Nov/2013

Curriculum Vitae
(□Principal Investigator ■ Sub-investigator)

Name	Jun Hasegawa				
Affiliated institution	Seishukai Clinic				
Department/ position	Dialysis Center / Physician				
Education	Graduated from Nippon Medical School Faculty of Medicine in 1981				
Medical licensure	■ Full Medical License (Japan) no. (261125), obtained in (1981) □ Full Dental License no. ( ), obtained in ( )				
Board certification					
Professional experience (approx. for last five years)	2001	-	Present	:	President & CEO, Hasegawa Hospital
	2005	-	Present	:	Dialysis Center, Seishukai Clinic
		-		:	
Area of expertise	Urology				
Professional memberships	• The Japanese Urological Association • The Japanese Society for Dialysis Therapy • The Japanese Society for Sexual Medicine				
Main researches, authorship, research papers, etc. (at most 10 most recent works related to clinical studies, etc.)	The anticancer drug sensitivity study of urinary organ malignancy Erectile Dysfuncion				
Experiences in clinical researches and post-market clinical studies (approx. for the last two years)	Item		Pharmaceutical product		Medical devices
	Number of studies conducted (brackets show studies in progress)		0studies (0studies)		0study (0studies)
	Main indications				
	Experience as principle investigator (no. of studies): □ Yes (studies) ■ No				
	Experience as sub-investigator (no. of studies): □ Yes (studies) ■ No				
Remarks*					

*If there has been no experience in clinical studies or post-market clinical studies in approximately the last two years but there was experience in the past, provide a brief explanation of the experience.

Signature: J. Hasegawa Date: 28/Nov./2013

Note) (When the hospital director is not equal to the principal investigator): The principal investigator should prepare 2 original copies of this form (affixed the names and seals or signed), one copy is submitted to the hospital director and one copy to the sponsor, respectively.
(When the hospital director is equal to the principal investigator): The principal investigator should prepare 1 original copy of this form (affixed the names and seals or signed), the original copy is submitted to the sponsor.

16.1.4.2 Site 2

16.1.4.2.1 Description and Address of Site 2

Site Name and Address	Description	Site Number
Tokyo Heart Center Osaki Hospital 5-4-12, Kita-Shinagawa, Shinagawa-ku, Tokyo 141-0001, Japan	This is a Medical Research Clinic.	TOK

16.1.4.2.2 CV of Personnel of Site 2 (PI, Sub-PI, Study Coordinator)

The Principal Investigator for this study was Masahiro Endo, MD.

The Sub-Investigators were:

Katsuo Kanmatsuse

Yumi Shimura

Osamu Hashimoto

CURRICULUM VITAE Page 1 of 1

Statement of Education and Qualifications

Date: 7/Jun/2013

Name (First, Middle, Last)	Academic Qualification(s) (e.g. MD, Medical License Number, etc)
Masahiro Endo	Medical License: 193755

Address (Name of Institution, Street, City, Postal Code, State or Province (if applicable), Country)

Tokyo Heart Center Osaki Hospital, 5-4-12 Kita-Shinagawa, Shinagawa, Tokyo 141-0001 Japan

Telephone Number (Country Code, Area Code, Number)	FAX Number (Country Code, Area Code, Number)
+81-3-5789-8100	+81-3-5789-8101

Education and Training (List all Colleges, Universities and Medical Schools attended incl. postdoctoral/fellowship training.)

Name and Location of Institution (City, State or Province and Country)	Degree and Year Awarded (if applicable)	Area of Study
Nihon University (Itabashi-ku, Tokyo)	1966	NA

Board certification/medical license

Name of Board certification / medical license	Area of Study
Medical license	NA
Trustees : Japanese College of Cardiology	Cardiology
Specialist,Trustees : The Japanese Association for Thoracic Surgery	Surgery
Specialist,Trustees : The Japanese Association for Cardiovascular Surgery	Surgery
Trustees : Japanese College of Angiology	Angiology
Trustees : Japanese Society for Artificial Organs	Artificial Organs
Director : The Japanese Association for Coronary Artery Surgery	Surgery
Specialist,Trustees : The Japan Society for Transplantation, The Japanese Circulation Society	Cardiology
Recognition medicine : Japan Surgical Society	Surgery
Trustees : Japanese Society for Clinical Surgery	Surgery

Professional Experience

Position/Title	Name and Location of Institution (City, State or Province and Country)	Dates (Start/Stop Dates as applicable)
Current: President	Tokyo Heart Center Osaki Hospital	2006-Present
Current: Honorary Professor	Tokyo Women's Medical University	2006-Present
Previous: Professor	Department of Cardiovascular Surgery, The Heart Institute of Japan, Tokyo Women's Medical University	1989-2006
Previous: Associate Professor	Department of Cardiovascular Surgery, The Heart Institute of Japan, Tokyo Women's Medical University	1981-1989
Previous: Assistant Professor	Department of Cardiovascular Surgery, The Heart Institute of Japan, Tokyo Women's Medical University	1973-1981

Previous participation in clinical trials (Within last 2 years)

Indication of Trial	Role in Trial (e.g. Investigator, Sub-Investigator)
Hypercholesterolemia	Investigator
Acute Coronary Syndrome	Sub-Investigator
Atrial Fibrillation	Sub-Investigator
Varicella Zoster (Shingles) Vaccine	Investigator

Training on ICH/GCP: YES ■ If yes, specify below NO ☐

WEB Training

Signature: Masahiro Endo Date: 7/JUN/2013

CURRICULUM VITAE Page 1 of 1

Statement of Education and Qualifications

Date: 7/Jun/2013

Name (First, Middle, Last)	Academic Qualification(s) (e.g. MD, Medical License Number, etc)
Katsuo Kanmatsuse	Medical License: 190274

Address (Name of Institution, Street, City, Postal Code, State or Province (if applicable), Country)

Tokyo Heart Center Osaki Hospital, 5-4-12 Kita-shinagawa, Shinagawa, Tokyo 141-0001 Japan

Telephone Number (Country Code, Area Code, Number)	FAX Number (Country Code, Area Code, Number)
+81-3-5789-8100	+81-3-5789-8101

Education and Training (List all Colleges, Universities and Medical Schools attended incl. postdoctoral/fellowship training.)

Name and Location of Institution (City, State or Province and Country)	Degree and Year Awarded (if applicable)	Area of Study
Nihon University	1965	NA

Board certification/medical license

Name of Board certification / medical license	Area of Study
Medical license	NA
Recognition medicine, Trustees : Japanese Association for Acute Medicine	Acute Medicine
Recognition medicine : The Japan Society of Clinical Pharmacology	Clinical Pharmacology
Recognition medicine, Trustees : The Japanese Society of Internal Medicine	Internal Medicine
Recognition medicine, Trustees : The Japanese Society of Intensive Care Medicine	Intensive Care Medicine
Recognition medicine, Trustees : The Japan Geriatrics Society	Geriatrics Society
Recognition specialist, Director : The Japanese Circulation Society	Cardiology
Trustees : Japanese College of Cardiology	Cardiology
Advising doctor : Japanese Association of Cardiovascular Intervention and Theraputics	Cardiology
Recognition medicine , Director, : Japanese Association of Cardioangioscopy	Cardioangioscopy
Trustees : Japanese College of Angiology	Angiology
Trustees : The Japanese Society of Electrocardiology	Electrocardiology
Trustees : The Japanese Heart Failure Society	Cardiology
Director : Japanese Society of Physiology	Physiology
Director : The Japan Society of Adult Diseases	Adult Diseases
Director : Japan Association for Clinical Monitoring	Clinical Monitoring
Chief director : Japanese Coronary Association	Cardiology
Director : The Japanese Society for Endvascular Intervention	Cardiology

Professional Experience

Position/Title	Name and Location of Institution (City, State or Province and Country)	Dates (Start/Stop Dates as applicable)
Current: Hospital Director	Tokyo Heart Center Osaki Hospital	2006-present
Previous: Visiting Professor	Nihon University	2004-2005
Previous: Hospital Director	Surugadai Nihon University Hospital	1998-2003

Previous participation in clinical trials (Within last 2 years)

Indication of Trial	Role in Trial (e.g. Investigator, Sub-Investigator)
Hypercholesterolemia	Sub-Investigator
Acute Coronary Syndrome	Sub-Investigator
Atrial Fibrillation	Sub-Investigator
Varicella Zoster (Shingles) Vaccine	Sub-Investigator

Training on ICH/GCP: YES ■ If yes, specify below NO □

WEB Training

Signature: Katsuo Kanmatsuse Date: 7/Jun/2013

Tokyo Heart Center Osaki Hospital

CURRICULUM VITAE

Statement of Education and Qualifications

Date: 7/Jun/2013

Name (First, Middle, Last)	Academic Qualification(s) (e.g. MD, Medical License Number, etc)
Yumi Shimura	Medical License: 351486

Address (Name of Institution, Street, City, Postal Code, State or Province (if applicable), Country)

Tokyo Heart Center Osaki Hospital, 5-4-12 Kita-shinagawa, Shinagawa, Tokyo 141-0001 Japan

Telephone Number (Country Code, Area Code, Number)	FAX Number (Country Code, Area Code, Number)
+81-3-5789-8100	+81-3-5789-8101

Education and Training (List all Colleges, Universities and Medical Schools attended incl. postdoctoral/fellowship training.)

Name and Location of Institution (City, State or Province and Country)	Degree and Year Awarded (if applicable)	Area of Study
Tokyo Women's Medical University	1992	NA

Board certification/medical license

Name of Board certification / medical license	Area of Study
Medical license	NA
Recognition specialist : The Japanese Society of Internal Medicine	Internal Medicine
Recognition specialist, Director : The Japanese Circulation Society	Cardiology
Advising doctor : Japanese Association of Cardiovascular Intervention and Theraputics	Cardiology

Professional Experience

Position/Title	Name and Location of Institution (City, State or Province and Country)	Dates (Start/Stop Dates as applicable)
Current: Chief of Cardiovascular Medicine	Tokyo Heart Center Osaki Hospital	2011-Present
Previous: Manager of Cardiovascular Medicine	Tokyo Heart Center Osaki Hospital	2007-2011
Previous: Physician	Medical Corporation Seiwakai Nishiarai Hospital	2007-2007
Previous: Physician	Medical Corporation Keiseikai Tokyo Hokubu Hospital	2006-2007
Previous: Physician	Medical Corporation Seiwakai Nishiarai Hospital	2003-2005

Previous participation in clinical trials (Within last 2 years)

Indication of Trial	Role in Trial (e.g. Investigator, Sub-Investigator)
Hypercholesterolemia	Sub-Investigator
Acute Coronary Syndrome	Sub-Investigator
Atrial Fibrillation	Sub-Investigator
Varicella Zoster (Shingles) Vaccine	Sub-Investigator

Training on ICH/GCP: YES ■ If yes, specify below NO ☐

WEB Training

Signature: Yumi Shimura Date: 7/Jun/2013

CURRICULUM VITAE Page 1 of 1

Statement of Education and Qualifications

Name (First, Middle, Last)	**Academic Qualification(s)** (e.g. MD, Medical License Number, etc)
Osamu Hashimoto	Medical License: 451893

Address (Name of Institution, Street, City, Postal Code, State or Province (if applicable), Country)

5-4-12 Kita-shinagawa, Shinagawa, Tokyo 141-0001 Japan

Telephone Number (Country Code, Area Code, Number)	**FAX Number (Country Code, Area Code, Number)**
+81-3-5789-8100	+81-3-5789-8101

Education and Training (List all Colleges, Universities and Medical Schools attended incl. postdoctoral/fellowship training.)

Name and Location of Institution (City, State or Province and Country)	**Degree and Year Awarded (if applicable)**	**Area of Study**
Shinshu University (Nagano)	2005	NA

Board certification/medical license

Name of Board certification / medical license	**Area of Study**
Medical license	NA
Certified Physician: The Japanese Society of Internal Medicine	Internal Medicine
Certified Physician: Japanese Association of Cardiovascular Intervention and Therapeutics	Cardiology

Professional Experience

Position/Title	**Name and Location of Institution (City, State or Province and Country)**	**Dates (Start/Stop Dates as applicable)**
Current Physician of cardiovascular medicine	Tokyo Heart Center Osaki Hospital	2012 - present
Previous		
Previous		

Previous participation in clinical trials (Within last 2 years)

Indication of Trial	**Role in Trial (e.g. Investigator, Sub-Investigator)**
Hypercholesterolemia	Sub-Investigator

Training on ICH/GCP: YES ■ If yes, specify below NO ☐

WEB Training

Signature (if required)	**Date**
Osamu Hashimoto	9/Feb/2016

16.1.4.3 CV of Key CRO Staff

16.1.4.3.1 List of Key CRO Staff

Covance Clinical Development Services:

Medical Director:	Luke Chung, MD, MPH

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)	Louise Wakenshaw, BSc, PhD

(b) (4)

Clinical Project Manager	(b) (4)
Clinical Project Leader	(b) (4)

16.1.4.3.2 CV of Key CRO Staff

LUKE CHUNG, MD, MPH

Covance Clinical Development Services
Medical Director, Singapore

#01-01 The Synergy Tower, 1 International Business Park, Singapore, S 609917
Tel: +65 6568 6588

Employment History

Covance Clinical Development Services, Singapore – Jul. 2010 – present
Medical Director – Jul. 2010 – present

- Provide medical and scientific leadership to ensure the integrity of the studies
- Provide oversight and guidance for programs in Asia-Pac region
- Responsible for medical monitoring of ongoing clinical trials
- Provide strategic consulting for clinical trials
- Liaise with thought leaders in various therapeutic indications
- Involve in clinical development plan
- Review clinical trial report
- Train project staff

ICON PLC, Singapore – Apr. 2007 – Jul. 2010
Senior Clinical Research Physician – Aug. 2008 – Jul. 2010

- Provided training / supervision to medical department staffs
- Assisted medical director in the general management / client interaction
- Participated in study proposals / business development activities

Clinical Research Physician – Apr 2007 – Aug. 2008

- Served as Project Physician for multiple global / regional clinical trials
- Collaborated in feasibility / protocol / CRF designs
- Provide ongoing medical / safety monitoring
- Trained project team members in therapeutic areas / protocols
- Act as medical advisor for protocol-related issues to investigators

National Healthcare Group, Singapore – Jul. 2005 – Apr. 2007
Asst. Manager, Clinical Services, Alexandra Hospital

- Oversaw Clinical Research Unit activities and clinical trials conducted in the hospital
- Served as Medical Administrator for hospital's clinical services operations

COVANCE

Name: Luke Chung

Private Group Practice, Seoul, Korea – Apr. 2003 – May. 2004
Physician, General Practice

Republic of Korea Army, Korea – Jan. 2000 – Mar. 2003
Medical Officer, May. 2000 – Mar. 2003

Therapeutic Experience

- **INFECTIOUS DISEASE:** HEPATITIS B, HEPATITIS C, HIV, SOFT SKIN & COMPLICATED SKIN STRUCTURE INFECTION, NOSOCOMIAL PNEUMONIA, VENTILATOR-ASSOCIATED PNEUMONIA (PHASE 3), POST-TRANSPLANT CMV INFECTION
- **INFLAMMATORY/RESPIRATORY:** COPD, ASTHMA, OSTEOARTHRITIS, RHEUMATOID ARTHRITIS (PHASES 2 ~ 3)
- **ENDOCRINOLOGY/NEPHROLOGY:** TYPE 2 DM, ESRD DUE TO DIABETIC NEPHROPATHY (PHASE 3)
- **ONCOLOGY:** BREAST CANCER, LUNG CANCER, COLORECTAL CANCER, PROSTATE CANCER, MALIGNANT MELANOMA, HEPATOCELLULAR CARCINOMA, CERVICAL CANCER (PHASES 1 ~ 3)
- **NEUROLOGY/PSYCHIATRY:** ACUTE ISCHEMIC STROKE, MAJOR DEPRESSIVE DISORDER, BIPOLAR DISORDER (PHASES 2 ~ 3), SCHIZOPHRENIA
- **CARDIOVASCULAR:** DEEP VEIN THROMBOSIS, HYPERTENSION (PHASE 3), HYPERLIPIDEMIA, ACS
- **GASTROENTEROLOGY:** ULCERATIVE COLITIS (PHASE 3), PEPTIC ULCER, EROSIVE ESOPHAGITIS, GASTROESOPHAGELA REFLUX DISEASE

Language Capabilities

- ENGLISH (FLUENT)
- KOREAN

Education/Training

- MASTER OF PUBLIC HEALTH, HARVARD SCHOOL OF PUBLIC HEALTH, BOSTON, MASSACHUSETTS, US
- ACCIDENT & EMERGENCY PHYSICIAN, CHUNG-JU HOSPITAL, CHUNG-JU CITY, CHUNG-BUK, KOREA
- INTERN/RESIDENT IN NEUROSURGERY, SAMSUNG MEDICAL CENTER, SEOUL, KOREA
- MEDICAL DOCTOR, COLLEGE OF MEDICINE –KOREA UNIVERSITY, SEOUL, KOREA

Memberships/Awards

- KOREA MEDICAL ASSOCIATION
- KOREA SOCIETY OF PREVENTIVE MEDICINE
- AMERICAN PUBLIC HEALTH ASSOCIATION

Other

- PHYSICIAN LICENSE NO 65061 (ACTIVE), THE MINISTRY OF HEALTH AND WELFARE, KOREA

Name: Luke Chung

Employee Signature: E. C. Chung

Date: February 12, 2014

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.

COVANCE

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

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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EUROPE/AFRICA +800.2682.2682 +44.1423.500888
ASIA PACIFIC +800.6568.3000 +65.6.5677333
www.covance.com

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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

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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

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

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)*

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