PMI RESEARCH & DEVELOPMENT

# Study ZRHM-PK-05-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 single-center, open-label, randomized, controlled, crossover study to investigate the nicotine pharmacokinetic profile and safety of Tobacco Heating System 2.2 Menthol (THS 2.2 Menthol) following single use in smoking, healthy subjects compared to menthol conventional cigarettes and nicotine gum |
| **Short Title:** | Nicotine pharmacokinetic profile and safety of Tobacco Heating System 2.2 Menthol (THS 2.2 Menthol) |
| **Study Number:** | ZRHM-PK-05-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):** | 16 November 2013 |
| **Principal Investigator and Affiliation:** | F. Nobuoka, MD<br>Ageo Medical Clinic<br>3133 Haraichi, Ageo City<br>Saitama 362-0021, Japan |
| **Sponsor:** | Philip Morris Products S.A.<br>PMI Research & Development<br>Quai Jeanrenaud 5<br>2000 Neuchâtel, Switzerland |
| **Sponsor Signatories:** | Christelle Haziza, PhD, Manager P1 Clinical Program, Clinical Scientist<br>Andrea Donelli, Clinical Scientist<br>Nicola Lama, PhD, Biostatistician<br>Patrick Picavet, MD, Medical Safety Officer |
| **Version:** | 1.0 |
| **Date:** | 12 May 2015 |

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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## 16.1.4.1 SITE 1

### 16.1.4.1.1 Description and Address of Site 1

| Site Name and Address | Description | Site Number |
|---|---|---|
| Ageo Medical Clinic<br>3133 Haraichi<br>Ageo City<br>Saitama 362-0021<br>Japan | This is a Medical Research Clinic. | AGE |

## 16.1.4.1.2 CV of Personnel of Site 1

The Principal Investigator for this study was Fumimasa Nobuoka, MD.

The Sub-Investigators were:

Aki Morishima

Hiroyuki Furuya

Koichiro Hayata

Masashi Taguchi

Yutaka Kanamaru

Form 1

| Reference number | |
|---|---|

As of June 4, 2013

# Curriculum Vitae
(■Principal Investigator □ Sub-investigator)

| | | | |
|---|---|---|---|
| Name | Fumimasa Nobuoka | | |
| Affiliated institution | Ageo Medical Clinic | | |
| Department/ position | Medical Examination Section /President & CEO | | |
| Education | Graduated from Juntendo University Faculty of Medicine in 1991 | | |
| Medical licensure | ■ Full Medical License (Japan) no. ( 360613 ), obtained in ( 1993 )<br>□ Full Dental License no. ( ), obtained in ( ) | | |
| Board certification | Board Certified Sports Doctor for Japan Medical Association | | |
| Professional experience (approx. for last five years) | May 2000 - May 2006 | President & CEO, Meguro Orthopaedics Surgery Internal Medicine | |
| | Jun 2006 - Present | President & CEO, Medical Examination Section, Ageo Medical Clinic | |
| Area of expertise | Orthopaedics and Spine Surgery | | |
| Professional memberships | • Japanese Orthopaedics association,<br>• The Japanese Society for Spine Surgery and Related Research<br>• Japanese Society of Clinical Sports Medicine<br>• The Japanese Association of Rehabilitation Medicine<br>• Japan College of Rheumatology | | |
| Main researches, authorship, research papers, etc. (at most 10 most recent works related to clinical studies, etc.) | NA | | |
| 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) | 86studies ( 22studies) | studies ( 0studies) |
| | Main indications | NA | |
| | Experience as principle investigator (no. of studies): ■ Yes ( 63studies) □ No | | |
| | Experience as sub-investigator (no. of studies):■ Yes ( 23studies) □ 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: Fumimasa Nobuoka Date: 4 / Jun / 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 June 26, 2013

# Curriculum Vitae
(□Principal Investigator ■ Sub-investigator)

| | | | |
|---|---|---|---|
| Name | Dr. Aki Morishima | | |
| Affiliated institution | Ageo Medical Clinic | | |
| Department/ position | Medical Doctor, Medical Examination Section | | |
| Education | Graduated from Juntendo University Faculty of Medicine in 2005 | | |
| Medical licensure | ■ Full Medical License (Japan) no. ( 447284 ), obtained in ( 2005 )<br>□ Full Dental License no. ( ), obtained in ( ) | | |
| Board certification | NA | | |
| Professional experience (approx. for last five years) | Apr 2008 - Mar 2009 | Infectious Diseases , Jichi Medical University Hospital | |
| | Apr 2009 - Present | Medical Examination Section, Ageo Medical Clinic | |
| Area of expertise | Infectious Diseases , Internal Medicine | | |
| Professional memberships | • Japanese Society of Internal Medicine<br>• Japan Association for Infectious Diseases | | |
| Main researches, authorship, research papers, etc. (at most 10 most recent works related to clinical studies, etc.) | Images in Emergency Medicine:Splenic Infarction Due to Sickle Cell Trait after Climbing Mt.Fuji;Western Journal of Emergency Medicine:Vol.9:No.3,Article14 (2008) | | |
| 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) | 65studies ( 8studies) | 0studies ( 0studies) |
| | Main indications | NA | |
| | Experience as principle investigator (no. of studies): □ Yes (0studies) ■ No | | |
| | Experience as sub-investigator (no. of studies):■ Yes (65studies) □ 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: Aki Morishima Date: 26 / Jun / 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 | |
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As of June 26, 2013

# Curriculum Vitae
(□Principal Investigator ■ Sub-investigator)

| | | | |
|---|---|---|---|
| Name | Dr. Hiroyuki Furuya | | |
| Affiliated institution | Ageo Medical Clinic | | |
| Department/ position | Medical Doctor, Medical Examination Section | | |
| Education | Graduated from Tokyo Medical University Faculty of Medicine in 2005 | | |
| Medical licensure | ■ Full Medical License (Japan) no. ( 447263 ), obtained in ( 2005 )<br>□ Full Dental License no. ( ), obtained in ( ) | | |
| Board certification | NA | | |
| Professional experience (approx. for last five years) | Jul 2008 - Jun 2009 | Juntendo University Shizuoka Hospital | |
| | Apr 2009 - Mar 2013 | Juntendo University Graduate School of Medicine | |
| | Apr 2012 - Present | Medical Examination Section, Ageo Medical Clinic | |
| Area of expertise | Orthopedics | | |
| Professional memberships | • Japanese Orthopedics Association<br>• Japanese Society for Regenerative Medicine<br>• Japanese Society for Fracture Repair<br>• Japanese Society for Biomaterials | | |
| Main researches, authorship, research papers, etc. (at most 10 most recent works related to clinical studies, etc.) | NA | | |
| 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) | 2studies ( 2studies) | 0studies ( 0studies) |
| | Main indications | NA | |
| | Experience as principle investigator (no. of studies): □ Yes (0studies) ■ No | | |
| | Experience as sub-investigator (no. of studies): ■ Yes (2studies) □ 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: H.Yoyuki Furuya Date: 26 / Jun / 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 June 26, 2013

# Curriculum Vitae
(□Principal Investigator ■ Sub-investigator)

| | | | |
|---|---|---|---|
| Name | Dr. Koichiro Hayata | | |
| Affiliated institution | Ageo Medical Clinic | | |
| Department/ position | Medical Doctor, Medical Examination Section | | |
| Education | Graduated from Nihon University Faculty of Medicine in 1997 | | |
| Medical licensure | ■ Full Medical License (Japan) no. ( 392100 ), obtained in ( 1997 )<br>□ Full Dental License no. ( ), obtained in ( ) | | |
| Board certification | Medical specialist of Japan Orthopedic surgery | | |
| Professional experience (approx. for last five years) | Aug 2002 - Jun 2005 | Massachusetts General Hospital | |
| | Mar 2006 - Present | Tokyo Women's Medical University Medical Center East | |
| | Aug 2009 Present | Medical Examination Section, Ageo Medical Clinic | |
| Area of expertise | Bone Metabolism , Hip Joint | | |
| Professional memberships | • Japan Orthopedic Association<br>• Japan College of Rheumatology<br>• Japanese Society for Joint Diseases | | |
| Main researches, authorship, research papers, etc. (at most 10 most recent works related to clinical studies, etc.) | Assessing Osteoly with Use of Highthrough Protein Chips(J.Bone Joint Surg Am.2007,89:1081-9) | | |
| 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) | 65studies ( 8studies) | 0studies ( 0studies) |
| | Main indications | NA | |
| | Experience as principle investigator (no. of studies): □ Yes (0studies) ■ No | | |
| | Experience as sub-investigator (no. of studies):■ Yes (65studies) □ 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: _____ Date: 26 / JUN / 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.
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Form 1

| Reference number | |
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As of June 26, 2013

# Curriculum Vitae
(□Principal Investigator ■ Sub-investigator)

| | | | |
|---|---|---|---|
| Name | Dr. Masashi Taguchi | | |
| Affiliated institution | Ageo Medical Clinic | | |
| Department/ position | Medical Doctor, Medical Examination Section | | |
| Education | Graduated from Dokkyo Medical University Faculty of Medicine in 2010 | | |
| Medical licensure | ■ Full Medical License (Japan) no. ( 489553 ), obtained in ( 2010 )<br>□ Full Dental License no. ( ), obtained in ( ) | | |
| Board certification | NA | | |
| Professional experience (approx. for last five years) | Apr 2010 - Mar 2012 | Tokyo Women's Medical University Medical Center East | |
| | Apr 2012 - Present | Medical Examination Section, Ageo Medical Clinic | |
| Area of expertise | Orthopedics | | |
| Professional memberships | • Japan Orthopedics Association<br>• Japan Society of Aerospace and Environmental Medicine<br>• Kanto Society of Orthopedics and Traumatology | | |
| Main researches, authorship, research papers, etc. (at most 10 most recent works related to clinical studies, etc.) | NA | | |
| 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) | 37studies ( 7studies) | 0studies ( 0studies) |
| | Main indications | NA | |
| | Experience as principle investigator (no. of studies): □ Yes (0studies) ■ No | | |
| | Experience as sub-investigator (no. of studies):■ Yes (37studies) □ 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: Masashi Taguchi Date: 26 / Jun / 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.
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Form 1

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|---|---|

As of June 26, 2013

Curriculum Vitae
(□Principal Investigator ■ Sub-investigator)

| | | | |
|---|---|---|---|
| Name | Dr. Yutaka Kanamaru | | |
| Affiliated institution | Ageo Medical Clinic | | |
| Department/ position | Medical Doctor, Medical Examination Section | | |
| Education | Graduated from Juntendo University Faculty of Medicine in 1994 | | |
| Medical licensure | ■ Full Medical License (Japan) no. ( 366338 ), obtained in ( 1994 )<br>□ Full Dental License no. ( ), obtained in ( ) | | |
| Board certification | Certified member of The Japanese Society of Internal Medicine<br>Medical specialist of Japanese Society of Nephrology<br>Member Doctor for Japan Occupational Health Physician | | |
| Professional experience (approx. for last five years) | Feb 2007 - Present | Nephrology Internal, Juntendo University | |
| | Apr 2007 - Present | Medical Examination Section, Ageo Medical Clinic | |
| | Jul 2011 - Present | President, Clinic Sowanie | |
| | Jul 2013 - Present | Higashi Shinjuku Clinic | |
| Area of expertise | Hypertension, Renal disease, Allergy disease | | |
| Professional memberships | • Japanese Society of Internal Medicine<br>• Japanese Society of Kidney<br>• Japanese Society for Immunology<br>• Japanese Society for Dialysis Therapy<br>• Japan Occupational Health Physician | | |
| Main researches, authorship, research papers, etc. (at most 10 most recent works related to clinical studies, etc.) | Attachment | | |
| 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) | 69studies ( 6studies) | 0studies ( 0studies) |
| | Main indications | NA | |
| | Experience as principle investigator (no. of studies): ■ Yes ( 6studies) □ No | | |
| | Experience as sub-investigator (no. of studies):■ Yes ( 63studies) □ 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: Yutaka Kanamaru Date: 26/Jun/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.

Clin Exp Immunol. 2011 Nov;166(2):235-50. doi: 10.1111/j.1365-2249.2011.

Negative regulation of inflammatory responses by immunoglobulin A receptor (FcαRI) inhibits the development of Toll-like receptor-9 signaling-accelerated glomerulonephritis.(Watanabe T, Kanamaru Y, Liu C, Suzuki Y, Tada N, Okumura K, Horikoshi S, Tomino Y.)

Sci Signal. 2011 Apr 19;4(169):ra24.

Inhibitory ITAM signaling traps activating receptors with the phosphatase SHP-1 to form polarized "inhibisome" clusters.(Pfirsch-Maisonnas S, Aloulou M, Xu T, Claver J, Kanamaru Y, Tiwari M, Launay P, Monteiro RC, Blank U.)

Mod Rheumatol. 2010 Jun;20(3):291-4. Epub 2010 Jan 15.

Improvement of rapidly progressive lupus nephritis associated MPO-ANCA with tacrolimus.(Morimoto S, Watanabe T, Lee S, Amano H, Kanamaru Y, Ohsawa I, Tomino Y, Takasaki Y.)

J Immunol. 2008 Feb 15;180(4):2669-78.

Inhibitory ITAM signaling by Fc alpha RI-FcR gamma chain controls multiple activating responses and prevents renal inflammation.(Kanamaru Y, Pfirsch S, Aloulou M, Vrtovsnik F, Essig M, Loirat C, Deschênes G, Guérin-Marchand C, Blank U, Monteiro RC)

Immunol Rev. 2007 Jun;217:79-95.

Mast cells and inflammatory kidney disease.(Blank U, Essig M, Scandiuzzi L, Benhamou M, Kanamaru Y)

Contrib Nephrol. 2007;157:148-52.

IgA Fc receptor I is a molecular switch that determines IgA activating or inhibitory functions.(Kanamaru Y, Blank U, Monteiro RC.)

Eur J Immunol. 2007 Apr;37(4):1116-28.

Fc alpha receptor I activation induces leukocyte recruitment and promotes aggravation of glomerulonephritis through the FcR gamma adaptor.(Kanamaru Y, Arcos-Fajardo M, Moura IC, Tsuge T, Cohen H, Essig M, Vrtovsnik F, Loirat C, Peuchmaur M, Beaudoin L, Launay P, Lehuen A, Blank U, Monteiro RC)

Blood. 2007 Jan 1;109(1):203-11. Epub 2006 Sep 21.

IgA Fc receptor I signals apoptosis through the FcRgamma ITAM and affects tumor growth.(Kanamaru Y, Tamouza H, Pfirsch S, El-Mehdi D, Guérin-Marchand C, Pretolani M, Blank U, Monteiro RC)

J Immunol. 2006 May 1;176(9):5607-15.

Mast cell-mediated remodeling and fibrinolytic activity protect against fatal glomerulonephritis.(Kanamaru Y, Scandiuzzi L, Essig M, Brochetta C, Guérin-Marchand C, Tomino Y, Monteiro RC, Peuchmaur M, Blank U.)

Shock. 2006 Jan;25(1):61-5.

B lymphocytes undergo apoptosis because of FcgammaRIIb stress response to infection: a novel mechanism of cell death in sepsis.(Pinheiro-da-Silva F, Chiamolera M, Charles N, Kanamaru Y, Velasco IT, Benhamou M, Monteiro RC)

## 16.1.4.2 SITE 2

Not applicable.

## 16.1.4.3 CV OF KEY CRO STAFF

- Covance Clinical Development Services:

| | |
|---|---|
| Medical Monitor | Luke Chung, MD, MPH |

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

| | |
|---|---|
| CDARO Project Manager | Kilda Russum, BSc |
| CDARO Data Manager | Paul Hope, BSc |
| CDARO Pharmacokineticist | Stuart Hossack, BSc |
| CDARO Statistician | Andrew Hedge, BSc, MSc |
| CDARO Medical Writer | Andrew Senior, BSc, PhD |

- CMIC Co Ltd. (Japan, Tokyo):

| | |
|---|---|
| Clinical Project Manager | Masako Aoyagi |
| Clinical Project Leader | Hirotsugu Inagaki |

# 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

**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

# KILDA RUSSUM

## Covance Clinical Development Services

### Project Manager II

SPRINGFIELD HOUSE, HYDE STREET, LEEDS, LS2 9LH, UK

**Tel:** 0113 237 3500

## Employment History

**COVANCE CLINICAL DEVELOPMENT SERVICES, LEEDS, UK** – Jul. 2007 – Present

PROJECT MANAGER II – Feb. 2009 – Present

- As below, including:
- Aiding with proposal requests and communicating specific client requirements

ASSOCIATE PHARMACOMETRICS PROJECT MANAGER – Jul. 2007 - Feb. 2009

- Primary client contact for all Covance CDARO departments; communicating with clients on a regular basis, responding to email and telephone calls, ensuring clients are kept up-to-date and actively promoting CDARO services whenever possible
- Generating the MS project schedule for each study, and ensuring the study is on track. Updating the schedule and renegotiating timelines when necessary
- Responsibility for timely production of deliverables, and communication of priorities and deadlines within CDARO
- Liaising with clients and vendors to arrange and receive documents and data transfers
- Organizing, chairing and recording minutes for internal and client meetings
- Ensuring that all allocated projects are carried out in accordance with protocols, analysis plans, SOPs and GCP

**TISSUE SCIENCE LABORATORIES, LEEDS, UK** – Feb. 2007 - May. 2007

QA OFFICER – Feb. 2007 - May. 2007

- Working in a medical device manufacturer QA department, ensuring product met all specified business regulations, specifications and standards.
- Aiding with the preparation of validation procedures for in-house processes
- Performing instrument maintenance and environmental and microbiological testing

COVANCE

**EURO/DPC, NORTH WALES, UK** – Aug 2002 – Dec 2006

SCIENTIST – Aug. 2005 - Dec. 2006

- Managing projects including validation and verification of procedures, materials and processes
- Managing investigations into immunoassay kit performance and troubleshooting issues
- Writing protocols and developing project plans, including goals, timescales and milestones
- Designing and supervising experiments, interpreting data, liaising with other departments and making critical decisions regarding products
- Providing technical leadership and direction, and training new staff

SUPERVISOR – Apr 2004 – Aug 2005

- Technical work as well as organising the working day of a busy laboratory
- Responsibility for training new staff and leading and motivating the laboratory team
- Performing statistical analysis of generated data
- Liaising with Product Manufacturing and QC departments
- Ensuring adherence to GLP/GMP

LABORATORY TECHNICIAN – Aug 2002 – Sep 2003

Performing manual and automated immunoassays and radioimmunoassay

- Recording, reviewing and analysing data using a Microsoft Excel package

Maintenance of Instruments

- Carrying out investigations and adherence to GLP/GMP

## Therapeutic Experience

- **NA**

## Language Capabilities

- ENGLISH - MOTHER TONGUE
- WELSH - FLUENT

## Education

- BACHELOR of SCIENCE in MEDICAL MICROBIOLOGY, UNIVERSITY of LEEDS, LEEDS, UK

## Memberships/Awards

- N/A

## Other

- Aug 2006 PRINCE2 Project Management Foundation

Employee Signature: K S Russum

Date: 12 JUNE 2013

# PAUL HOPE

## Covance Clinical Development Services

### CLINICAL DATA MANAGER II

SPRINGFIELD HOUSE, HYDE STREET, LEEDS, UK

**Tel:** 0113 237 3500

## Employment History

**COVANCE CLINICAL DEVELOPMENT SERVICES, LEEDS, UK** – Jul. 2001 – Present
**CLINICAL DATA MANAGER II** – Mar. 2005 - Present

- Lead Data Manager on Phase I/II studies with full responsibility for all data management activities leading to database lock
- Review study quality via QC including validation, queries, critical, non-critical, documentation, coding
- SAE reconciliation
- Maintain study files
- Review draft CRF
- Attend client meetings
- Attend client or internal audits
- Training of new staff on project specific, global and Data Management processes
- Input into writing, reviewing and updating SOPs
- Communicating with internal and external vendors

**DATA MANAGER** – Jul. 2001 – Mar. 2005

- Lead Data Manager on Phase I/II studies with full responsibility for all data management activities leading to database lock
- Review study quality via QC including validation, queries, critical, non-critical, documentation, coding
- Validation
- Query integration
- SAE reconciliation
- Maintain study files
- Review draft CRF
- Attend client meetings
- Attend client or internal audits
- Communicating with internal and external vendors

COVANCE

**NATIONAL AUSTRALIA BANK, LEEDS, UK** – Aug. 1997 – Jan. 2000
**BRANCH ADMINISTRATION** – Aug. 1997 – Jan. 2000

- Liaising with the branches daily to ensure that any suspected fraudulent activity was investigated

## Therapeutic Experience

- N/A

## Language Capabilities

- ENGLISH – MOTHER TONGUE

## Education

- BACHELOR of ARTS in HISTORY, HUDDERSFIELD UNIVERSITY, HUDDERSFIELD, UK

## Memberships/Awards

- ASSOCIATION for CLINICAL DATA MANAGEMENT (ACDM)

## Other

- N/A

Employee Signature: P. Hope

Date: 19- NOV - 2013

# 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.

**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

# 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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# 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

**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

# 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.

**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.

# 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.

CMIC
Pharmaceutical Value Creator

*As of MAR 13 2014*

# MASAKO AOYAGI

GOTANDA FIRST BLDG., 2-8-1 NISHIGOTANDA SHINAGAWA-KU
TOKYO, 141-0031, JAPAN
Tel. +81 3 5719 6359 • Fax. +81 3 5434 6507 • E-mail. masako-aoyagi@cmic.co.jp

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## EXPERIENCE

**Feb.2001-Presen CMIC Co., Ltd.** **Tokyo, Japan**

***Project Management Department***

- Project Management of international Investigator initiated study for Lymphangioleiomyomatosis (LAM)
- Project Management of global study for non-valvular atrial fibrillation
- Site grant payment management
- Project Management of Cigarette Studies
- Assistant Project Manager of Dermatology phase IIb study

***Clinical Research Division***

- CRA of anti-diabetic phase III study
- Lead CRA and liaison of global community-acquired pneumonia (CAP) retrospective study
- Project Leader of clinical study for cigarette short-term and long-term study
- Project Leader of Migraine phase I study (ICCC project)
- Support of clinical study in Korea for Japanese Pharmaceutical Company
  - Pharmacogenomics study
  - Antiarrhythmic phase I study
- Support of protocol development for medical device
- Project Leader for Medical device clinical research, TKA total knee arthroplasty

**Oct. 1997-Mar.2000 Farcos Company** **Tokyo, Japan**

***Pharmacist at insurance pharmacy***

**Apr.1995-Jul.1997 Nippon Steri Company,** **Tokyo, Japan**

***Supervisor Pharmacist***

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## EDUCATION

**Kyoritsu College of Pharmacy** **Tokyo, Japan**

*Bachelor of pharmacology, March 1995*

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## TRAINING

**MedTrials** **Texas, USA**

*GCP and Clinical Trial Management Training, September 2002*

**PPD** **North Carolina, USA**

*Clinical foundation Program, June 2005*

**AMA, American Management Association** **Tokyo, Japan**

*Effective Discussions in Global Business, January 2014*

**ADDITIONAL QUALIFICATIONS**

**CMIC CRA Certification, May 2001**
**Japan CRO Association CRA Certification, Oct, 2011**

**Masako Aoyagi**
**Signature** 青柳雅子
**Date** 13 Mar 2014

**CMIC Co., Ltd.**
Gotanda First Bldg. 2-8-1 Nishigotanda,
Shinagawa-ku, Tokyo 141-0031
TEL:+81-3-5719-6303

| | | | |
|---|---|---|---|
| **NAME:** | Hirotsugu Inagaki | **CMIC CRA Certification:** | 12/10/2003 |

**SUMMARY:**

| | |
|---|---|
| 10/2003 - | CMIC Group |
| 04/1998 - 09/2003 | Teikoku Hormone Mfg.co,Ltd |

## Qualification

Pharmacist

## Experience

### 01/2012 - CMIC Group

| | | | |
|---|---|---|---|
| **Position:** | CRA<br>Project Leader | **Type of work:** | CRA |
| **Number of sites in charge:** | 14 | | |
| **Drug Classification:** | Kidney | | |
| **Study Type:** | Others | | |
| **Target disease:** | Autosomal Dominant Polycystic Kidney Disease(ADPKD) | | |
| **Miscellaneous:** | Observational Study<br><Site Initiation Visits,Monitoring Visit,SDV><br>Total number of sites:14.<br>Total number of subjects:240.<br>Project leader support and project support as CRA.<br>I was appointed as the project leader for this project from July-2012. | | |

### 04/2011 - 10/2011 CMIC Group

| | | | |
|---|---|---|---|
| **Position:** | Team Leader | **Type of work:** | CRA |
| **Number of sites in charge:** | 0 | | |
| **Drug Classification:** | Neurohypophysial hormone | | |
| **Study Type:** | Phase. II | | |
| **Target disease:** | Nocturnal Enuresis | | |
| **Miscellaneous:** | The number of sites:37 sites, The number of cases:177 examples(Medication: 113 examples)<br>CRF recovery, A clinical conference documentation, preparation / holding correspondence, End procedure of a clinical trial, Clinical trial data change of jurisdiction.<br>It was check of a monitoring report, direct inspection implementation record, and CRF as Subproject Leader.<br>It cooperated with PM and DM section and clinical conference data creation and holding preparations were made. | | |

### 08/2009 - 03/2011 CMIC Group

| | | | |
|---|---|---|---|
| **Position:** | Project Leader | **Type of work:** | CRA |
| **Number of sites in charge:** | 0 | | |
| **Drug Classification:** | Neurohypophysial hormone | | |

| | |
|---|---|
| **Study Type:** | Phase.Ⅲ |
| **Target disease:** | Primary Nocturnal Enuresis |
| **Miscellaneous:** | The number of sites:15 sites, The number of cases:174 examples(Medication:89 examples)<br>Feasibility investigation,Institution selection,Monitoring,<br>CRF recovery, A clinical conference documentation, preparation / holding correspondence, End procedure of a clinical trial, Clinical trial data change of jurisdiction.<br>It was check of a monitoring report, direct inspection implementation record, and CRF as Project Leader.<br>Experience correspondence on the advance preparations corresponding to PMDA conformity investigation. |

## 09/2008 - 07/2009 CMIC Group

| | | | |
|---|---|---|---|
| **Position:** | Team Leader | **Type of work:** | CRA |
| **Number of sites in charge:** | 0 | | |
| **Drug Classification:** | Blood and humoral Drug | | |
| **Study Type:** | Phase.Ⅲ | | |
| **Target disease:** | Chronic-renal-failure patient | | |
| **Miscellaneous:** | Chronic-renal-failure patient (preservation term) phaseⅢ.<br><br><Monitoring Visit,SDV,Close-out Visit><br>Whole country: Generalization of Tokyo base:31 among 80 sites (the number of cases: 220 examples) institution (the number of cases: 115 examples), and project leader support as Subproject Leader. | | |

## 09/2007 - 08/2008 CMIC Group

| | | | |
|---|---|---|---|
| **Position:** | Team Leader | **Type of work:** | CRA |
| **Number of sites in charge:** | 0 | | |
| **Drug Classification:** | Blood and humoral Drug | | |
| **Study Type:** | Phase.Ⅲ | | |
| **Target disease:** | Chronic-renal-failure patient | | |
| **Miscellaneous:** | Chronic-renal-failure patient (preservation term) phaseⅢ.<br><br><Site Initiation Visit,Monitoring Visit,SDV,Close-out Visit><br>Whole country: Support a project leader among 30 institutions (the number of cases: 115 examples) as a subproject leader of institution:27 assigned to our company institution (the number of cases: 100 examples).<br>Experience correspondence on the advance preparations corresponding to PMDA conformity investigation. | | |

## 12/2006 - 08/2007 CMIC Group

| | | | |
|---|---|---|---|
| **Position:** | CRA | **Type of work:** | CRA |
| **Number of sites in charge:** | 3 | | |
| **Drug Classification:** | Blood and humoral Drug | | |
| **Study Type:** | Phase.Ⅲ | | |
| **Target disease:** | Chronic-renal-failure patient | | |
| **Miscellaneous:** | Chronic-renal-failure patient (preservation term) phaseⅢ.<br><br><Site Selection,Site Initiation Visit,Monitoring Visit,SDV,Close-out Visit><br>In charge of the 3 institutions (Monitor)<br>The number of the cases in its duty:12 Examples | | |

## 09/2005 - 11/2006 CMIC Group

| | | | |
|---|---|---|---|
| **Position:** | CRA | **Type of work:** | CRA |
| **Number of sites in charge:** | 2 | | |
| **Drug Classification:** | Blood and humoral Drug | | |
| **Study Type:** | Phase. Ⅲ | | |
| **Target disease:** | Chronic-renal-failure patient | | |
| **Miscellaneous:** | Chronic-renal-failure patient (peritoneal dialysis) phase Ⅲ.<br><br><Site Selection,Site Initiation Visit,Monitoring Visit,SDV,Close-out Visit><br>In charge of the 2 institutions (Monitor)<br>The number of the cases in its duty:11 Examples | | |

## 01/2004 - 01/2005 CMIC Group

| | | | |
|---|---|---|---|
| **Position:** | CRA | **Type of work:** | CRA |
| **Number of sites in charge:** | 3 | | |
| **Drug Classification:** | Blood and humoral Drug | | |
| **Study Type:** | Phase. Ⅱ | | |
| **Target disease:** | Chronic-renal-failure patient | | |
| **Miscellaneous:** | Chronic-renal-failure patient (preservation term) phase Ⅱ.<br><br><Site Selection,Site Initiation Visit,Monitoring Visit,SDV,Close-out Visit><br>In charge of the 3 institutions (Monitor)<br>The number of the cases in its duty:8 Examples | | |

## 10/2003 - 08/2005 CMIC Group

| | | | |
|---|---|---|---|
| **Position:** | CRA | **Type of work:** | CRA |
| **Number of sites in charge:** | 3 | | |
| **Drug Classification:** | Blood and humoral Drug | | |
| **Study Type:** | Phase. Ⅲ | | |
| **Target disease:** | Chronic-renal-failure patient | | |
| **Miscellaneous:** | Chronic-renal-failure patient (preservation term) phase Ⅲ.<br><br><Site Selection,Site Initiation Visit,Monitoring Visit,SDV,Close-out Visit><br>In charge of the 3 institutions (Monitor)<br>The number of the cases in its duty:8 Examples<br><br>10/2003-12/2003 Introductory Training for CRA<br>Monitor introduction training and In-company monitor authorization qualification acquisition. | | |

## 04/1998 - 09/2003 Teikoku Hormone Mfg.co,Ltd

| | | | |
|---|---|---|---|
| **Position:** | Team Member | **Type of work:** | MR |
| **Number of sites in charge:** | | | |
| **Drug Classification:** | Antiulcer drug,Prostate-cancer-treatment agent ,Hormone tablet | | |
| **Study Type:** | | | |
| **Target disease:** | | | |
| **Miscellaneous:** | April,1998<br>Teikoku Hormone Mfg.Co,Ltd.<br>Entrance newcomer introduction training<br><br>June,1998<br>Medicine operating headquarters(Chiba Saitama branch) | | |

The Saitama office was assigned.

October,1998
It was the Saitama Minami western part as MR.
(Wako, Asaka, Niiza, Fujimi, Kami-Fukuoka)
It took charge of a hospital (seven hospitals) and a medical practitioner.

April,2001
It moved to the 2nd team of the Saitama office.
It took charge of the eastern Saitama(Iwatsuki, Kasukabe, Sugito-cho, Kuki, Satte, Kazo, Gyoda) hospital (eight hospitals), the Hasuda hospital, and a medical practitioner.

September,2003
Teikoku Hormone Mfg.Co,Ltd.
I left a company.

## Education

04/1994 - 03/1998 **Tokyo University of Pharmacy and Life Sciences**

## Language (English)

**Level:** Entry

Date : 28 - Jan - 2014

Signature : Hiroyuki Inagaki

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