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SMi Presents the 8th Annual Conference and Exhibition on...

Adaptive Designs in Clinical Trials

Bringing technological advances to patients in the most efficient manner

Holiday Inn Regents Park, London, UK

18 - 19 APRIL 2016

HIGHLIGHTS FOR 2016:

- **Discuss** the European regulatory framework and approaches to novel designs
- **Evaluate** the role of biomarker adaptive designs in oncology
- **Examine** the role of an independent data safety monitoring board
- **Learn** adaptive design in Bayesian statistic
- **Explore** the impact of adaptive changes in clinical trials
- **Study** the development of new drugs in orphan diseases
- **Optimise** dose finding design on oncology

CHAIRS FOR 2016:

Loïc Darchy, Head of Statistical Methodology Group, **Sanofi R&D**

Alex Sverdlov, Associate Director of Biostatistics, **EMD Serono**

KEYNOTE SPEAKERS INCLUDE:

- **Bo Huang,** Director of Biostatistics, **Pfizer USA**
- **Philip Hougaard,** Vice President, Biometrics, **Lundbeck A/S**
- **Giacomo Mordenti,** Senior Director, Head of Biostatistics, **Grunenthal**
- **Frank Fleischer,** Team Leader Clinical Biostatistics, **Boehringer-Ingelheim**
- **Bruce Turnbull,** Professor of Statistics, **Cornell University**

PLUS AN INTERACTIVE HALF-DAY POST-CONFERENCE WORKSHOP
Wednesday 20th April 2016, Holiday Inn Regents Park, London, UK

Design, Analysis and Simulation of Adaptive Clinical Trials Using ADDPLAN

Workshop Leader:
Silke Jörgens, Senior Statistical Consultant, **ICON plc**
8.30am - 12.30pm

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8th Annual Adaptive Designs in Clinical Trials

Day One | Monday 18th April 2016

8.30 Registration & Coffee

9.00 **Chairman's Opening Remarks**
Loïc Darchy, Head of Statistical Methodology Group, **Sanofi R&D**

LATEST DEVELOPMENTS IN ADAPTIVE DESIGNS

OPENING ADDRESS

9.10 **Adaptive designs in practice**
- Case studies of adaptive designs in practice
- Transforming a Phase II trial into a Phase II/III adaptive design
- Usage of historical and within trial information for decision making
- Adaptive trial examples in the early phase

Frank Fleischer, Team Leader Clinical Biostatistics, **Boehringer-Ingelheim**

9.50 **Seamless pPhase I/II dose finding designs with efficacy and safety endpoints**
- Advantages of pursuing seamless phase I/II trial designs in the oncology setting
- Optimal and sequential adaptive designs to achieve experimental objectives of phase I/II trials
- A simulation study to compare various state-of-the-art phase I/II designs for bivariate binary efficacy-toxicity outcomes
- Incorporating covariates to enable personalised dose-finding
- Statistical software, information technology, and regulatory aspects

Alex Sverdlov, Associate Director of Biostatistics, **EMD Serono**

10.30 Morning Coffee

11.00 **Biomarker driven early phase oncology trials; opportunities and challenges**
- Pharmacodynamic biomarkers in early phase trials
- Immune monitoring
- Challenges in biomarker driven trials

Sidath Katugampola, Biomarker Drug Development Manager, **Cancer Research UK**

11.40 **Panel discussion: The role of biomarker-driven adaptive designs in clinical development**
- Early phase studies
- Clinical design strategies
- Patient perspectives
- Challenges and ongoing research developments

Loïc Darchy, Head of Statistical Methodology Group, **Sanofi R&D**

12.20 Networking Lunch

LEADING STRATEGIES FOR CLINICAL DEVELOPMENT

1.30 **Opportunities of adaptive enrichment designs in the era of precision medicine**
- Opportunities and challenges in the era of biomarker-driven targeted therapies
- Overview of enrichment designs in statistical literature
- Case study 1: Bayesian predictive probability design for a phase 2 POC study
- Case study 2: Adaptive enrichment with sample size re-estimation for a phase 3 oncology study

Bo Huang, Director of Biostatistics, **Pfizer**

2.10 **Optimising clinical trials in neuroscience**
- Adaptive designs in neurology
- Integrating new biomarkers into clinical development
- Developing new strategies for testing multiple therapeutics

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

2.50 Afternoon Tea

3.20 **Adaptive clinical trials: A DSMB perspective**
- A series of vignettes will be presented based on the speaker's experiences from serving on the DSMB for adaptive trials.
- Pitfalls that may occur during the conduct of an adaptive trial; how they might be avoided.
- How members with differing interests interact at DSMB meetings with each other, with the sponsor, with a CRO, and with a "firewall"

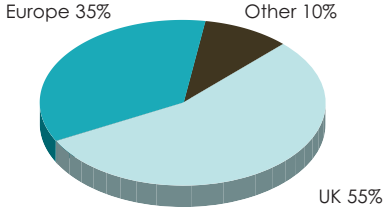
Bruce W. Turnbull, Professor of Statistics, School of Operations, **Cornell University**

4.00 **Point estimates and confidence intervals for phase II/III clinical trials when multiple endpoints are used to make treatment selection**
- Multi-arm and multi-stage
- Treatment selection
- Multiple endpoints
- Point estimation
- Confidence intervals

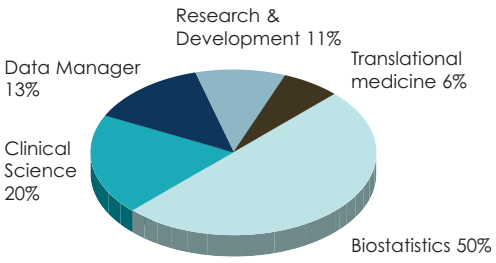
Peter Kimani, Assistant Professor, **University of Warwick**

4.40 Chairman's Closing Remarks and Close of Day One

Attendees by geo location – Adaptive Designs in Clinical Trials 2015



Attendees by Industry Sector – Adaptive Designs in Clinical Trials 2015



WHO SHOULD ATTEND:
Directors, VPs, Chiefs, Heads, Principals, Managers of

- Clinical trial managers and associates
- Biostatisticians
- Directors of business development
- Data managers
- Senior statisticians
- Professors of statistics
- Directors of Clinical trials
- Medical doctors
- Clinical scientists

8th Annual Adaptive Designs in Clinical Trials

Day Two | Tuesday 19th April 2016

8.30 Registration & Coffee

9.00 **Chairman's Opening Remarks**
Alex Sverdlov, Associate Director of Biostatistics, **EMD Serono**

CHALLENGES AND OBSTACLES OF ADAPTIVE DESIGNS

OPENING ADDRESS

9.10 **Adaptive designs in proof-of-concept studies (Phase IIa) and dose-finding studies (Phase IIb)**
- Simultaneously doing proof-of-concept and finding the dose(s) for future studies
- Finding the single best dose or a treatment window with several acceptable doses?
- Choosing the most informative doses or the most promising doses (the conflict between individual and collective ethics)?
- Joint consideration of efficacy and safety

Philip Hougaard, Vice President, Biometrics, **Lundbeck A/S**

9.50 **Be Adaptive: bright hope or buzz word? A mid-size company perspective**
- Adaptive design: what, where and why
- Adaptive development program
- Some cases studies in pain

Giacomo Mordenti, Senior Director, Head of Biostatistics, **Grunenthal**

10.30 Morning Coffee

11.00 **Early dialogue with regulatory agencies during development and impact on programme and study design**
- Facilitate the development of therapeutic that are available to all patients across the EU
- Increase early dialogue between different stakeholders
- Increase patients' involvement

Bob Clay, Managing Director, **Highbury Regulatory Science Limited**

11.40 **Adaptive designs and Bayesian statistic**
- The design of Bayesian Methods in clinical trials
- Sub group analysis
- Challenges of sample size estimation

Sophie Carr, MD and Principal Analyst, **Bays Consulting Ltd**

12.20 Networking Lunch

OPTIMISING DRUG DEVELOPMENTS

1.30 **Improving adaptive designs**
- Decision making during an adaptive design
- Deriving an efficient rule for sample size modification
- Optimising adaptive designs with treatment selection or subset selection
- Assessing the benefits of an adaptive design – when are these worthwhile?

Christopher Jennison, Professor of Statistics, **University of Bath**

2.10 **Diagnosis and treatment of neurodegenerative dementia: A clinical dilemma**
- Overview and classification of degenerative dementia
- Diagnosis and overlaps of degenerative dementias
- Vascular cognitive impairment and its relationship with degenerative dementias
- Pre-dementia stadium is the ideal target for treatment: When and how

Filippo Baldacci, Medical Doctor, Department of Clinical and Experimental Medicine, Neurology Unit, **University of Pisa**

2.50 Afternoon Tea

3.20 **Improving covariate-adaptive designs**
- The elements of covariate-adaptive randomisation
- Maintaining the type I error rate
- Likelihood-based inference following the designs
- Marginal and global balance
- Incorporating information on responses

Steve Coad, Reader in Statistics, **School of Queen Mary, University of London**

4.00 **Adaptive dose finding designs**
- How to approach adaptive designs for non-statisticians
- Increasing productivity in Phase III trials by optimising decision-making and trial efficiency
- Where do the greatest uncertainties lie?
- Improving patient experience

Senior representative, European Medical Agency*

4.40 Chairman's Closing Remarks and Close of Day Two

*subject to final confirmation

Supported by

INTERACTIVE HALF-DAY
POST-CONFERENCE WORKSHOP
Wednesday 20th April 2016
8.30am – 12.30pm
Holiday Inn Regents Park, London, UK

Design, Analysis and Simulation of Adaptive Clinical Trials Using ADDPLAN

Leader:
Silke Jörgens, Senior Statistical Consultant, **ICON plc**

Overview of the workshop:
ADDPLAN is a statistical software package for the design, simulation and analysis of adaptive clinical trials. ADDPLAN's functionality covers all phases of clinical drug development. It offers full insight into operating characteristics of a wide range of adaptive designs.

This workshop provides a short overview of ADDPLAN's, focusing on the design, simulation and analysis of confirmatory adaptive designs with one or more test treatment arms using ADDPLAN.

Key Benefits of Attending:
- Learn how to design confirmatory adaptive trials
- Get acquainted with ADDPLAN simulation functionalities to support submissions of well and less well understood adaptive designs
- See how ADDPLAN supports interim and final analysis decision making
- Experience how to use ADDPLAN DF for innovative dose-finding designs as MCPMod and CRMs

Programme

08.30 **Registration and coffee**

09.00 **Session 1: Overview of ADDPLAN Modules**
- Introduction
- ADDPLAN BASE, MC, PE and DF

09.30 **Session 2: Two-armed Adaptive Clinical Trials**
- Designing and Simulating a Trial
- Interim and Final Analysis

10.30 **Coffee Break**

11.00 **Session 3: Overview of ADDPLAN DF Functionalities**
- Dose Escalation Designs
- Nonlinear modelling, contrast tests and MCPMod

11.30 **Session 4 title: Multi-armed Adaptive Clinical Trials**
- Design and Simulation
- Interim and Final Analysis

12.30 **End of Workshop**

About the Workshop Leader:

Dr. Silke Jörgens, Senior Statistical Consultant, is part of ICON's Innovation Center which provides methodological input into adaptive study designs and also develops ICON's proprietary software for Adaptive Designs, ADDPLAN®. She gained her PhD in adaptive trial methodology at the Institute for Medical Statistics, Informatics and Epidemiology (IMSIE), Faculty of Medicine, Albertus-Magnus University Cologne, Germany. Dr. Jörgens has more than 10 years' experience in statistical consulting, biometrical planning, and statistical evaluation of clinical trials, along with experience in statistical lecturing and training with a focus on adaptive design methodology and relevant software.

About the Organisation:
ICON plc is a global provider of drug development solutions and services to the pharmaceutical, biotechnology and medical device industries. The company specialises in the strategic development, management and analysis of programs that support clinical development - from compound selection to Phase I-IV clinical studies. With headquarters in Dublin, Ireland, ICON currently, operates from 77 locations in 38 countries and has approximately 11,700 employees.

SMi Pharmaceutical 2016 Planner:

JANUARY

Pharmaceutical Microbiology
20th - 21st January 2016
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Social Media In The Pharmaceutical Industry
20th - 21st January 2016
Holiday Inn Kensington Forum, London, UK

Pre-Filled Syringes
27th - 28th January 2016
Copthorne Tara Hotel,
London, UK

FEBRUARY

Parallel Trade
8th - 9th February 2016
Holiday Inn Kensington Forum, London, UK

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15th - 16th February 2016
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MARCH

Superbugs & Superdrugs - A Focus on Antibacterials
16th - 17th March 2016
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Paediatric Clinical Trials
16th - 17th March 2016
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APRIL

Asthma & COPD
11th - 12th April 2016
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Controlled Release
18th - 19th April 2016
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London, UK

Adaptive Designs
18th - 19th April 2016
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London, UK

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25th - 26th April 2016
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New Jersey, USA

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