



## PMI RESEARCH & DEVELOPMENT

### **Study ZRHR-REXC-03-EU**

### **Clinical Study Report Appendix 16.1.4**

### **List of Investigators and Other Important Participants,**

### **Descriptions of Qualifications and Research Facilities**

<b>Study Title:</b>	A randomized, controlled, open-label, 3-arm parallel group, single-center study to demonstrate reductions in exposure to selected smoke constituents in smoking, healthy subjects switching to the Tobacco Heating System 2.2 (THS 2.2) or smoking abstinence, compared to continuing to use conventional cigarettes, for 5 days in confinement
<b>Study Number:</b>	ZRHR-REXC-03-EU
<b>Product Name:</b>	Tobacco Heating System 2.2 (THS 2.2)
<b>Study Initiated (first subject screened):</b>	29 June 2013
<b>Study Completed (last subject last visit):</b>	26 September 2013
<b>Principal Investigator and Affiliation:</b>	Katarzyna Jarus-Dziedzic, MD, PhD BioVirtus Research Site Sp. z o.o., Mokra 7 05-830 Kajetany, Poland
<b>Sponsor:</b>	Philip Morris Products S.A. PMI Research & Development Quai Jeanrenaud 5 2000 Neuchâtel, Switzerland
<b>Sponsor Signatories:</b>	Christelle Haziza, PhD, Manager P1 Clinical Program, Clinical Scientist Andrea Donelli, Clinical Scientist Guillaume de La Bourdonnaye, MEng, MSc, Biostatistician Kausar Aamir, MD, PhD, Medical Safety Officer
<b>Version:</b>	2.0
<b>Date:</b>	08 March 2016

This study was conducted in accordance with Good Clinical Practice.

#### **Confidentiality Statement**

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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
BioVirtus Research Site Sp. z o.o., Mokra 7 05-830 Kajetany, Poland	This is a Clinical Research Facility.	BIO



#### **16.1.4.1.2 CV of Personnel of Site 1**

The Principal Investigator for this study was Katarzyna Jarus-Dziedzic, MD, PhD.

The Sub-Investigators for this study were:

Oleg Tkhorivskyi, MD

Joanna Domagala-Kulawik, MD, PhD, Prof.

Anna Wyzgal, MD, PhD

Krzysztof Mozol, PhD

Anna Grazyna Stepinska, MD

Tomasz Ciacka, MD, PhD

Ewa Jakubowska, MD, PhD

Dariusz Dziedzic, MD, PhD

Monika Franczuk, MD, PhD





## Statement of Qualifications/Abbreviated CV of Investigator

Name (First Name Last Name and Academic Qualification(s))

Katarzyna Jarus-Dziedzic MD, PhD

Address (Name of Institution, Street, City, State, Postal Code, Country)

BioVirtus Research Site Sp. z o.o.,  
ul. Mokra 7,  
05-830 Kajetany, Poland

## Education and Training (From baccalaureate through postdoctoral/fellowship training)

Name of Institution and Location	Degree and Year Conferred	Area of Study
Instytut Medycyny Doswiadczalnej i Klinicznej Polskiej Akademii Nauk, ul. Pawlinskiego 5, 02-106 Warsaw, Poland	II Degree Specialization in Neurosurgery and Neurotraumatology	2000 Neurosurgery and Neurotraumatology
Uniwersytet Medyczny we Wroclawiu, ul. Pasteura 1, 50 – 367 Wroclaw, Poland	PhD	1998 Neurosurgery and Neurotraumatology
Uniwersytet Medyczny we Wroclawiu, ul. Pasteura 1, 50 – 367 Wroclaw, Poland	I Degree Specialization in Neurosurgery and Neurotraumatology	1997 Neurosurgery and Neurotraumatology
Uniwersytet Medyczny we Wroclawiu, ul. Pasteura 1, 50 – 367 Wroclaw, Poland	MD	1993

## Certification/Medical Licensure/License/Approval to conduct Clinical Research (If applicable)

Type/State	Year Issued	Number
Medical Licence	1993	1712347

## Professional Experience (Current and Previous Positions)

Position	Institution/Employer and Location	Dates of Employment
President / Medical and Scientific Director / Investigator	BioVirtus Research Site Sp. z o.o., Mokra 7, 05-830 Kajetany, Poland	From: 2013 To: present
President / Medical and Scientific Director / Investigator	Clinical Research Group Sp. z o.o. ul. Opaczewska 48 lok 18, 02-201 Warsaw, Poland	From: 2012 To: present
Medical Director	MTZ Clinical Research Sp. z o.o., ul. Pawlinskiego 5, 02-106 Warsaw, Poland	From: 2003 To: 2012
Neurologist / Neurosurgeon	Szpital Bielanski, ul. Ceglowska 80, 01-809 Warsaw, Poland	From: 2001 To: present
Doctor	Szpital Sw. Anny, ul. Barska 16/20, 02-106 Warsaw, Poland	From: 1998 To: 2001
Associate Professor	Instytut Medycyny Doswiadczalnej, ul. Pawlinskiego 5, 02-106 Warsaw, Poland	From: 1998 To: present
Associate Professor	Uniwersytet Medyczny we Wroclawiu, ul. Pasteura 1, 50-367 Wroclaw, Poland	From: 1994 To: 1998


## Relevant Clinical Trial Experience (or GCP training)

Bioavailability and Bioequivalence - Analgesic, Antipyretic, Antilanginal, Antihypertensive, Antihistaminic, Antiosteoporotic, Anianorectic, Antiviral, Antipsychotic, Antidepressant, Antibiotic, Statins, Antiepileptic, Anti diabetic, Antivertigo, Antivaricose, topical corticosteroids. - 45 studies, Oncology, Haematology, Cardiology, Dermatology, Gynaecology, Special population of subjects- Phase I / II - 32 studies, Phase III - 17 studies, Medical experiments- 4 studies, Dermocosmetics

Other- 10 studies



## Statement of Qualifications/Abbreviated CV of Investigator

I hereby certify that this document is an accurate representation of my qualifications.	For translation of non-English CV, please complete below. I hereby certify to the best of my knowledge that the English text of this document represents an accurate translation of the original CV provided.
	Translator Name
Investigator Signature	Translator Signature
25.06.2013	Date
Date	

Clinical Site Specialized in Bioequivalence, Early Phases  
and Special Populations Clinical Trials

### Curriculum Vitae

First Name	Last Name	Title
Oleg	Tkhorivskyi	MD

Professional licence
2604880

Study Site Address
BioVirtus Research Site Sp. z o.o., Mokra 7, 05-830 Kajetany near Warsaw

Current appointment/s			
Name and location of Institution	Position	From	To
BioVirtus Research Site Sp. z o.o., Mokra 7, 05-830 Kajetany near Warsaw	Investigator	2013	Present
Prof. SPSK them. A. Gruca, Department of Orthopaedic Surgery, Center of Postgraduate Education, ul. Konarski 13, Otwock	Resident Doctor	2011	Present

Previous appointments			
Name and location of Institution	Position	From	To
MTZ Clinical Research Sp. z o.o., Pawinskię 5, 02-106 Warsaw, Poland	Sub-Investigator	2012	213
SPCSK, Banacha 1a, 02-097 Warsaw, Poland	Trainee Doctor	2010	2011
Regional hospital of Ivano-Frankivsk, Fedkovycha 91, Ivano-Frankivsk, Ukraine	Neurosurgeon Doctor	2006	2010
Medical University of Ivano-Frankivsk, Galycka 2, Ivano-Frankivsk, Ukraine	Assistant professor in orthopedical department	2005	2007



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and Special Populations Clinical Trials

Education		
Name and location of Institution	Degree, specialization, board certification, licence	Date obtained
Donecky Medical University, Ukraine	Doctor Neurosurgeon	2006
Ivano-Frankivsk Medical Academy, ul. Galycka 2, Ivano-Frankivsk, Ukraine Doctor Orthopedist 2005	Doctor Orthopedist	2005
Medical University of Ivano-Frankivsk, Galycka 2, Ivano-Frankivsk, Ukraine	MD	2003

Trainings (selected)		
Subject	Name of Institution and location	Date
GCP	MTZ Clinical Research Sp. z o.o.	2012
New techniques to stabilize the spine	Spine surgery Polish company	2010
Surgery of the skull and spine	Neurosurgery Institute, Kiev, Ukraine	2010
VI International Symposium on Spine	Surgery Institute Sytenko, Kharkov, Ukraine	2008
V International Symposium on Spine	Surgery Institute Sytenko, Kharkov, Ukraine	2007

Main areas of professional Interests	
<ul style="list-style-type: none"><li>• New technology in spine surgery,</li><li>• Patofiziologia spinal cord injuries,</li><li>• Spinal shock,</li><li>• Mechanisms of vascular ischemia of the spinal cord,</li><li>• Cranio-cervical stabilization.</li></ul>	

Professional experience in clinical research		
Therapeutic area /Indication	Responsibilities	Phase
Antineoplastic	Investigator	Bioequivalence - 2 studies



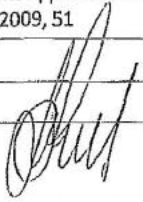


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and Special Populations Clinical Trials

Drugs used to treat dermatology Blood and blood forming organs Antineoplastic	Investigator	Phase I - 2 studies Phase III - 2 studies
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**Publications**

1. Potapov A, Tkhorivskiy O, Balan S, Kostytski M, Fedak V.  
Epidural adhesiolysis in lumbar pain syndroms. 4-th neurosurgery conference,  
Dnipropetrovsk, 2008.
2. Sulyma V, Kostytski M, Balan S, Tkhorivskiy O.  
Such factors influencing the choice of surgical treatment in lumbar pain syndroms.  
Orthopedi, thraumatology, prot, 2005, N4, 32-35
3. Sulyma V, Balan S, Tkhorivskiy O.  
Some aspects of microsurgical decompression of the vertebral canal with complicated  
lumbar spine osteochondrosis. Clinical anatomy and surgery, Vol 4, N4, 2005, 24-26
4. Tkhorivskiy O, Balan S, Potapov A.  
Long-term results application of epidural adhesiolysis in lumbar pain syndroms,  
Neurosurgery, 2009, 51

Signature	Date
	22.01.2015



Ośrodek badań klinicznych biorównoważności,  
faz wczesnych oraz badań ze specjalnymi populacjami pacjentów

## Curriculum Vitae

First Name	Last Name	Title
Joanna	Domagała-Kulawik	MD, PhD, Prof.

Professional licence
5710003

Study Site Address
Clinical Research Group Sp. z o.o., ul. Opaczewska 43/18, 02-201 Warsaw, Poland

Current appointment/s			
Name and location of Institution	Position	From	To
Clinical Research Group Sp. z o.o., Ul. Opaczewska 43/18, 02-201 Warsaw, Poland	Investigator/ Pulmonologist	2012	Present
BioVirtus Research Site Sp. z o.o., ul. Mokra 7, 05-830 Kajetany, Poland	Investigator/ Pulmonologist	2013	Present
MTZ Clinical Research Sp. z o.o. Ul. Pawinskiego 5, 01-102 Warsaw, Poland	Investigator/ Pulmonologist	2011	Present
Medical Academy of Warsaw, Department and Clinic of Internal Diseases, Pneumology and Allergology, Warsaw, Poland	Associate Professor	1998	Present

Previous appointments			
Name and location of Institution	Position	From	To
Independent Public Central Clinical Hospital Clinic of Pneumology, Warsaw	Pulmonologist	1983	1996
Clinic of Vascular Diseases and Hypertension , Independent Public Central Clinical Hospital, Warsaw	Pulmonologist	1981	1982
Department of Pathology, Institute of Oncology, Warsaw	Pulmonologist	1979	1981





Ośrodek badań klinicznych biorównoważności,  
faz wczesnych oraz badań ze specjalnymi populacjami pacjentów

Academic Qualifications		
<i>Name and location of Institution</i>	<i>Degree, specialization, board certification, licence</i>	<i>Date obtained</i>
Medical University of Warsaw, Poland	Professor	2013
Medical Exams Center, Łódź, Poland	Specialization (1 <sup>st</sup> degree) in lungs diseases	2012
Medical Academy of Warsaw, Poland	Assistant Professor	2004
Medical Academy of Warsaw, Poland	PhD	1996
CMKP in Warsaw, Poland	Specialization (2 <sup>nd</sup> degree) in patomorphology	1994
WZIOS in Warsaw, Poland	Specialization (1 <sup>st</sup> degree) in patomorphology	1989
CMKP in Warsaw, Poland	Specialization (2 <sup>nd</sup> degree) in internal diseases	1987
WZIOS in Warsaw, Poland	Specialization (1 <sup>st</sup> degree) in internal diseases	1982
1 <sup>st</sup> Faculty of Medicine, Medical Academy of Warsaw, Poland	MD	1979

Trainings		
<i>Subject</i>	<i>Name of Institution and location</i>	<i>Date</i>
Good Clinical Practice	MTZ Clinical Research Sp. z o.o. Pawlińskiego 5, 01-102 Warsaw	2012

Professional experience in clinical research		
<i>Therapeutic area /indication</i>	<i>Responsibilities</i>	<i>Phase</i>
Asthma treatment	Principal Investigator	Phase II (2 studies)
Tobacco products	Pulmonologist/Spirometry assessment	Medical Experiment



Ośrodek badań klinicznych biorównoważności,  
faz wczesnych oraz badań ze specjalnymi populacjami pacjentów

#### Publications

1. Clinical manifestation and radiological features of small cell lung cancer (SCLC).  
Sudul T, Domagała-Kulawik J.  
Wiad Lek. 2012;65(2):97-101. Polish.
2. Endotoxin markers in bronchoalveolar lavage fluid of patients with interstitial lung diseases.  
Szponar B, Larsson L, Domagała-Kulawik J.  
Multidiscip Respir Med. 2012 Dec 22;7(1):54. doi: 10.1186/2049-6958-7-54.
3. [Lung cancer. In 100 years of monograph by Issak Adler].  
Domagała-Kulawik J.  
Pneumonol Alergol Pol. 2012;80(6):581-2. Polish.
4. Systemic inflammation in peripheral arterial disease with or without coexistent chronic obstructive pulmonary disease: analysis of selected markers.  
Wozniak K, Sleszycka J, Saffanowska A, Wiechno W, Domagała-Kulawik J.  
Arch Med Sci. 2012 Jul 4;8(3):477-83. doi: 10.5114/aoms.2012.29403.
5. Th1/Th2/Th17-related cytokines in the bronchoalveolar lavage fluid of patients with sarcoidosis: association with smoking.  
Urbankowski T, Hoser G, Domagała-Kulawik J.  
Pol Arch Med Wewn. 2012;122(7-8):320-5.
6. [Sarcoidosis and tobacco smoking--clinical picture, diagnostic tests results and bronchoalveolar lavage fluid composition].  
Urbankowski T, Knyziak-Medrzycka I, Domagała-Kulawik J, Chazan R.  
Pol Merkur Lekarski. 2012 May;32(191):298-301. Polish.
7. [Factors influencing asthma course and the degree of control in the patients assessed with own questionnaire and Asthma Control Test (ACT)].  
Krasnodębska P, Hermanowicz-Salamon J, Domagała-Kulawik J, Chazan R.  
Pneumonol Alergol Pol. 2012;80(3):198-208. Polish.
8. [Highlights from the ERS Congress in Amsterdam, 24-28 September, 2011].  
Domagała-Kulawik J, Korzeniewska-Kosela M, Maskey-Warzęchowska M, Sobiecka M.  
Pneumonol Alergol Pol. 2012;80(2):178-85. Polish. No abstract available.



Ośrodek badań klinicznych biorównoważności,  
faz wczesnych oraz badań ze specjalnymi populacjami pacjentów

9. IL-6 and IL-13 in induced sputum of COPD and asthma patients: correlation with respiratory tests. Grubek-Jaworska H, Paplińska M, Hermanowicz-Salamon J, Białek-Gosk K, Dąbrowska M, Grabczak E, Domagała-Kulawik J, Stepien J, Chazan R. Respiration. 2012;84(2):101-7. doi: 10.1159/000334900. Epub 2012 Feb 3.
10. [Mediastinal neuroendocrine tumor (atypical carcinoid probably of thymic origin) imitating teratoma--case report]. Zielińska-Krawczyk M, Domagała-Kulawik J, Chazan R. Pol Merkur Lekarski. 2011 Nov;31(185):280-3. Polish.
11. [Asthma as a psychosomatic disease. The causes, scale of the problem, connection with alexithymia and asthma control]. Moes-Wójtowicz A, Wójtowicz P, Postek M, Domagała-Kulawik J. Pneumonol Alergol Pol. 2012;80(1):13-9. Polish.
12. Bronchoalveolar lavage total cell count in interstitial lung diseases--does it matter? Domagała-Kulawik J, Skirecki T, Maskey-Warzechowska M, Grubek-Jaworska H, Chazan R. Inflammation. 2012 Jun;35(3):803-9. doi: 10.1007/s10753-011-9378-5.
13. [Fifth Polish-French Pneumonological Conference, Cracow, 8-9 October 2010]. Domagała-Kulawik J. Pneumonol Alergol Pol. 2011;79(4):315-6. Polish. No abstract available.
14. [Highlights from the ERS Congress in Barcelona, 18-22 September, 2010 (Part 1)]. Chorostowska-Wynimko J, Domagała-Kulawik J, Fijałkowska A, Koseła MK, Kuca P, Radzikowska E, Szturmowicz M. Pneumonol Alergol Pol. 2011;79(2):151-64. Polish. No abstract available.
15. [Recommendation of the Polish Respiratory Society for bronchoalveolar lavage (BAL) sampling, processing and analysis methods]. Chciałowski A, Chorostowska-Wynimko J, Fał A, Pawłowicz R, Domagała-Kulawik J. Pneumonol Alergol Pol. 2011;79(2):75-89. Polish. No abstract available.
16. CD4+/CD25+ cells in systemic inflammation in COPD. Domagała-Kulawik J, Hoser G, Dąbrowska M, Safianowska A, Chazan R. Scand J Immunol. 2011 Jan;73(1):59-65. doi: 10.1111/j.1365-3083.2010.02474.x.
17. [Seventh Polish Scientific Session of Students' Scientific Association of the Medical University of





Ośrodek badań klinicznych biorównoważności,  
faz wczesnych oraz badań ze specjalnymi populacjami pacjentów

Warsaw "problems of prevention lung diseases" Warsaw, March 20(th) 2010].

Leszczyk M, Miłkowska P, Domagała-Kulawik J.

Pneumonol Alergol Pol. 2010;78(4):310-4. Polish. No abstract available.

18. [Sarcoidal reaction in lung adenocarcinoma in 50-years old man].

Stepień J, Domagała-Kulawik J, Chadzyński R, Kupis W, Chazan R.

Pneumonol Alergol Pol. 2010;78(4):302-5. Polish.

19. Relationship between airway inflammation and remodeling in patients with asthma and chronic obstructive pulmonary disease.

Górska K, Krenke R, Kosciuch J, Korczynski P, Zukowska M, Domagała-Kulawik J, Maskey-Warzechowska M, Chazan R.

Eur J Med Res. 2009 Dec 7;14 Suppl 4:90-6.

20. The value of cytological diagnosis of small cell lung carcinoma.

Domagała-Kulawik J, Górnicka B, Krenke R, Mich S, Chazan R.

Pneumonol Alergol Pol. 2010;78(3):203-10.

21. [Exposure to passive smoking among current smokers and non-smokers].

Chadzyński R, Woźniak K, Nowogórska A, Domagała-Kulawik J.

Pneumonol Alergol Pol. 2009;77(5):440-5. Polish.

22. [Prevalence and difficulties in chronic obstructive pulmonary disease diagnosis in patients suffering from severe peripheral arterial disease].

Sleszycka J, Woźniak K, Banaszek M, Wiechno W, Domagała-Kulawik J.

Pol Merkur Lekarski. 2009 Aug;27(158):92-6. Polish.

23. T-regulatory cells in COPD or tumour environment.

Domagała-Kulawik J, Maskey-Warzechowska M.

Eur Respir J. 2009 Jul;34(1):284; author reply 285-6. doi: 10.1183/09031936.00025609. No abstract available.

24. [Third Polish-French pneumonological conference, Warsaw, 24-25 October 2008. Abstracts].

Domagała-Kulawik J, Zielonka TM.

Pneumonol Alergol Pol. 2009;77(2):211-20. Polish. No abstract available.

25. Characterization of a new small cell lung cancer (SCLC) cell line STP54 derived from a metastatic bioplate of a combined type of SCLC with Non-SCLC component.



Ośrodek badań klinicznych biorównoważności,  
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- Skirecki T, Hoser G, Domagała-Kulawik J, Kawiak J.  
Folia Histochem Cytobiol. 2009;47(1):111-5. doi: 10.2478/v10042-009-0018-y.
26. Simplified method of dynamic contrast-enhanced computed tomography in the evaluation of indeterminate pulmonary nodules.  
Dabrowska M, Zukowska M, Krenke R, Domagała-Kulawik J, Maskey-Warzechowska M, Bogdan J, Pachon R, Chazan R.  
Respiration. 2010;79(2):91-6. doi: 10.1159/000213760. Epub 2009 Apr 17.
27. Diagnosis and management of premature ventricular complexes-associated chronic cough.  
Stec SM, Grabczak EM, Bielicki P, Zaborska B, Krenke R, Kryński T, Dabrowska M, Domagała-Kulawik J, Domeracka-Kolodziej A, Sikorska A, Kulakowski P, Chazan R.  
Chest. 2009 Jun;135(6):1535-41. doi: 10.1378/chest.08-1814. Epub 2009 Mar 24.
28. [Analysis of solitary pulmonary nodules found in chest radiographs].  
Dabrowska M, Kolasa A, Zukowska M, Lesiński J, Domagała-Kulawik J, Maskey-Warzechowska M, Krenke R, Rowiński O, Chazan R.  
Pneumonol Alergol Pol. 2009;77(1):37-42. Polish.
29. Does the established cause of chronic cough depend on diagnostic approach?  
Grabczak EM, Dabrowska M, Krenke R, Domeracka-Kolodziej A, Domagała-Kulawik J, Arcimowicz M, Hamera M, Chazan R.  
J Physiol Pharmacol. 2008 Dec;59 Suppl 6:285-96.
30. Comparison of cellular and biochemical markers of airway inflammation in patients with mild-to-moderate asthma and chronic obstructive pulmonary disease: an induced sputum and bronchoalveolar lavage fluid study.  
Gorska K, Krenke R, Domagała-Kulawik J, Korczynski P, Nejman-Gryz P, Kosciuch J, Hildebrand K, Chazan R.  
J Physiol Pharmacol. 2008 Dec;59 Suppl 6:271-83.
31. Eosinophilic airway inflammation in chronic obstructive pulmonary disease and asthma.  
Gorska K, Krenke R, Korczynski P, Kosciuch J, Domagała-Kulawik J, Chazan R.  
J Physiol Pharmacol. 2008 Dec;59 Suppl 6:261-70.
32. Role of bronchoalveolar lavage in the initial diagnosis of smoking-related interstitial lung diseases.  
Domagała-Kulawik J, Maskey-Warzechowska M, Krenke R, Chazan R.



Ośrodek badań klinicznych biorównoważności,  
faz wczesnych oraz badań ze specjalnymi populacjami pacjentów

J Physiol Pharmacol. 2008 Dec;59 Suppl 6:243-51.

33. Effects of cigarette smoke on the lung and systemic immunity.

Domagała-Kulawik J.

J Physiol Pharmacol. 2008 Dec;59 Suppl 6:19-34. Review.

34. [Evaluation of the indication of carbon monoxide in exhaled air].

Woźniak K, Moes A, Chadzyński R, Domagała-Kulawik J.

Przegl Lek. 2009;66(10):632-5. Polish.

35. [Methodology of induced sputum induction and processing—recommendation of Polish Respiratory Society].

Chmielowicz B, Obojski A, Barczyk A, Sozańska E, Kycler Z, Demkow U, Domagała-Kulawik J; Polskie Towarzystwo Chorób Płuc.

Pneumonol Alergol Pol. 2008;76(5):378-94. Polish. No abstract available.

36. BAL in the diagnosis of smoking-related interstitial lung diseases: review of literature and analysis of our experience.

Domagała-Kulawik J.

Diagn Cytopathol. 2008 Dec;36(12):909-15. doi: 10.1002/dc.20944. Review.

37. [The relationship between markers of airway inflammation and thickness of the basement membrane in patients with asthma].

Górska K, Krenke R, Kościuch J, Przybyłowski T, Domagała-Kulawik J, Hildebrand K, Baran W, Kujawa M, Chazan R.

Pneumonol Alergol Pol. 2007;75(4):363-9. Polish.

38. [Difficulties in the interpretation BALF and induced sputum cell smears].

Domagała-Kulawik J.

Pneumonol Alergol Pol. 2007;75(3):261-7. Review. Polish.

39. [The frequency of allergy in lung cancer patients].

Tolak K, Omernik A, Zdan O, Ragus D, Domagała-Kulawik J, Rudziński P, Chazan R.

Pneumonol Alergol Pol. 2006;74(2):144-8. Polish.

40. [Breast carcinoma and anaplastic gastric carcinoma with pleural metastases in patient after mastectomy 30 years ago].

Kościuch J, Zielenka TM, Ziółkowski B, Domagała-Kulawik J, Bogacka-Zatorska E, Chazan R.





Ośrodek badań klinicznych biorównoważności,  
faz wczesnych oraz badań ze specjalnymi populacjami pacjentów

Pneumonol Alergol Pol. 2006;74(1):129-31. Polish.

41. [Diagnosis of tuberculous lymphadenitis based on the fine needle aspiration samples analysis].  
Fangrat A, Domagała-Kulawik J, Krenke R, Safianowska A, Walkiewicz R, Chazan R.  
Pneumonol Alergol Pol. 2006;74(1):126-8. Polish.

42. [Macrophage phenotype in induced sputum in asthma subjects].  
Hermanowicz-Salamon J, Domagała-Kulawik J, Maskey-Warzechowska M, Chazan R.  
Pneumonol Alergol Pol. 2006;74(1):101-5. Polish.

43. [The role of fiberoptic bronchoscopy in the diagnostic algorithm of solitary pulmonary nodule].  
Dąbrowska M, Krenke R, Domagała-Kulawik J, Zukowska M, Górnicka B, Bogdan J, Chazan R.  
Pneumonol Alergol Pol. 2006;74(1):16-20. Polish.

44. [Adenosine deaminase activity in tuberculous and malignant pleural effusions].  
Safianowska A, Krenke R, Dmowska-Sobstyl B, Bogacka-Zatorska E, Domagała-Kulawik J, Chazan R.  
Pneumonol Alergol Pol. 2006;74(1):5-9. Polish.

45. Increased proportion of Fas positive CD8+ cells in peripheral blood of patients with COPD.  
Domagała-Kulawik J, Hoser G, Dąbrowska M, Chazan R.  
Respir Med. 2007 Jun;101(6):1338-43. Epub 2006 Nov 21.

46. Expression of macrophage surface markers in induced sputum of patients with chronic obstructive pulmonary disease.  
Domagała-Kulawik J, Maskey-Warzechowska M, Hermanowicz-Salamon J, Chazan R.  
J Physiol Pharmacol. 2006 Sep;57 Suppl 4:75-84.

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Domagała-Kulawik J, Hoser G, Safianowska A, Grubek-Jaworska H, Chazan R.  
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Ośrodek badań klinicznych biorównoważności,  
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Ośrodek badań klinicznych biorównoważności,  
faz wczesnych oraz badań ze specjalnymi populacjami pacjentów

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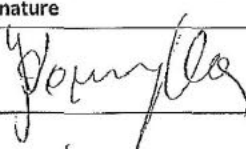
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Signature	Date
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Clinical Site Specialized in Bioequivalence, Early Phases  
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### Curriculum Vitae

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Current appointment/s			
Name and location of Institution	Position	From	To
BioVirtus Research Site Sp. z o.o., ul. Mokra 7, 05-830 Kajetany, Poland	Investigator	2013	Present
Teaching Hospital Dzieciatka Jezus, ul. Lindleya 4, 02-005 Warsaw, Poland	Resident	2010	Present

Previous appointments			
Name and location of Institution	Position	From	To
Independent Public Central Teaching Hospital, ul. Banacha 1a, 02-097 Warsaw, Poland	Intern	2009	2010
Independent Public Health Care, Dziadowo, Poland	Trainee	2007	2009

Education		
Name and location of Institution	Degree, specialization, board certification, licence	Date obtained
Medical University in Warsaw, Poland	Ph. D.	In course
Medical University in Warsaw, Poland	MD	2009





Clinical Site Specialized in Bioequivalence, Early Phases  
and Special Populations Clinical Trials

Trainings (selected)		
Subject	Name of Institution and location	Date
Good Clinical Practice	BioVirtus Research Site Sp. z o.o., ul. Mokra 7, 05-830 Kajetany, Warsaw	2013

Professional experience in clinical research
Participated in numerous clinical studies in the field of cardiology in the daily work of the hospital.

Publications
<ol style="list-style-type: none"><li>1. Admission ST elevation in lead aVR as the factor improving complex risk stratification Przegląd Lekarski 2007/64/suplement 1, s.41</li><li>2. The clinical implications and prognostic value of paced rhythm in ECG on admission in patients with ACS - Przegląd Lekarski 2008/65 /suplement 1</li><li>3. EKG characteristics of stent' restenosis following primary angioplasty procedure- Kardioprofil - vol.6/ Nr 2(23)/2008</li><li>4. Use of the EKG in risk assessment of patients with pulmonary embolism, Przegląd Lekarski 2008/65/suplement 1</li><li>5. Occurrence of metabolic syndrome components in population of patients with cardiovascular diseases - Polski Przegląd Kardiologiczny suplement 1/08, s. 24</li><li>6. The frequency of non-diagnosed chronic kidney disease in patients with cardiovascular diseases Polski Przegląd Kardiologiczny suplement 1/08, s. 45</li><li>7. Risk of incidence of obstructive sleep apnea syndrome among patients with cardiovascular diseases - Archives of Medical Science 2009,suppl.2</li><li>8. Availability of public automatic external defibrillators in Warsaw as of 09.05,2009- Kardiologia Polska 2010 Jan;68(1):41-6 and abstract Availability of public automatic external defibrillators in Warsaw as of 09.05,2009 – Polski Przegląd Kardiologiczny, s. 4</li><li>9. Szymański F.M., Karpiński G., Grabowski M., Roik M., Wyzgał A., Hryniewicz A., Filipiak K.J. Elektrokardiograficzne cechy restenoz w stencie u pacjentów po zabiegu pierwotnej angioplastyki, Kardioprofil - vol.6/ Nr 2(23)/2008 s.137-142</li><li>10. Cacko A., Wyzgał A., Galas A., Grabowski M., Filipiak K.J., Opolski G.: Availability of automed external defibrillators in the city of Warsaw – status for May 2009 , Kardiologia Polska Styczeń 2010, tom 68, numer 1, s. 41- 7</li><li>11. Wyzgał A., Hryniewicz-Szymańska A., Grabowski M. Zagadnienia ogólne dotyczące układu sercowo-naczyniowego, czyli co pacjent powinien wiedzieć o: chorobach układu sercowo- naczyniowego? Vademecum pacjenta – choroby układu sercowo-naczyniowego. Strona 15- 19. Via Medica. Gdańsk 2009 ISBN 9788375551563</li><li>12. Irmela T, Wyzgał A, Grabowski M. Czynniki ryzyka chorób układu sercowo-naczyniowego, czyli co pacjent powinien wiedzieć o: wpływie hormonalnej terapii zastępczej na układ sercowo-naczyniowy? Vademecum pacjenta – choroby układu sercowo-naczyniowego.</li></ol>



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- Strona 139-142. Via Medica. Gdańsk 2009 ISBN 9788375551563
13. Wyzgał A, Imiela T, Grabowski M. Choroby układu sercowo-naczyniowego, czyli co pacjent powinien wiedzieć o zwężeniu tętnic nerkowych? Vademecum pacjenta – choroby układu sercowo-naczyniowego. Strona 221-224. Via Medica. Gdańsk 2009 ISBN 9788375551563
  14. Imiela T, Wyzgał A, Grabowski M. Zagadnienia ogólne dotyczące układu sercowo-naczyniowego, czyli co pacjent powinien wiedzieć o: wpływie hemodializ na układ sercowo-naczyniowy? Vademecum pacjenta – choroby układu sercowo-naczyniowego. Strona 49-54. Via Medica. Gdańsk 2009 ISBN 9788375551563
  15. D. Korczak, A. Wyzgał Epidemiology of Thromboembolism Venous Thromboembolism edited by P. Pruszczyk, M. Ciurzyński, M. Kostrubiec Medical Tribune 2012
  16. D. Korczak, A. Wyzgał Risk factor of thromboembolism Venous Thromboembolism edited by P. Pruszczyk, M. Ciurzyński, M. Kostrubiec Medical Tribune 2012 Szymański FM, Cacko A, Leszczyk M, Wyzgał A, Hryniewicz-Szymańska A, Grabowski M. Przewlekłe leczenie farmakologiczne po STEMI – leczenie przeciwplatek/przeciwkrzepiwe. Ostre zespoły wieńcowe z uniesieniem odcinka ST. Od badań klinicznych do wytycznych. Strona 170-181. Via Medica. Gdańsk 2009 ISBN 9788375990829
  17. Wyzgał A, Hryniewicz-Szymańska A, Szymański FM, Leszczyk M, Cacko A, Grabowski M. Zachowania prozdrowotne. Ostre zespoły wieńcowe z uniesieniem odcinka ST. Od badań klinicznych do wytycznych. Strona 203-212. Via Medica. Gdańsk 2009 ISBN 9788375990829
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  20. Wyzgał A. Ocena czynników ryzyka przed przeszczepieniem nerki a częstość zdarzeń sercowo-naczyniowych i zgonu po zabiegu Przegląd Doniesień Naukowych Polskiego Towarzystwa Kardiologicznego [www.ptkardio.pl](http://www.ptkardio.pl)
  21. Wyzgał A. Wpływ objętości kontrastu zastosowanego podczas pierwotnej przeszłkowej angioplastyki wieńcowej na występowanie nefropatii pokontrastowej i jej powikłań Przegląd Doniesień Naukowych Polskiego Towarzystwa Kardiologicznego [www.ptkardio.pl](http://www.ptkardio.pl)
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### Curriculum Vitae

First Name	Last Name	Title
Krzysztof	Mozol	Ph. D.

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Current appointment/s			
Name and location of Institution	Position	From	To
BioVirtus Research Site Sp. z o.o., Mokra 7, 05-830 Kajetany, Poland	Investigator	2013	Present
MTZ Clinical Research Sp. z o.o., Pawlińskiego 5, 02-106 Warsaw, Poland	Investigator	2009	Present
Institute „Pomnik - Centrum Zdrowia Dziecka”, al. Dzieci Polskich 20, 04-730 Warsaw, Poland	Senior Assistant	1999	Present

Previous appointments			
Name and location of Institution	Position	From	To
Cardiff and Wales NHS Trust, University Hospital of Wales, Heath Park, CF14 4XW, Great Britain	Senior Assistant	2008	2009
Swansea NHS Trust, Morriston Hospital, Heol Maes Eglwys, Swansea, SA6 6NL, Great Britain	Assistant	2007	2007
Great Ormond Street Hospital for Children NHS Trust, Great Ormond Street, London WC1N 3JH, Great Britain	Assistant	2005	2005
Bieleński Hospital, Ceglowska 80, 01-809 Warsaw, Poland	Junior Assistant	1992	2008

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Education		
<i>Name and location of Institution</i>	<i>Degree, specialization, board certification, licence</i>	<i>Date obtained</i>
Institute „Pomnik - Centrum Zdrowia Dziecka”, al. Dzieci Polskich 20, 04-730 Warsaw, Poland	Specialization in cardiac surgery	2011
Institute „Pomnik - Centrum Zdrowia Dziecka”, al. Dzieci Polskich 20, 04-730 Warsaw, Poland	Ph. D.	2004
Bielanski Hospital, Ceglowska 80, 01-809 Warsaw, Poland	Specialization (2 <sup>nd</sup> degree) in pediatric surgery	2002
Pomorska Medical Academy, Rybacka 1, 70-204 Szczecin, Poland	MD	1991

Trainings (selected)		
<i>Subject</i>	<i>Name of Institution and location</i>	<i>Date</i>
Good Clinical Practice	MTZ Clinical Research Sp. z o.o., Warsaw, Poland	2012
Treatment of congenital heart defects in newborns	Institute „Pomnik - Centrum Zdrowia Dziecka”, al. Dzieci Polskich 20, 04-730 Warsaw, Poland	2011
Thoracic organ transplantation and treatment of acute heart failure	Jagiellonian University - Medical College, Department of Cardiovascular Surgery and Transplantology, Cracow	2011
Preparation, storage and implantation of heart valve allogennych	Jagiellonian University - Medical College, Department of Cardiovascular Surgery and Transplantology, Cracow	2011
Surgical treatment of thoracic aortic aneurysms	Jagiellonian University - Medical College, Department of Cardiovascular Surgery and Transplantology, Cracow	2011
Corrective Actions of heart valves	Silesian Medical University, II Department of Cardiac Surgery	2011
Minimally invasive techniques in the treatment of ischemic heart disease	Silesian Medical University, II Department of Cardiac Surgery	2011
Treatment of congenital heart defects	Medical Centre of Postgraduate Education	2011
Thoracic organ transplantation and	Jagiellonian University - Medical College, Department of Cardiovascular Surgery	2011



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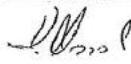
- The Fibrolan<sup>®</sup> ointment in burn wound treatment in children. Bydgoskie Zeszyty Lekarskie. 1996; 11: 30-35.
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  6. Mozol K, Szafrński T.  
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  8. Mossakowska B, Mozol K.  
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  15. Maruszewski B, Kansy A, Burczyński P, McKay R., Pastuszko A, Tysarowski P, Birbach M, Mozol K, Mirkowicz-Malek M, Brzezińska-Rajszyś G, Kościeszka A, Kawalec W, Manowska M.





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- Extracardiac total cavopulmonary connection (ETCPC) as the method of choice for the final palliation in children with functionally single ventricle *Cardiol. Young* 2001 Vol. 11 suppl. 1 s. 142
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18. Burczyński P, Mozol K, Markowicz-Malek M, Kansy A, Maruszewski B.  
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Differences in ECMO uses in treatment of respiratory failure and postoperative circulation support. *Standardy Medyczne* 2007; 4(5): 636-40.
21. Mozol K, Haponiuk I, Mirkowicz-Malek M, Maruszewski B.  
Systemic Inflammatory Response Syndrome following open heart surgery in children. *Standardy Medyczne* 2007, 5(1): 37-41
22. Mozol K, Byszewski A, Burczyński P, Haponiuk I, Mirkowicz-Malek M, Maruszewski M.  
Blood saving technique in small infants undergoing open heart surgery. *Standardy Medyczne* 2008; 5: 209-16
23. Mozol K, Haponiuk I, Kansy A, Maruszewski B, Byszewski A.  
Economic Evaluation of Mini-circuit Uses in Infants Undergoing Open Heart Surgery. *Kardiol.Pol.* 2008; 66 (9): 925-930
24. Mozol K, Haponiuk I, Burczyński P, Kansy A, Birbach M, Łaniewski-Wołk P, Byszewski A, Maruszewski B.  
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25. Mozol K, Burczyński P, Haponiuk I. *Kardiol. Pol.* 2011;69(10):1066-8.  
Late right pulmonary artery stenosis after arterial switch operation in mirror image dextrocardia and situs inversus totalis.

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	25.06.2013



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Clinical Site Specialized in Bioequivalence, Early Phases  
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Current appointment/s			
Name and location of Institution	Position	From	To
BioVirtus Research Site Sp. z o.o., Mokra 7, 05-830 Kajetany, Poland	Investigator	2013	Present
Bielanski Hospital, Department of Neurosurgery, Ceglowska 80, 01-809 Warsaw, Poland	Neuro-Anesthetist	2002	Present

Previous appointments			
Name and location of Institution	Position	From	To
MTZ Clinical Research Sp. z o.o., Pawinskiego 5, 02-106 Warsaw, Poland	Investigator	2005	2011
Department of Neurosurgery, Institute of Experimental and Clinical Medicine, Polish Academy of Sciences, Pawinskiego 5, 02-106 Warsaw, Poland	Senior Assistant	1975	2002

G.S



Clinical Site Specialized in Bioequivalence, Early Phases  
and Special Populations Clinical Trials

Education		
<i>Name and location of Institution</i>	<i>Degree, specialization, board certification, licence</i>	<i>Date obtained</i>
Neurology Clinic, Uppsali, Sweden	Scholarship of Royal Swedish Academy	1986
Department of Neurosurgery, Institute of Experimental and Clinical Medicine, Polish Academy of Sciences, Pawlinskiego 5, 02-106 Warsaw, Poland	Specialization (2 <sup>nd</sup> degree) in Anaesthesiology	1981
Hospital of Saint Anna, Barska 16/20, Department of Internal Diseases, 02-315 Warsaw, Poland	Specialization (1 <sup>st</sup> degree) in Internal Diseases	1975
Medical Academy, Żwirki i Wigury 61, 02-091 Warsaw, Poland	MD	1971

Trainings (selected)		
<i>Subject</i>	<i>Name of Institution and location</i>	<i>Date</i>
Good Clinical Practice	MTZ Clinical Research Sp. z o.o., Warsaw, Poland	2011
Post diploma training	Hospital of Saint Anna, Barska 16/20, Department of Internal Diseases, 02-315 Warsaw, Poland	1972

Professional experience in clinical research		
<i>Therapeutic area /Indication</i>	<i>Responsibilities</i>	<i>Phase</i>
Anticancer drugs Respiratory system Nervous system Cardiovascular system Alimentary tract and metabolism Antiinfectives for systemic use Anti-inflammatory drugs	Investigator	Bioequivalence - 17 studies
Nervous system Dermatology Musculo-skeletal system AntiInfectives for systemic use	Investigator	Phase I – 6 studies

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## Publikacje

1. Czernicki Z, Berdya J, Stepinska G, Jurkiewicz J.  
Evaluation of craniospinal system condition using standardized volume-pressure loadings.  
Acta Neurochir (Wien). 1995;133(3-4):191-4
2. Stepinska G, Czernicki Z, Berdya J, Jurkiewicz J.  
Evaluation of craniospinal system condition using standardized volume-pressure loadings.  
Acta Neurochir (Wien). 1995;133(3-4):191-4.
3. Czernicki Z, Tomita H, Ito U, Jurkiewicz J, Stepinska G, Walecki J  
[Application of transcranial Doppler ultrasonography in the assessment of cerebrovascular reactivity studies and cerebral vascular reserve estimation in patients with focal brain injury]  
Neurol Neurochir Pol. 1994 May-Jun;28(3):351-61. Polish.
4. Czernicki Z, Berdya J, Stepinska G, Pawlowski G, Grochowski W, Jurkiewicz J  
[Application of physiological loadings in evaluation of intracranial volume-pressure relations. II. Clinical studies]  
Neurol Neurochir Pol. 1994 Jan-Feb;28(1):43-7. Polish.
5. Stepinska G, Czernicki Z, Berdya J, Jurkiewicz J  
[Diagnosis of brain stem ischemia by transcranial Doppler ultrasonography]  
Neurol Neurochir Pol. 1994 Jan-Feb;28(1):57-63. Polish.
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[Application of physiological data in evaluation of the intracranial volume-pressure interaction.  
An experimental study.]  
Neurol Neurochir Pol. 1992 Sep-Oct;26(5):677-83. Polish.
7. Tychmanowicz K, Czernicki Z, Pawlowski G, Stepinska G  
[Relation between resorption resistance of cerebrospinal fluid and the degree of intracranial pressure]  
Pol Tyg Lek. 1992 Apr 6-13;47(14-15):314-6. Polish.
8. Tychmanowicz K, Czernicki Z, Pawlowski G, Stepinska G.  
ICP dependent changes of CSF outflow resistance.  
Acta Neurochir (Wien). 1992;117(1-2):44-7.
9. Stepinska G, Czernicki Z, Berdya J  
[Evaluation of the usefulness of cerebral perfusion pressure in threatened cerebral ischemia]  
Neurol Neurochir Pol. 1992;Suppl 1:243-50. Polish.
10. Czernicki Z, Stepinska G  
[Circulatory and respiratory disorders caused by increased intracranial pressure]

G.S.



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and Special Populations Clinical Trials

Neurol Neurochir Pol. 1987 Jul-Aug;21(4-5):384-9. Polish.

11. Kwiatkowski A, Stepinska G, Czernicki Z

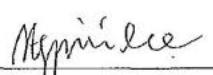
[Fatal reactions following blood transfusions]

Pol Tyg Lek. 1978 May 8;33(19):777-8. Polish. No abstract available.

12. Czernicki Z, Jurkiewicz J, Stepinska G, Kwiatkowski A

[Concentration of lactates, sodium and potassium in brain tissue obtained during  
neurosurgery]

Neurol Neurochir Pol. 1977 Nov-Dec;11(6):683-7. Polish.

Signature	Date
	28.06.2013



Clinical Site Specialized in Bioequivalence, Early Phases  
and Special Populations Clinical Trials

### Curriculum Vitae

First Name	Last Name	Title
Tomasz	Clątka	MD, PhD

**Professional licence**

8715516

**Study Site Address**

BioVirtus Research Site Sp. z o.o., Mokra 7, 05-830 Kajetany near Warsaw

**Current appointment/s**

Name and location of Institution	Position	From	To
BioVirtus Research Site Sp. z o.o., Mokra 7, 05-830 Kajetany near Warsaw	Investigator	2013	Present
Department of General, Vascular, and Transplantant Surgery, Medical University of Warsaw, Banacha 1A, 02-097 Warsaw, Poland	Clinical Associate	2001	Present

**Previous appointments**

Name and location of Institution	Position	From	To
MTZ Clinical Research Sp. z o. o., Pawlinskiego 5, 02- 106 Warsaw, Poland	investigator	2007	2012
Emergency Department City of Warsaw, Poland	Senior Assistant	1999	2006

**Education**

Name and location of Institution	Degree, specialization, board certification, licence	Date obtained
Department of General, Vascular and Transplantation, Medical University of Warsaw, ul. Banach 1A, 02-097 Warsaw	II degree of specialization in general surgery	2007





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Department of General, Vascular, and Transplantant Surgery, Medical University of Warsaw, Banacha 1A, 02-097 Warsaw, Poland	PhD	2007
Department of General, Vascular and Transplantation, Medical University of Warsaw, ul. Banach 1A, 02-097 Warsaw	I degree of specialization in general surgery in 2001	2001
Medical Academy of Bialystok, Jana Kilinskiego 1, 15-089 Bialystok, Poland	MD	1998

Trainings (selected)		
Subject	Name of Institution and location	Date
GCP	MTZ Clinical Research Sp. z o.o., Warszawa	2012
Emergency Procedure	MTZ Clinical Research Sp. z o.o., Warszawa	2011

Professional experience in clinical research		
Therapeutic area /Indication	Responsibilities	Phase

Publications
Conference abstracts and proceedings (40) published in English periodicals and in Polish-language periodicals.

Signature	Date
	27. Jan 2013



Ośrodek badań klinicznych biorównoważności,  
faz wczesnych oraz badań ze specjalnymi populacjami pacjentów

### Curriculum Vitae

First Name	Last Name	Title
Ewa	Jakubowska	MD, PhD

**Professional licence**

1620872

**Study Site Address**

Biovirtus Research Site Sp. z o.o., ul. Mokra 7, 05-830 Kajetany, Poland

**Current appointment/s**

<i>Name and location of Institution</i>	<i>Position</i>	<i>From</i>	<i>To</i>
BioVirtus Research Site Sp. z o.o., ul. Mokra 7, 05-830 Kajetany, Poland	Cardiologist	2013	Present
Center of Cardiology Anin ul. Płowiecka 37, 04-501 Warsaw, Poland	Cardiologist	2007	Present
Private medical practice ul. Pereca 2 lok. 228, 00-849 Warsaw, Poland	Cardiologist - Physician	1997	Present

**Previous appointments**

<i>Name and location of Institution</i>	<i>Position</i>	<i>From</i>	<i>To</i>
MTZ Clinical Research Sp. z o.o., ul. Pawińskiego 5, 02-106 Warsaw, Poland	Consulting cardiologist	2006	2010
Private Health Care-Publishing House „Adam” ul. Rolna 103, Warsaw, Poland	Cardiologist	2005	2007
Institute of Cardiology ul. Alpejska 42, 04-682 Warsaw, Poland	Clinical Associate	1985	2005
Clinical Department of Health Care Hospital for Colleges in Warsaw, Poland	Physician	1982	1985



Ośrodek badań klinicznych biorównoważności,  
faz wczesnych oraz badań ze specjalnymi populacjami pacjentów

Academic Qualifications		
Name and location of Institution	Degree, specialization, board certification, licence	Date obtained
Institute of Cardiology ul. Alpejska 42, 04-682 Warsaw, Poland	PhD	2005
Institute of Cardiology ul. Alpejska 42, 04-682 Warsaw, Poland	Specialization (2 <sup>nd</sup> degree) in cardiology	1999
Center of Postgraduate Medical Education, ul. Marymoncka 99-103, Warsaw, Poland	Specialization (2 <sup>nd</sup> degree) in internal diseases	1993
WZIOS, Warsaw, Poland	Specialization (1 <sup>st</sup> degree) in internal diseases	1986
Medical Academy of Warsaw, Warsaw, Poland	M.D.	1982

Trainings		
Subject	Name of Institution and location	Date
Good Clinical Practice	BioVirtus Research Site Sp. z o.o., ul. Mokra 7, 05-830 Kajetany, Poland	2013

Professional experience in clinical research
Sub-investigator in numerous bioequivalency and Phase I studies.

Publications
1. Lipka R, Jakubowska E. Simultaneous determination of ethylenediamine-N,N,N',N'-tetrakis(methylene phosphonate) and ascorbic acid in "cold" radiopharmaceutical kit. Acta Pol Pharm. 2008 Sep-Oct;65(5):507-13.
2. Jakubowska E, Ryba M, Hruby Z. Sub-investigator in numerous bioequivalency and Phase I studies. Fabry disease. Przegl Lek. 2006;63(4):218-9.
3. Prochorec-Sobieszek M, Billińska ZT, Grzybowski J, Michałak E, Jakubowska E, Sobieszkańska-Małek M, Deptuch T, Walczak E, Wagner T, Walski M, Różański J, Kiedrowski

Ośrodek badań klinicznych biorównoważności,  
faz wczesnych oraz badań ze specjalnymi populacjami pacjentów

M, Lubiszewska B, Hoffman P, Różyło W.

Cardiac amyloidosis diagnosed by endomyocardial biopsy. Clinical, histopathological, immunohistochemical and ultrastructural studies.

Kardiologia. 2005 Jul;63(7):20-35.

4. Kowalik E, Jakubowska E, Hoffman P.

[Congenitally corrected transposition of the great arteries in a 72 year old man--a case report].

Kardiologia. 2004 Jul;61(7):56-8.

5. Hoffman P, Wójcik AW, Różański J, Siudańska H, Jakubowska E, Włodarska EK, Kowalski M.

The role of echocardiography in diagnosing double chambered right ventricle in adults.

Heart. 2004 Jul;90(7):789-93.

6. Tucholska-Lenart A, Wujec J, Samborski J, Jakubowska E.

Allele frequencies for 10 STR loci in a population from central Poland.

Forensic Sci Int. 2002 Sep 26;129(2):131-3.

7. Kowalski M, Hoffman P, Siudańska H, Jakubowska E, Rydlewska-Sadowska W.

Clinical and echocardiographic assessment of a right-to-left shunt across an atrial septal defect secondary to tricuspid regurgitation.

Acta Cardiol. 2001 Aug;56(4):233-7.

Signature	<i>Ewa Jakubowska</i>	Date	<i>25.07.2013</i>





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### Curriculum Vitae

First Name	Last Name	Title
Dariusz	Dziedzic	MD, PhD

Professional licence
5738366

Study Site Address
BioVirtus Research Site Sp. z o.o., Mokra 7, 05-830 Kajetany near Warsaw

Current appointment/s			
Name and location of Institution	Position	From	To
BioVirtus Research Site Sp. z o.o., Mokra 7, 05-830 Kajetany near Warsaw	Investigator	2013	Present
Department of Endoscopy, Department of Surgery, National Tuberculosis and Lung Diseases Research Institute, Plocka 26, 01-138 Warsaw, Poland	Head of Department	2000	Present
Department of Surgery, National Tuberculosis and Lung Diseases Research Institute, Plocka 26, 01-138 Warsaw, Poland	Associate Professor	1997	Present

Previous appointments			
Name and location of Institution	Position	From	To
MTZ Clinical Research Sp. z o.o., Pawinskiego 5, 02-106 Warsaw, Poland	Investigator	2003	2011
Department of Thoracic Surgery Medical Academy in Wroclaw, Grabiszynska 105, 53-430 Wroclaw, Poland	Clinical Assistant	1994	1997
Centre of Research of Tuberculosis and Chest Diseases in Wroclaw, Grabiszynska 105, 53-439 Wroclaw Poland	Intern	1993	1994

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Education		
<i>Name and location of Institution</i>	<i>Degree, specialization, board certification, licence</i>	<i>Date obtained</i>
European Board of Thoracic Surgery, Great Britain	European Specialisation in General Thoracic Surgery	2003
Department of Surgery, National Research Institute of Tuberculosis and Chest Diseases, Warsaw, Poland	Specialization (2 <sup>nd</sup> degree) in Thoracic Surgery	2001
Department of General Surgery, University Hospital in Cologne, Germany	DAAD scholarship	2000
Department of Thoracic Surgery Medical Academy in Wroclaw, Grabiszynska 105, 53-430 Wroclaw, Poland	PhD	1998
Department of Thoracic Surgery Medical Academy in Wroclaw, Poland	Specialization (1 <sup>st</sup> degree) in Surgery	1997
Medical Academy of Wroclaw, W.Pasteura 1, 50-367 Wroclaw, Poland	MD	1993

Trainings (selected)		
<i>Subject</i>	<i>Name of Institution and location</i>	<i>Date</i>
GCP	MTZ Clinical Research Sp. z o.o., Pawinskiego 5, 02-106 Warsaw, Poland	2011
Importance of data quality in clinical studies	Consent Clinical Consulting	2006
Service Type Mr ECG. Blue	Medical Center ASPEL	2006
Statistical analysis in clinical studies cz.I	Medical Statistics Department, National Institute of Hygiene	2003
Training in General Surgery General Surgery Japan	Toranomon Hospital, Tokyo, Japan	1997
Training in General Surgery General Surgery	Knappschafts Krankenhaus, Bochum, Germany	1994



Clinical Site Specialized in Bioequivalence, Early Phases  
and Special Populations Clinical Trials

**Main areas of professional interests**

- New method of diagnosis and surgery treatment of emphysema and lung cancer.
- Interventional bronchoscopy in thoracic diseases
- Bronchoscopic diagnosis and assessment of efficacy of treatment in patient with pulmonary diseases
- Endoscopical screening of the early lung cancer in the special group (f.e. heavy smokers)
- Diagnosis and surgery treatment of emphysema.
- Qualification to lung volume reduction surgery in patients with severe emphysema
- Qualification to lung transplantation.
- Evaluation spirometry of heavy smokers.
- Screens of neoplastic markers in sputum of smokers.
- New surgical technique of lung cancer operations.
- Medical writing (study documentation preparation),
- Study literature search

**Professional experience in clinical research**

<i>Therapeutic area /Indication</i>	<i>Responsibilities</i>	<i>Phase</i>
The central nervous system Cardio vascular respiratory Antineoplastic Urinary system and sex hormones Alimentary tract and metabolism Drugs used to treat Musculo - Skeletal Anti-inflammatory drugs	Investigator	Bioequivalence - 21 studies
The central nervous system dermatology Musculo - Skeletal	Investigator	Phase I - 4 studies



Clinical Site Specialized in Bioequivalence, Early Phases  
and Special Populations Clinical Trials

#### Publications

1. Prokopowicz J., Nowicka L., Guz K., Orlowski T.M., Dziedzic D.: *Perioperative management of a post heart transplantation patient with renal failure qualified to lung resection*. Medical Science Monitoring, 2000,6(1),137-140
2. Dziedzic D., Orlowski T.M., Jakimiuk R.: *Experimental study of the effects of different stapling devices in healing of the mechanically sutured bronchial stump*. Eur.J.Cardio Thorac.Surg. 2000,17,111-116
3. Prokopowicz J., Nowicka L., Guz K., Orlowski T.M., Dziedzic D.: *Perioperative management of a post heart transplantation patient with renal failure qualified to lung resection*. Med Sci Monit. 2000 Jan-Feb;6(1):137-40.
4. Jarus-Dziedzic K., Zub W., Dziedzic D., Jelen M., Krotochwil J., Mierzejewski M.: *Multiple metastases of carcinoma basocellulare into spinal column*. J Neurooncol. 2000 May;48(1):57-62.
5. Dziedzic D., Orlowski T.M., Jakimiuk R.: *Experimental study of the effects of different stapling devices in healing of the mechanically sutured bronchial stump*. Eur J Cardiothorac Surg. 2000 Feb;17(2):111-6.
6. Orlowski T.M., Dudek K., Dziedzic D.: *Endoscopic management of Zencker's diverticulum*. Abstract 13, 3<sup>th</sup> Conference On General Thoracic Surgery, Lausanne, 1995.
7. Orlowski T.M., Gietkiewicz K., Dziedzic D.: *Bronchial carcinoid tumours*. Abstract 143, 3<sup>th</sup> Conference On General Thoracic Surgery, Lausanne, 1995.
8. Jakimiuk W., Orlowski T.M., Marciniak M., Dziedzic D., Chabowski M.: *Tracheal resection of recurrent stenosis-experimental study*. Abstract 7, 5<sup>th</sup> Conference On General Thoracic Surgery, Wrocław, 1995.
9. Orlowski T.M., Kornaszewska M., Dudek K., Dziedzic D., Marciniak M.: *Stenting of the tracheobronchial tree*. Abstract 76, 5<sup>th</sup>

Signature	Date
	28.06.2013





Ośrodek badań klinicznych biorównoważności,  
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### Curriculum Vitae

First Name	Last Name	Title
Monika	Franczuk	MD, PhD

Professional licence
1190935

Study Site Address
BioVirtus Research Site Sp. z o.o., 05-830 Kajetany, Poland

Current appointment/s				
Name and location of Institution	Position		From	To
BioVirtus Research Site Sp. z o.o., ul. Mokra 7, 05-830 Kajetany, Poland	Investigator		2013	Present
Instytut Gruźlicy i Chorob Płuc, ul. Płocka 26, 01-138 Warsaw, Poland	Senior Lecturer		2003	Present

Previous appointments				
Name and location of Institution	Position		From	To
Instytut Gruźlicy i Chorob Płuc, ul. Płocka 26, 01-138 Warsaw, Poland	Research Assistant		2001	2003
Instytut Gruźlicy i Chorob Płuc, ul. Płocka 26, 01-138 Warsaw, Poland	Junior Assistant		1998	2001

#### Academic Qualifications

Name and location of Institution	Degree, specialization, board certification, licence	Date obtained
Instytut Gruźlicy i Chorob Płuc, ul. Płocka 26, 01-138 Warsaw, Poland	Specialization 2 <sup>nd</sup> Degree in Pneumology	2003
Instytut Gruźlicy i Chorob Płuc,	PhD	2001

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www.biovirtus.eu

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Regon: 146421910  
KRS: 0000447730  
Kapitał zakładowy: 100.000 PLN



Ośrodek badań klinicznych biorównoważności,  
faz wczesnych oraz badań ze specjalnymi populacjami pacjentów

ul. Płocka 26, 01-138 Warsaw, Poland		
Instytut Gruzlicy i Chorob Płuc, ul. Płocka 26, 01-138 Warsaw, Poland	Specialization 1 <sup>st</sup> Degree in Internal Medicine	1998
Centralny Szpital Kliniczny WAM Ul. Szaserów 128	Postgraduate training	1994
Akademia Medyczna, ul. Zwirki i Wigury 61, Warsaw, Poland	MD	1993

#### Trainings

Subject	Name of Institution and location	Date
NA		

#### Professional experience in clinical research

Therapeutic area /Indication	Responsibilities	Phase
SM patients	Co-investigator	Phase III, 2008
Asthma patients	Co-investigator	Phase II, 2008
COPD patients	Co-investigator	Phase III, 2007
COPD patients	Co-investigator	Phases III, 2006-2007
COPD patients	Co-investigator	Phases III, 2004-2005

#### Publication

1. Interstitial lung disease in patients with primary biliary cirrhosis Bartosiewicz M, Stępnion-Szcześniak I, Jędrzych M, Radwan-Röhrenscheff P, Lewandowska K, Langfort R, Oniszh K, Franczuk M, Kuś J. *Pneumonol Alergol Pol.* 2012;80(5):471-81. Polish.
2. Recognition of exercise-induced bronchoconstriction: a task for a medal Franczuk M. *Pneumonol Alergol Pol.* 2011;79(6):379-81. Review. Polish. No abstract available.
3. Abnormalities in high-resolution computed tomography of the lungs in patients with idiopathic pulmonary arterial hypertension -- correlation with hemodynamic parameters and prognostic significance. Kacprzak A, Szturmowicz M, Burakowska B, Fijałkowska A, Kurzyna M, Wieteska M, Florczyk M, Zylkowska J, Franczuk M, Wesołowski S, Torbicki A. *Pneumonol Alergol Pol.* 2009;77(1):23-30. Polish.
4. Odpowiedzi oddechowe na stymulację CO<sub>2</sub> u chorych na obturacyjny bezdech senny z

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ul. Mokra 7, 05-830 Kajetany  
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NIP: 534-248-96-62  
Regon: 146421910  
KRS: 0000447730  
Kapitał zakładowy: 100.000 PLN



Ośrodek badań klinicznych biorównoważności,  
faz wczesnych oraz badań ze specjalnymi populacjami pacjentów

przewlekła hiperkapnia. Franczuk, Monika; Radwan, Leszek; Piwaczewski, Robert; et al. *Pneumonologia i Alergologia Polska* Volume: 74 Issue: 4 Pages: 383-90 Published: 2006

5. Value of spirometry in detecting volume restriction in interstitial lung disease patients - Spirometry in interstitial lung diseases Boros, PW; Franczuk, M; Wesolowski, S, *RESPIRATION* Volume: 71 Issue: 4 Pages: 374-379 2004

6. Zmiany "mieszane" - weryfikacja rozpoznania typu zaburzeń wentylacyjnych. Boros, Piotr; Franczuk, Monika; Wesolowski, Stefan; *Pneumonologia i Alergologia Polska* Volume: 71 Issue: 11-12 Pages: 527-32 Published: 2003

7. Strategia GOLD, wczesne wykrywanie pocho, a potrzeba "złotego" standardu spirometrii. Wesolowski, Stefan; Boros, Piotr; Franczuk, Monika, *Pneumonologia i Alergologia Polska* Volume: 70 Issue: 9-10 Pages: 439-43 Published: 2002

8. Respiratory responses to chemical stimulation in patients with obstructive sleep apnoea. Radwan, L; Maszczyk, Z; Koziej, M; et al.; *Monaldi archives for chest* Volume: 55 Issue: 2 Pages: 96-100 Published: 2000-Apr

9. Odpowiedź oddechowa na zmianę oporu wdechowego u chorych na obturacyjny bezdech senny. Radwan, L; Koziorowski, A; Maszczyk, Z; et al. *Pneumonologia i alergologia polska* Volume: 68 Issue: 1-2 Pages: 44-56 Published: 2000

10. Zmienność okołodobowa parametrów czynnościowych płuc u osób zdrowych. Franczuk, M; Kowalski, J; *Pneumonologia i alergologia polska* Volume: 65 Issue: 1-2 Pages: 96-103 Published: 1997

11. Zmienność okołodobowa czynności płuc w astmie oskrzelowej. Kowalski, J; Franczuk, M.; *Pneumonologia i alergologia polska* Volume: 65 Issue: 1-2 Pages: 104-12 Published: 1997

12. Chemiczna regulacja oddychania u chorych na obturacyjny bezdech senny. Radwan, L; Maszczyk, Z; Koziej, M; et al., *Pneumonologia i alergologia polska* Volume: 65 Issue: 7-8 Pages: 446-56 Published: 1997

13. Wzorzec oddychania i ciśnienie okluzji u chorych z obturacją dróg oddechowych po inhalacji leku rozszerzającego oskrzela. Franczuk, M; Radwan, L; Maszczyk, Z; et al., *Pneumonologia i alergologia polska* Volume: 65 Issue: 7-8 Pages: 457-64 Published: 1997

Signature	Date
	28.06.2013





## **16.1.4.2 SITE 2**

Not applicable.





### 16.1.4.3 CV OF KEY CRO STAFF

Project Manager	Alex Wilkinson, BSc
Medical Monitor	Katerina Bovtenko, MD MSc
Data Manager	Paul Hope, BSc
Pharmacokineticist	Stuart Hossack, BSc
Statistician	Andrew Hedge, BSc, MSc
Medical Writer	Andrew Senior, BSc, PhD



## ALEX WILKINSON

### Covance Clinical Development Services PROJECT MANAGER II, PROJECT INTEGRATION

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

#### Employment History

##### **COVANCE CLINICAL DEVELOPMENT SERVICES, LEEDS, UK – Jun. 2013 – Present** **PROJECT MANAGER II, PROJECT INTEGRATION – Jun. 2013 – Present**

- Primary client contact for all Covance CDARO departments; communication 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 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.

##### **QUEST DIAGNOSTICS, LONDON, UK – Apr. 2011 – Jun. 2013** **PROJECT MANAGER, CLINICAL TRIALS – Apr. 2011 – Jun. 2013**

- Primary point of contact for sponsor and other third party vendors with the overall management responsibility of the central laboratory component of clinical trials.
- Management of internal cross-functional teams, with regionally based project managers, associates and logistics
- Design and present central laboratory component training at investigator meetings and lead training seminars to ensure site adherence to the study.
- Tailor monitoring based on clients individual needs, protocol specific primary, secondary and safety end points.
- Program the clinical trial management system (CTMS), design and implement the data validation plan to verify the trial set up meets the project management plan requirements agreed by the sponsor.
- Liaise with CRO's and other third party vendors in study monitoring and data reconciliation activities to ensure data is delivered to meet study milestones.
- Study cost proposal & budget management.

**COVANCE**



Name: ALEX WILKINSON

**THE DOCTORS LABORATORY (SONIC HEALTHCARE), LONDON, UK – Nov. 2010 – Mar. 2011**

**MEDICAL LABORATORY ASSISTANT, SAMPLE RECEPTION – Nov. 2010 – Mar. 2011**

- Prepare and quality-check pathological specimens & documentation for PCR amplification for the analysis of Chlamydia and Gonorrhea.
- Perform subject and specimen demographic data capture into the LIMS software WinPath.

**THE DOCTORS LABORATORY (SONIC HEALTHCARE), LONDON, UK – Jan. 2007 – Jan. 2011**

**DEPUTY CLINICAL TRIALS MANAGER (PROJECT MANAGER), CLINICAL TRIALS – Jan. 2007 – Jan. 2011**

- Management of clinical study pathology, study specific training and logistics for clinical trials from Phase I-III level in an extremely busy department.
- Prepare, revise and execute client-vendor budgetary agreements and service agreements.
- Provide feedback on sales and feasibility to client RFTs & RFPs. Source & implement new assays internally & externally if required.
- Liaise with internal/external legal and QA, to analyze & identify key contractual provisions and issues.
- Evaluate and revise client drug trial pathology protocols for providing improved specimen collection and quality clinical data.
- Assist and lead Data Management and Medical Laboratory staff in study specific provisions.
- Program the clinical trial management system (CTMS) with study specific information.
- Assist in internal and external audits, client-vendor meetings, SOP creation and maintenance. Provide introductory tours of the analytical facilities to prospective and current clients.
- Design and presentation of technical guides, reference ranges and training for clinicians and clinical/medical laboratory staff.

**PAREXEL INTERNATIONAL, PHASE I CPRU, LONDON, UK – Aug. 2006 – Jan. 2007**

**RADIATION PROTECTION SUPERVISOR, CLINICAL TRIALS – Aug. 2006 – Jan. 2007**

- Supervise the use of radioactive isotopes in clinical and laboratory setting.
- Create, implement and maintain any standard operating procedures.
- Training and competency testing of staff.

**PAREXEL INTERNATIONAL, PHASE I CPRU, LONDON, UK – Jul. 2005 – Aug. 2006**

**MEDICAL LABORATORY ASSISTANCE, CLINICAL TRIALS – Jul. 2005 – Aug. 2006**

- Handling and processing of human specimen samples for drug development and safety analysis.

**Therapeutic Experience**

- **ONCOLOGY:** PITUITARY ADENOMA (CUSHINGS SYNDROME), ACROMEGALY, BASAL CELL CARCINOMA, MERKEL CELL CARCINOMA (I-III)
- **INFECTIOUS DISEASES:** HEPATITIS C AND HIV (II-III)
- **CARDIOVASCULAR:** HEART FAILURE (III)
- **NEUROMUSCULAR:** RELAPSING & REMITTANT MULTIPLE-SCLEROSIS (II-III)
- **NON-ACQUIRED AUTOIMMUNE DISEASES:** SYSTEMIC LUPUS ERYTHEMATOSUS
- **RESPIRATORY:** ASTHMA (II-III) & OBSERVATIONAL/EXPLORATORY INHALED ALLERGEN STUDIES
- **GENERAL MEDICINES:** HYPERTENSION, DIABETES & DEPRESSION (I-III)

**Language Capabilities**

- ENGLISH – MOTHER TONGUE



Name: ALEX WILKINSON

### Education

- BACHELOR of SCIENCE (HON'S) in BIOLOGY, BRUNEL UNIVERSITY, LONDON, UK
- 4 A LEVELS, POOLE GRAMMAR SCHOOL, POOLE, UK
- 1 AS LEVEL, POOLE GRAMMAR SCHOOL, POOLE, UK

### Memberships/Awards

- APMP PROJECT MANAGEMENT ACCREDITATION, ASSOCIATION FOR PROJECT MANAGEMENT, PRINCES RISBOROUGH, UK

### Other

- N/A

Employee Signature: Alex Wilkinson

Date: 26-SEP-2013





## Katerina Bovtenko, MD

### Covance Clinical Development Services

#### Medical Director

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

#### Employment History

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

**Medical Director – March 2013 – present**

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

**Associate Medical Director – Jun 2011 – Feb 2013**

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

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

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

**Senior Clinical Research Associate – Sep 2008 – May 2011**

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

**COVANCE**

**Katerina Bovtenko, MD**

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

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

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

**Co-Project Manager – Sep 2007 – Apr 2008**

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

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

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

**Clinical Research Associate – Dec 2003– Nov 2006**

- Site management and monitoring, audits



Katerina Bovtenko, MD

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

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

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

### Therapeutic Experience

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

### Language Capabilities

- English, French, Ukrainian and Russian

### Education

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

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

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

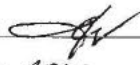
### Memberships/Awards

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

### Other

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

A list of abstracts and presentations is available upon request.

Employee Signature: 

Date: 1 Apr 2014

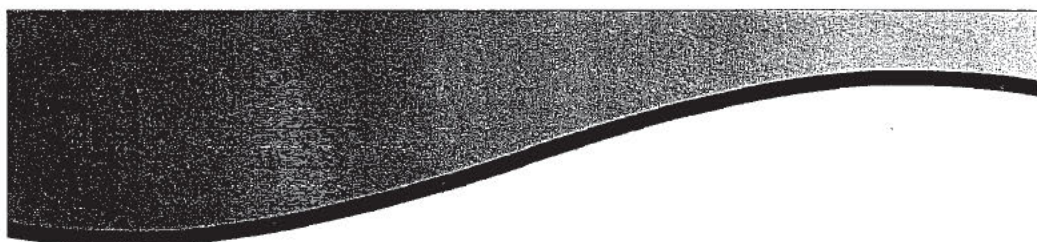


Katerina Bovienko, MD

## Appendix I

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





**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**



Name: PAUL HOPE

**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.



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**

- BACHELOR 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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## ANDREW HEDGE

### Covance Clinical Development Services PRINCIPAL STATISTICIAN

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

#### Employment History

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

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

##### BIostatistician III – Mar. 1997 – Mar. 2013

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

##### SENIOR STATISTICIAN – Mar. 1993 – Mar. 1997

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

##### STATISTICIAN – Mar. 1990 – Mar. 1993

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

##### TRAINEE STATISTICIAN – Aug. 1989 – Mar. 1990

- Produce randomizations
- Analysis of pre-clinical trial data

**COVANCE**



Name: ANDREW HEDGE

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

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

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

- Sell insurance to the general public

**Therapeutic Experience**

- N/A

**Language Capabilities**

- ENGLISH - MOTHER TONGUE

**Education**

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

**Memberships/Awards**

- STATISTICIANS IN THE PHARMACEUTICAL INDUSTRY (PSI)

**Other**

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

Employee Signature: Andrew Hedge

Date: 04 JUN 2014



Name: ANDREW HEDGE

## Appendix I

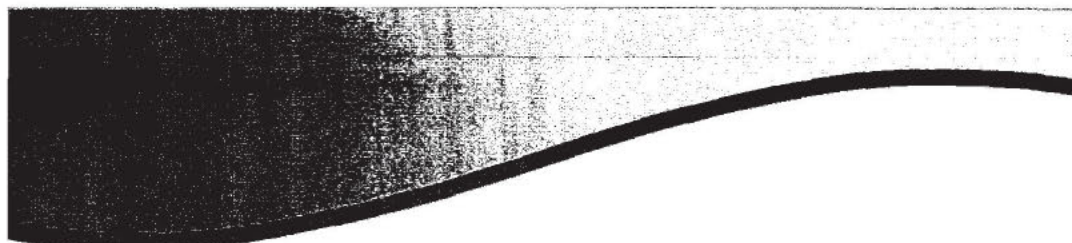
### Presentations/Teaching Courses

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

### Publications

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





**ANDREW SENIOR**  
**Covance Clinical Development Services**  
**MEDICAL WRITER II**

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

**Employment History**

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

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

**MEDICAL WRITER I – Mar 2010 – Jun 2012**

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

**PRISM IDEAS, CHESHIRE, UK – May 2009 – Feb 2010**

**MEDICAL WRITER – May 2009 – Feb 2010**

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

**COVANCE**



Name: ANDREW SENIOR

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

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

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

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

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

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

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

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

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

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



Name: ANDREW SENIOR

### Therapeutic Experience

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

### Language Capabilities

- ENGLISH – MOTHER TONGUE

### Education

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

### Memberships/Awards

- N/A

Employee Signature: A. Senior

Date: 11 April 2014

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



Name: ANDREW SENIOR

## Appendix I

MEDICAL WRITER OF THE FOLLOWING MANUSCRIPTS:

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