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"Very informative and well organised."

- GSK, event attendee, 2013

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SMi presents its 13th annual conference on...

Clinical Trials in CNS

Marriott Regents Park Hotel, London, UK

11 - 12
NOV
2014



Conference Chairs:

- **Richard Wyse**, Director of Research and Development, **The Cure Parkinson's Trust**
- **Craig Ritchie**, Clinical Senior Lecturer, **Imperial College London**

Key Speakers:

- **Tine Bryan Stensbøl**, Divisional Director Discovery Pharmacology Research, **Lundbeck**
- **Alan Palmer**, Co-Founder and Director, **MS Therapeutics**
- **Veronique Bragulat**, Clinical Imaging Manager, **GSK**
- **Sophie Dix**, Senior Research Scientist, Neurodegenerative Diseases Drug Hunting Team, **Eli Lilly**
- **David Willé**, Applied Statistician, **GSK**
- **Peter Joseph Jongen**, Founding Director, **MS4 Research Institute**
- **Ernst-Wilhelm Radue**, CEO, **MIAC AG**
- **Edwin Johnson**, Director, **Stockholm Brain Institute**
- **Shahid Zaman**, Affiliated Lecturer, **University of Cambridge**

...and many more!

Why Attend This Event:

- **Understand** the recent failures in CNS development and how translation did not work
- **Examine** the multi-stakeholder approach to self-management and multidisciplinary care in patients with MS
- **Discuss** the past, present and future of CNS medicines research
- **Analyse** novel biomarkers for the brain
- **Review** the collaboration between industry and academic partnering

PLUS AN INTERACTIVE HALF-DAY POST-CONFERENCE WORKSHOP

Thursday 13th November 2014, Marriott Regents Park Hotel, London

Clinical Trials in CNS: The role of academic institutions as CROs

Workshop Leader: **Professor Ernst-Wilhelm Radue**, CEO, **MIAC**

8.30am - 12.30pm

www.clinicaltrials CNS.com

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8.30 Registration & Coffee

9.00 Chairman's Opening Remarks

Richard Wyse, Director of Research and Development,
The Cure Parkinson's Trust

IMPROVING CLINICAL TRIAL OUTCOMES AND DESIGNS

9.10 Analysis of brain MRI for diagnosis of MS

- MRI features represents neuropathology
- Cerebral atrophy in MS
- Data flow and data transfer
- Quality control
- Making diagnosis clinic – MRI lesions

Ernst-Wilhelm Radue, CEO, **MIAC AG**

9.50 Analysis of recent failures in CNS drug development and how translation did not deliver

- Overview of the recent clinical trials in CNS
- Translational tools used
- Bridging the gap between pre-clinical and clinical CNS trials

Edwin Johnson, Director, **Stockholm Brain Institute**

10.30 Morning Coffee

11.00 The multi-stakeholder approach to self-management and multidisciplinary care in patients with MS

- The need to include all stakeholders in MS
- MSmonitor as a solution to professional care and self-management of MS
- Recent additions and development to the web-based program
- The opportunity to adapt the program to other neurodegenerative diseases?
- How has this interactive tool impacted on the patient

Peter Joseph Jongen, Founding Director, **MS4 Research Institute**

11.40 CNS medicines research: Past, present and future

- The history of CNS medicines R&D
- The CNS medicines landscape today
- The future of CNS pharmacotherapy

Alan Palmer, Co-Founder and Director, **MS Therapeutics**

12.20 Networking Lunch

1.30 Patient recruitment and retention issues in CNS clinical trials

- Patient population insights that need to be considered in designing recruitment and retention programs for CNS trials
- Retaining the enrolled patient throughout the trials
- Recruitment and retention issues in patients with neurodegenerative disorders

Speaker TBC

BIOMARKERS & CNS

2.10 The use of neuroimaging biomarkers in drug development

- Understanding the brain mechanism
- The role of CNS biomarkers
- Latest studies carried out and results

Mitul Mehta, Senior Lecturer, **King's College London**

2.50 Afternoon Tea

3.20 Imaging multicentre clinical trials: Challenges and best practice specific to CNS

- Overview of multicentre clinical trials in CNS
- Challenges of imaging in multicentre trials
- How to improve quality?
- How to implement new techniques?

Veronique Bragulat, Clinical Imaging Manager, **GSK**

4.00 Investigation of novel functional and metabolic MRI biomarkers for the preclinical assessment of tau pathology in AD

- Preclinical biomarkers of tau pathology in Alzheimer's disease
- Drug discovery
- Magnetic resonance imaging, metabolism and experimental therapeutics

Niall Colgan, Research Associate, **UCL Centre for Advanced Biomedical Imaging**

4.40 Chairman's Closing Remarks and Close of Day One

WHO SHOULD ATTEND THIS CONFERENCE:

You should attend this event if you are a Medical Director, Research Scientist, Fellow, Statistician, Senior Research Scientist, Director, Academic from within the Pharmaceutical or Healthcare industry with responsibilities in the following areas:

- CNS Clinical Discovery/Nervous System Research
- Clinical Trial Management and Operation
- CNS Therapeutics and Molecular Profiling
- Neurology/Neuroscience
- Pain Research/Management
- Biomarkers and Imaging
- Pre-Clinical/Clinical R&D
- Clinical Pharmacology
- Patient Recruitment
- Translational Medicine
- Biostatistics and Modelling
- Emerging Targets/Lead Optimisation
- Genomics/Bioinformatics/Neuroinformatics

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+44 20 7827 6134, or email:
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8.30 Registration & Coffee

9.00 Chairman's Opening Remarks
Craig Ritchie, Clinical Senior Lecturer, **Imperial College London**

LATEST DEVELOPMENTS AND STUDIES IN CNS RESEARCH

9.10 The NEWMEDS project: New frontiers in Schizophrenia research

- Achievement of a public private partnership
- Have we progressed our understanding of Schizophrenia in the last 5 years
- Novel animal models of schizophrenia
- Opportunities for the future: developing novel drugs for schizophrenia. Where do we stand?

Tine Bryan Stensbøl, Divisional Director Discovery Pharmacology Research, **Lundbeck**

9.50 Incentives for research: facilitating industry and academic partnering

- What are the challenges in CNS research and how can partnering help in drug discovery
- Recent experiences from partnering and collaborations
- Future opportunities

Sophie Dix, Senior Research Scientist, Neurodegenerative Diseases Drug Hunting Team, **Eli Lilly**

10.30 Morning Coffee

11.00 Do Alzheimer's and Parkinson's disease share common genetic risk?

- Examining the genetic overlap between PD and AD
- Data combined from various countries for genome-wide analysis
- Results of the study

Valentina Escott-Price, Senior Lecturer, **Institute of Psychological Medicine and Clinical Neurosciences**

11.40 Proof of concept trials in Alzheimer's dementia: Novel approaches adapting to the needs

- What was wrong with the old way of doing things
- The definition of secondary prevention and meaning of Proof of Concept
- Global consortia and their approach to the problem
- Can we sustain a new 'machine' for phase 2 AD trials in Europe

Craig Ritchie, Clinical Senior Lecturer, **Imperial College London**

12.20 Networking Lunch

1.30 Latest developments in Parkinson's disease

- Developing new treatments to address motor and cognitive symptoms in Parkinson's Disease (PD)
- Challenges in carrying out clinical trials in PD
- How likely is it to translate current research in PD to other diseases of the CNS?

Richard Wyse, Director of Research and Development, **The Cure Parkinson's Trust**

2.10 Clinical studies in Alzheimer's disease in Down syndrome

- Understanding the mechanisms of AD in trisomy of chromosome 21
- The role of amyloid and mitochondrial dysfunction in dementia and people with Down's syndrome
- Latest results obtained from studies

Shahid Zaman, Lecturer, **University of Cambridge**

“ I needed this conference to quickly boost my understanding of current clinical trial activity. This was a great success. ”

BioAdaptives, Inc. event attendee, 2013

2.50 Afternoon Tea

3.20 The PharmaCog project

- The rationale behind the PharmaCog project
- The challenges for new drug development in Alzheimer's disease
- Project results achieved

David Willé, Applied Statistician, **GSK**

4.00 Pre-clinical trials: New treatment targeting versatile protein in Parkinson's disease

- Activation of the Sigma-1 receptor as a defence mechanism
- Results from the pre-clinical studies
- Future clinical trials on Alzheimer's patients?

Veronica Francardo, Assistant Professor, **Lund University**

4.40 Chairman's Closing Remarks and Close of Day Two

Supported by



HALF-DAY POST-CONFERENCE WORKSHOP

Thursday 13th November 2014 | 8.30am – 12.30pm

Marriott Regents Park Hotel, London

Clinical Trials in CNS: The role of academic institutions as CROs

Overview of workshop:

The aim of the workshop is to identify the common issues that arise during a clinical trial and to provide the necessary solutions for a successful partnership amongst all stakeholders.

Why you should attend:

- To enhance your understanding of regulations and documentations as well as the differences between the EMA & FDA approach
- To gain an in depth understanding of the importance of data management and quality control in Clinical Trials
- To understand the key responsibilities and procedures of all partners involved

Programme:

8.30 Registration and coffee

09.00 Opening Remarks

09.10 **I Introduction of new lab methods into clinical use**

- Validation, recognize and transfer clinical relevance
- Security for patients and CRO/ Lab
- Insurances, authorship

09.40 **II Regulations and Documentation**

- Differences EMA/FDA
- Responsibilities Hospital, CRO
- Selection of patients/precipitants
- Form of Documentation
- Controlling procedures and participants

10.10 **III Quality control**

- Methods are feasible for control, new development of control methods
- Clinical Trail units/regular Audits
- Topics which have to be covered

10.40 Morning coffee

11.10 **IV Data Management**

- Clinical centres which have to be involved
- Anonymisation
- Storage for clinical and study reasons
- Data Transfer

11.40 **V Cooperation**

- Selection of collaborators (students, Doctors)
- Trained, untrained, specialized
- Communication of progress and drawbacks
- Solving difficult situations

12.15 Closing Remarks and wrap up

12.30 End of Workshop

About the workshop host:



Ernst-Wilhelm Radue is CEO of the MIAC, an affiliated company of the University Hospital Basel. He received his undergraduate training at the Universities of Erlangen, Duesseldorf and Zurich, and obtained his medical degree from the University Hospital in Freiburg, Germany, where he also specialised in Neurology and Psychiatry in 1979. He deepened his studies in Neuroradiology at the Lysholm Department of the Hospital for Nervous Diseases in London and went on to specialize in Radiology, Neuroradiology and Neurology in Basel, Switzerland, in 1984. In 1993 he was appointed Professor of Neuroradiology. From 1984-2009 he was Head of the Department of Neuroradiology at the University Hospital Basel. Upon retirement in 2009 he is CEO of the MIAC.

His main research interests have been multiple sclerosis, cerebrovascular diseases, brain tumours and functional MRI. In 1995, he founded the MIAC in Basel, thus focussing his research ambitions on multiple sclerosis. Since then, the Medical Image Analysis Center has carried out under his responsibility several international multicentre studies, mainly in MS.

SEPTEMBER

Cancer Vaccines

15 - 16 September 2014, London

Biosimilars and Biobetters

29 - 30 September 2014, London

OCTOBER

**European Pharmaceutical
Pricing and Reimbursement**

13 - 14 October 2014, London

Orphan Drugs

20 - 21 October 2014, London

**COPD: Novel Therapeutics and
Management Strategies**

20 - 21 October 2014, London

Point of Care

27 - 28 October 2014, London

NOVEMBER

Cell Based Assays

19 - 20 November 2014, London

Clinical Trials in CNS

11 - 12 November 2014, London

DECEMBER

Cold Chain Distribution

2 - 3 December 2014, London

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CLINICAL TRIALS IN CNS 2014

Conference: Tuesday 11th and Wednesday 12th November 2014, Marriott Regents Park Hotel, London | Workshop: Thursday 13th November 2014, London

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