SMi present their 11th annual conference on...

**Clinical Trials in CNS**

Monday 5th and Tuesday 6th November 2012, Copthorne Tara Hotel, London

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**KEY SPEAKERS INCLUDE:**

- **Frank Miller**
  Principal Statistician and Principal Scientist
  AstraZeneca

- **Johan Luthman**
  Senior Programme Leader
  Merck & Co.

- **Lars Bauer**
  Senior Medical Director, TA CNS
  UCB Biosciences GmbH

- **Michael O’Neill**
  Senior Research Advisor
  Eli Lilly

- **Florian von Raison**
  Global Program Head, Development Pharma
  Novartis Pharma AG

- **Jennifer Li**
  Associate Senior Biologist
  Eli Lilly

- **Keith Wesnes**
  Practice Leader
  Bracket Global

- **Bruno Pitrosky**
  Global Program Lead, Primary Care
  Pfizer PGRD

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**WHY ATTEND THIS EVENT:**

- **Learn** of the latest drug developments combating the key diseases in CNS, from Alzheimer’s and dementia, to depression and Schizophrenia
- **Discuss** the cutting issues of the industry, from the ethics of outsourcing, to proving efficacy
- **Explore** the latest innovations in pre-clinical discovery, trial optimisation and biomarker identification
- **Discover** new ways to manage and adapt a clinical trial to ensure its success and efficiency
- **Network** with key members of the industry involved in every part of clinical trials: from bench to bedside

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**PLUS TWO INTERACTIVE HALF-DAY POST-CONFERENCE WORKSHOPS**

**Wednesday 7th November 2012, Copthorne Tara Hotel, London, UK**

A: Ensuring efficiency and communication in partnerships within CNS clinical trials

**Workshop Leaders:**

- Lori Wright, President & CEO, Thievon-Wright Consulting Group
- Steve Satek, Senior Vice President, Thievon-Wright Consulting Group

8.30am – 12.30pm

B: Ethical decision making in clinical drug development

**Workshop Leader:**

- Mike Emanuel, Managing Director, SintoPharm

1.00pm – 5.00pm

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8.30 Registration and Coffee
9.00 Chairman's Opening Remarks
   Lars Bauer, Senior Medical Director, TA CNS, UCB Biosciences GmbH

CNS CLINICAL TRIAL MANAGEMENT AND LOGISTICS

9.10 KEYNOTE ADDRESS:
   Management of a Global Clinical Program: Challenges and Opportunities
   • Global partnerships: challenges in an international investment
   • Structuring a global clinical project team: the issues faced and how to overcome them to maximise trials efficiency
   • The cultural differences of differing countries and how this affects their attitudes towards trials and program
   • Addressing the objectives of a global clinical trial/program by integrating the countries/area specificities
   Bruno Pitrosky, Global Program Lead, Primary Care, Pfizer PGRD

9.45 What are the properties of cognitive function tests that determine their suitability to identify time-based changes in clinical trials?
   • Analyses of neuropsychological tests used in high-profile longitudinal ageing studies (eg ADNI) have shown apparent year on year improvements in the elderly.
   • These ‘gold-standard’ tests are widely regarded to have excellent ‘psychometric properties’; so why are many not fit for the purpose of assessing change when administered repeatedly?
   • Could computerised administration of these neuropsychological tests improve their capabilities?
   • How do such tests perform in comparison to automated cognitive tests specifically designed for repeated administration?
   Keith Wesnes, Practice Leader, Bracket Global

10.30 Morning Refreshments

PRECLINICAL OPTIMISATION AND MODELLING

11.00 Optimising clinical trial designs using ideas from optimal design theory
   • Optimal choice of doses in a dose-finding trial
   • An Phase Ia/b adaptive design in a chronic pain setting
   • Choosing the time points for cognitive assessments in Alzheimer’s disease trials
   • Important steps when theoretical ideas are implemented in real clinical trials
   Frank Miller, Principal Statistician and Principal Scientist, AstraZeneca

11.40 Precidential models and translational approaches for the treatment of neurodegenerative diseases
   • Summary of mechanisms in neurodegenerative diseases
   • Overview of key animal models used for Alzheimer’s Disease and Parkinson’s Disease
   • Examples of data for projects/mechanisms in these animal model systems
   • Examples of measures and end-points to aid in progression of projects to the clinic
   • Importance of target engagement and pharmacodynamic biomarkers for CNS drug targets
   Michael O’Neill, Senior Research Advisor, Eli Lilly

12.20 Networking Lunch

13.00 The value of brain banking for CNS research
   •Brain banking in the UK: tissue collection, diagnosis, quality and access
   • Cohort recruitment and longitudinal assessment: increasing the scientific
   • Value of donated tissue
   • The importance of tissue banking in clinical trials and biomarker validation
   • The future: centralised coordination and multi-sample biobanks in order to increase research potential
   Claire Troakes, Brain Bank Coordinator, London Neurodegenerative Diseases Brain Bank, Kings College London

13.40 Identifying novel biomarkers in the central nervous system
   • Negative biases in emotional processing measured in a behavioural test battery and in neuroimaging paradigms with fMRI
   • Antidepressant drugs affect the behavioural and neural processing of emotional information prior to clinical changes in mood.
   • Emotional biomarker tests for drug development and screening of novel compounds for depression
   • Early changes in emotional processing in therapeutic actions of antidepressant treatments in depression
   Catherine Harmer, Department of Psychiatry, Oxford University

14.30 Close of Day One

CLINICAL TRIAL SAFETY AND DEVELOPMENT

15.40 Quantifying the safety of CNS drugs
   • Inaccessibility of the CNS for biomarkers
   • Subtle consequences of psyche pharmacology
   • Composite endpoints in CNS clinical trials
   • Absence of harm on mortality
   John Warren, Former Expert Medical Assessor, MHRA; Director, Medicines Assessment Ltd.

16.20 A Refreshing New Approach to CNS Development
   • Why do so many trial results end up in the ‘grey zone’ and 4/5 projects never repay their investment?
   • Product Design: an essential step missing from Pharma development
   • Earlier thinking of potential value
   • How you can avoid the development ‘graveyard’
   Graham Cox, Principal IDEAtor, IDEAPharma

17.00 Chairman’s Closing Remarks

17.10 Close of Day One

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CURRENT DEVELOPMENTS IN NEURODEGENERATIVE TREATMENTS

9.10 KEYNOTE ADDRESS:
The latest developments and discoveries in neurodegenerative disorders: a case study of Parkinson’s Disease
- Motor complications in PD: Why is it so complex?
- L-dopa induced dyskinesia (LID): reduction of dyskinesia as goal of PD management and therapy
- LID: from the pathways to predictive animal models
- Last developments in humans: which target to choose?
Florian von Raison, Global Program Head, Development Pharma, Novartis Pharma AG

9.50 Progression of biomarkers for Alzheimer’s disease
- New opportunities to follow brain function and dysfunction: research on Alzheimer’s disease.
- Critical AD biomarker validation and qualification work done via public-private pre-competitive partnerships.
- Detecting very early stages of AD pathology, and following the disease progression with new technologies
- The pharmacodynamics actions of putative disease modifying therapeutic approaches in healthy volunteers and in AD patients.
- Paving the way of using AD biomarkers as supportive evidence of disease modifying treatment effects.
Johan Luthman, Senior Programme Leader, Merck & Co.

10.30 Morning Coffee

11.00 Non-motor symptoms in Parkinson’s disease
- Clinical features of Parkinson’s disease
- The patient’s burden of non-motor symptoms
- How to address non-motor symptoms
- Examples from recent clinical trials
Lars Bauer, Senior Medical Director, TA CNS, UCB Biosciences GmbH

11.40 Novel targets, partnerships and emerging clinical trials in Parkinson’s Disease
- Driven by GWAS, new drug targets recently found to be relevant to PD biochemistry are now being actively developed
- Results of recent trials (such as drug repositioning programmes using anti-diabetic drugs with PD-relevant biochemistry) promise to change the trajectory of neurological decline, and revolutionize treatment
- A new global initiative, led by CPT, involving pilot proof-of-concept clinical screening in PD patients of drugs targeting these new pharmaceutical approaches, will dramatically increase the number of PD clinical trials
- The Parkinson’s charities, far more than governments or pharmaceutical companies, now set the global agenda for choosing what therapeutic interventions advance into PD clinical trials
Richard Wyse, Director of Research and Development, The Cure Parkinson’s Trust

12.20 Networking Lunch

13.50 Clinical trials in multiple sclerosis
- The case for Tandem Ratings in clinical trials
- Enhancing Signal detection with Tandem Ratings administered by site based raters and computer.
- Application of Tandem Rating to subject eligibility assessments
- Obtaining validated learning for improved trial design
Peter Joseph Jongen, Founding Director, Neurology, MS4 Research Institute

14.30 Enhanced signal detection: using tandem assessments of psychiatric symptoms in RCTs
- The latest developments and discoveries in neurodegenerative disorders: a case study of Parkinson’s Disease
- Motor complications in PD: Why is it so complex?
- L-dopa induced dyskinesia (LID): reduction of dyskinesia as goal of PD management and therapy
- LID: from the pathways to predictive animal models
- Last developments in humans: which target to choose?
Peter Joseph Jongen, Founding Director, Neurology, MS4 Research Institute

15.10 Afternoon Tea

15.40 Preclinical monitoring of neurophysiology/behaviour as a Translational Biomarker of CNS Activity
- Lack of success in clinical trials of psychiatric disorders due to the difficulty in interpreting drug effects on rodent behaviour alone
- Monitoring physiological responses during behavioural tasks to validate animal assays and disease models
- Using oxygen amperometry to identify brain circuitry engaged in complex behavioural tasks and the response to drug exposure in the freely moving rat as a correlate of neuroimaging techniques
Jennifer Li, Associate Senior Biologist, Eli Lilly

16.20 Clinical trial design: ensuring efficiency and adaptability, with a focus on MS as an example
- Changes in Trials of Relapsing-Remitting MS over time
- The big challenge-Progressive MS
- Measuring Progressive MS
- Increasing efficiency in trials of Progressive MS
- Current and recent trials in Progressive MS
Jeremy Chataway, Consultant Neurologist/Hon Senior lecturer, University College London

17.00 Chairman’s Closing Remarks

17.10 Close of Day Two
Overview of workshop
Too many studies fail to meet predetermined timelines and become riddled with unforeseen challenges and problems due to poor communication among all of the stakeholders. This workshop will address ways to ensure that effective and efficient lines of communication are established between sponsors, CROs, sites and other vendors from the outset of any given trial. A clear delineation of roles and responsibilities of each party must be understood by everyone. As challenges arise, whether expected or unexpected, it is critical that all parties discuss ways to overcome those challenges in a cooperative and collegial way. A communication plan is essential and unfortunately, often developed too late.

Why you should attend:
Clinical research professionals who have any role in the implementation and execution of a clinical trial should attend this workshop to share their experiences and offer solutions based upon those experiences. This workshop will be most productive if all stakeholders have a voice including sponsors, CROs, investigators and other site staff, rater training experts, and other vendors.

Programme
8.30 Registration & coffee
9.00 Welcome & introductions
9.10 Shared experiences
  • How often is a communication plan implemented early?
  • How often are all stakeholders involved in developing the communication plan?
  • Experiences of the workshop leaders and attendees
9.50 Strengthening relationships
  • The sponsor-site relationship – is it broken?
  • Sharing burden – timelines, training, costs
  • Vendors as partners rather than service providers
10.30 Morning coffee
11.00 Study Initiation & execution - getting off on the right foot!
  • Negotiation of clinical trial agreements
  • Study initiation camps – do they work?
  • Collaboration = communication
11.40 Open discussion, Q&A and case studies session
12.30 Close of workshop

About the workshop host
Lori Wright, President & CEO, Thievon-Wright Consulting Group
Lori Wright has over 27 years of experience in the clinical trial industry, the past 17 focused in the CNS field. She held high various senior level positions within the CRO, SMO and site industries before becoming an independent consultant, forming and managing one of the most well-respected CNS research network in the US, and assisting sponsors in the identification of the best-suited partners for any given CNS research trial.

About Thievon-Wright Consulting Group
Thievon-Wright Consulting Group, founded in 1998, is a consulting organization specializing in the management and conduct of Central Nervous System (CNS) and clinical pharmacology trials. Our organization represents an elite network of research organizations specializing in CNS research and early phase drug development. TWCG links pharmaceutical, biotechnology and CRO clinical study teams with appropriate, experienced research facilities and necessary resources to successfully execute their clinical research trials. With access to Key Opinion Leaders in various therapeutic areas, TWCG is frequently consulted very early on in the process of developing a drug development program providing protocol input as well as operational advice.
Overview of workshop
With the complexities of global clinical research it is imperative to be able to judge a particular study design according to defined ethical criteria and codes of ethical conduct. The workshop will utilise a CNS simulated case history to increase understanding and awareness of clinical research ethical principles and decision making and highlight some of the key dilemmas faced by pharmaceutical companies in the development of their clinical programmes. Contents will include issues of placebo use, informed consent, comparator medication and country selection as well as other identified often contentious criteria.

Why you should attend:
The workshop will provide insight into some of the dilemmas faced by drug developers and will be of importance to investigators, regulators and, of course, patients. With particular regard to the ethics of study design and identification of suitable patient populations, the workshop will also explore the decision making processes to resolve these ethical dilemmas.

Programme

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<tr>
<th>Time</th>
<th>Activity</th>
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<tbody>
<tr>
<td>13.00</td>
<td>Registration &amp; coffee</td>
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<tr>
<td>13.30</td>
<td>Welcome &amp; introductions</td>
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<tr>
<td>13.40</td>
<td>Introductory overview of major principles behind clinical research ethics including Declaration of Helsinki</td>
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<td>• Ethical principles</td>
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<td>• Ethical Decision making</td>
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<td>14.20</td>
<td>Introduction to case history and initial discussion of key issues</td>
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<td></td>
<td>• Overview of CNS protocol case history</td>
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<td>• Study design issues and ethical dilemmas</td>
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<td>• Discussion of ethical conflicts</td>
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<td>15.00</td>
<td>Morning coffee</td>
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<td>15.30</td>
<td>Further discussion of issues</td>
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<td>• Including consent, vulnerable populations, acute vs chronic illness, placebo as comparator</td>
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<td>16.10</td>
<td>Summary of case history discussion and group feedback</td>
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<tr>
<td>17.00</td>
<td>Close of workshop</td>
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About the workshop host
Mike Emanuel, Managing Director, SintoPharm

Mike Emanuel has extensive experience in the pharmaceutical industry including a long career at Johnson & Johnson where he was Vice President of Global Clinical Operations for Europe, Middle East and Africa, leading a team of over 400 clinical research professionals operating in 27 countries. At J&J he was European representative for the Company’s global research ethics team. On leaving J&J he was Associate Director of the National Institute for Health Research, Clinical Research Network (NIHR CRN) with responsibility for the development of relationships with the Pharmaceutical Industry. He is currently Managing Director of the pharmaceutical consultancy, SintoPharm. As well as creating and running programmes on the Ethics of Clinical Research he is an active member of a UK based Research Ethics Committee.

About SintoPharm
SintoPharm provides personalised health care consultancy to the pharmaceutical and biotechnology industry and government organisations specialising in all aspects of clinical trial strategy and operations. Areas of expertise include: consultancy support for clinical operations organisation and functional excellence, clinical study design though to strategy of implementation (including CRD and other vendor selection), new trial set up and rescue of on-going trials struggling to meet timeline objectives and design and delivery of clinical research ethics training and awareness programmes.
DELEGATE DETAILS

Please complete fully and clearly in capital letters. Please photocopy for additional delegates.

Title: ____________________________  Forename: ______________________________
Surname: __________________________  Date of Birth: _________________________
Department/Division: ______________________________  Email: _______________________
Company/Organization: __________________________  Company VAT Number: ________
Address: __________________________________________  Address (if different from above): __________________________________________
Post/Zip Code: __________________________  Country: __________________________
Town/City: _________________________________
Signature: ___________________________  Date: _____________________________

I agree to be bound by SMi’s Terms and Conditions of Booking.

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Town/City: _________________________________

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