REGISTER BY 16TH DECEMBER TO SAVE £400
REGISTER BY 31ST JANUARY TO SAVE £200
REGISTER BY 28TH FEBRUARY TO SAVE £100

SMi
LINKING BUSINESS *with* INFORMATION

SMi Presents the 9th Annual Conference on...

Adaptive Designs in Clinical Trials

Driving innovation and success in medical product development

COPTHORNE TARA HOTEL, KENSINGTON, LONDON, UK

CONFERENCE:
3RD - 4TH
WORKSHOP: 5TH

APRIL
2017

REASONS TO ATTEND:

- **Learn** adaptive design approaches and appropriate use
- **Hear** from regulatory agencies on the latest changes and protocol for drug and device approval
- **Evaluate** the strength and pitfalls of leading adaptive design approaches
- **Discuss** the latest trends in Bayesian statistics, biomarker driven design and other adaptive design approaches
- **Study** the development of new drugs in key therapy areas such as: Neurodegeneration, oncology and cardiovascular disease
- **Benefit** from real industry led case studies of adaptive design drug development
- **Optimise** drug and device development through an adaptive design approach
- **Overcome** hurdles to installing adaptive design into trials

CHAIRS FOR 2017:

- **Alex Sverdlov,** Director, **Statistical Scientist, Novartis**
- **James Matcham,** Head of Biometrics, Early Clinical Development, **AstraZeneca**

KEYNOTE SPEAKERS INCLUDE:

- **Loic Darchy,** Head of Statistical Methodology Group, **Sanofi R&D**
- **Simon Kirby,** Senior Director, **Pfizer**
- **Frank Fleischer,** Principal Methodology Statistician, **Boehringer-Ingelheim**
- **Bo Haung,** Director, Clinical Statistics, **Pfizer Inc.**
- **Christine Fletcher,** Executive Director Biostatistics, **Amgen Ltd**
- **Tom Parke,** Director of Statistical Software, **Berry Consulting**

PLUS AN INTERACTIVE HALF-DAY POST-CONFERENCE WORKSHOP | 5TH APRIL 2015, COPTHORNE TARA HOTEL, KENSINGTON, LONDON, UK

Writing Clinical Trial Simulators

Workshop Leader:
Tom Parke, Director of Software Solutions, **Berry Consultants**
1.30pm - 5.30pm

CPD CERTIFIED
The CPD Certification Service

@SMIPHARM

www.adaptivedesigns.co.uk

Register online or fax your registration to +44 (0) 870 9090 712 or call +44 (0) 870 9090 711

9th Annual Adaptive Designs in Clinical Trials

Day One | Monday 3rd April 2017 www.adaptivedesigns.co.uk

08:30 **Registration & Coffee**

09:00 **Chairman's Opening Remarks**
Alex Sverdlov, Director, Statistical Scientist, **Novartis**

APPROACHES IN ADAPTIVE DESIGNS

09:10 **Adaptive multi-arm randomisation approaches and methodology to clinical trials**
- Methodology for applying randomisation approaches to clinical trials
- Applying multi-arm randomisation to drug development
- Examples of randomisation application and methodology

Alex Sverdlov, Director, Statistical Scientist, **Novartis**

09:50 **Hot topics and case studies in adaptive designs from a company's perspective**
- Towards an adaptive platform based approach in oncology dose finding
- Statistical Go / NoGos and alternative development pathways
- Adaptive designs in the biosimilar framework
- Case studies

Frank Fleischer, Principal Methodology Statistician, **Boehringer-Ingelheim**

10:30 **Morning Coffee & Networking Break**

11:00 **Adaptive aspects in clinical development in Grünenthal**
- Single trials with adaptive design vs adaptive nature of clinical development programs
- Adaptive trial design aspects specific to indication pain/drug class opioids
- Case studies of trials with adaptive designs in GRT

Cécile Dubois, Head Biostatistics, **Grünenthal**

11:40 **Adaptive design: Historical perspective of how it arose**
- What was the old system?
- Why was it insufficient?
- What happens next?

John Warren, Director, **Medicines Assessment Ltd**

12:20 **Networking Lunch**

CLINICAL DEVELOPMENT STRATEGIES

13.30 **Bayesian adaptive design in device development**
- The adaptive design of device clinical trials
- Operational and logistical pitfalls common in device development
- Important differences to consider between adaptive device and drug development
- Case studies of Bayesian statistics in practise in devices

Giacomo Mordenti, Global Biometrics Director, **Livanova**

14:10 **Adaptive clinical development: From patent to market**
- Adaptive clinical designs can speed development and cut costs
- Upfront effort is required
- Talk to the regulators about your ideas

Michael Davies, Co-Founder & Chief Medical Officer, **Blueberry Therapeutics Ltd**

14:50 **Afternoon Tea & Networking**

15:20 **The integration of adaptive designs into neuroscience drug development**
- Relevant new clinical developments in Parkinson's disease
- Major impact of disease-modifying therapeutics
- Overcoming challenges
- Developing innovative new strategies for testing drug combinations

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

16:00 **Testing a secondary endpoint after a group sequential test**
- Inference after a group sequential test needs care
- Some plausible looking methods are not actually valid
- We describe a general framework for multiple testing in the group sequential setting
- We discuss testing a secondary hypothesis after stopping to reject the primary null hypothesis

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

16:40 **Chairman's Closing Remarks and Close of Day One**

Register online at www.adaptivedesigns.co.uk

SUPPORTED BY

08:30 **Registration & Coffee**

09:00 **Chairman's Opening Remarks**
James Matcham, Head of Biometrics, Early Clinical Development, **AstraZeneca**

OPTIMISING DRUG DEVELOPMENT IN KEY THERAPY AREAS

09:10 **Building an adaptive design capability in early development**
- Describing the journey at AstraZeneca
- Building skills and confidence in designing adaptive clinical trials
- Implications for early phase decision making.

James Matcham, Head of Biometrics, Early Clinical Development, **AstraZeneca**

09:50 **Adaptive designs: How preclinical, translational and big data can contribute to a better design**
- Adaptive design often require a model underlying hypotheses
- Developing these model is not easy when lacking of internal clinical data
- Preclinical (non-clinical) data can be very useful, but often require to use translational expertise to be used efficiently
- Big Data is also an incredible source of knowledge, but requires also a careful management to be integrated in a model

Emmanuel Pham, VP Biometrics, **Ipsen**

10:30 **Morning Coffee & Networking Break**

11:00 **Bayesian adaptive trials for medical device and pharmaceutical trials**
- The design, modelling and simulation of bayesian methods in drug and device clinical trials
- Platform / Master protocol designs
- Case studies of bayesian statistics in practise – the EPAD trial
- Innovative adaptive design to address immediate threats – Ebola trial 2015

Tom Parke, Director of Statistical Software, **Berry Consulting**

11:40 **Adaptive design to check the dose range of a dose-ranging study**
Studies of adaptive dose-ranging designs have not necessarily found advantages for adaptive designs however adaptive designs may have a role to play in checking that the dose range
- The 3 parameter Emax model and empirical justification for focusing on this model
- Adaptations to try to ensure that the dose range goes low enough and high enough
- Simulation study
- Results of simulation study
- Conclusions

Simon Kirby, Senior Director, **Pfizer**

12:20 **Networking Lunch**

INDUSTRY-LED APPROACHES TO CLINICAL TRIAL SUCCESS

13:30 **Enrichment designs in oncology**
- Overview of enrichment designs in statistical literature
- Opportunities and challenges of enrichment design in oncology target therapies and development
- Case Studies for adaptive enrichment

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

14:10 **Adaptive dose finding designs in oncology early phase trials: An industry experience**
- Overview of adaptive early dose-finding studies
- A time-to-event continual reassessment method with adaptive weight function incorporating cyclical data
- The practical implications of adaptive design on Pfizer oncology drug development with two case studies

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

14:50 **Afternoon Tea & Networking**

15:20 **ICH E9(R1) and adaptive designs**
- Introduce the new estimand and sensitivity analysis framework
- Consider if the new framework will impact the design, conduct, analysis and reporting of adaptive trials
- Discuss whether any new unique challenges will be introduced by the framework

Christine Fletcher, Executive Director Biostatistics, **Amgen Ltd**

16:00 **Biomarker-driven drug development in oncology**
- The logistic and statistical challenges posed in event driven late-stage oncology trials
- Subpopulations and predictive biomarkers – a translational approach to adaptive design
- Adaptive design from early development to Phase III

Reserved for top pharma company

16:40 **Chairman's Closing Remarks and Close of Day Two**

Alternatively fax your registration to +44 (0)870 9090 712 or call +44 (0)870 9090 711

HALF DAY POST-CONFERENCE WORKSHOP
Wednesday 5th April 2017 | 1.30pm - 5.30pm
Copthorne Tara Hotel, Kensington, London, UK

Writing Clinical Trial Simulators

Workshop Leader:
Tom Parke, Director of Software Solutions, **Berry Consultants**

Workshop overview:
The use of simulation is growing in the design of clinical trial designs as an augmentation of, or replacement for, sample size calculations. Usually this is in order to be able to: estimate operating characteristics of the planned trial other than simply power, to be able to estimate actual type-1 error and power taking into account factors such as the effect of dropouts, and to be able to use trial designs that are too complex for sample size calculation such as adaptive designs.

Key benefits of attending:
This course will introduce statisticians to the software and engineering skills required to write and use a trial simulator. It is intended for statisticians with some experience of programming in R, and introduce them to the design considerations of writing a simulator in R and the testing skills necessary to show that the simulator is correct. It will also introduce statisticians with some experience of trial design to how to think like and engineer and use simulations to test and guide design decisions - how important it is to be able to present single simulations and how to present operating characteristics from many simulations.

Agenda

1.30 **Registration & Coffee**

2.00 **Opening remarks and introductions**

2.10 **Session 1: Introduction**
- What is clinical trial simulation
- Why we need to (and should want to) simulate our trial designs

2.50 **Session 2: Case Study**
- The background
- The trial design
- The structure of the simulator

3.30 **Coffee**

4.00 **Session 3: Writing a Simulator for the case study**
- Lookup tables
- Output files
- Parallel processing

4.40 **Session 4: So we've got a simulator. Now what?**
- How to look at the results
- What to present and how to present it
- Testing

5.20 **Closing remarks**

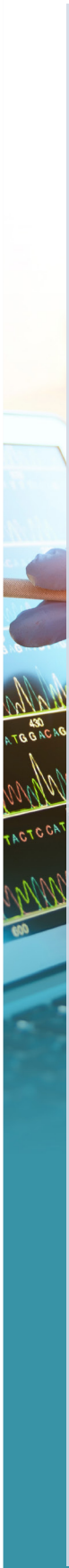
5.30 **End of workshop**

About the Workshop Leader:
Tom Parke is Director of Software Solutions for Berry Consultants. Tom's passion and experience has been software for adaptive clinical trials. Prior to joining Berry Consultants, he was Head of Clinical Trial Solutions for Tessella Ltd. While at Tessella for nearly 20 years, he managed the development and running of the software system to support Pfizer's ASTIN Stroke trial, and has setup multiple software systems to support different aspects of many adaptive clinical trials, mostly designed by Berry Consultants. In parallel, he managed projects to develop clinical trial simulators, first with Pfizer, then Wyeth, before acting as the expert advisor and reviewer to the joint development of FACTS with Berry Consultants. Prior to working at Tessella, he worked for Inmos, Imperial Software Technology, and Praxis on compilers, operating systems and real time control systems. He graduated with a Joint First Class Honours in Math and Computer Science from Bristol University in 1979.

About the organisation:
Berry Consultants is a statistical consulting company specializing in the Bayesian approach to medical statistics, an approach that is radically changing the way research is done throughout the medical industry in both device and drug development. Berry Consultants employs world renowned experts in Bayesian statistics and strives to set the standard for innovative clinical trial design and analysis in the statistical and medical communities.

Berry Consultants
Statistical Innovation

SMi PHARMACEUTICAL EVENT PLANNER 2017



JANUARY

Pharmaceutical Microbiology
18th - 19th January 2017, London, UK

Social Media In The Pharma Industry
18th - 19th January 2017, London, UK

Pre-Filled Syringes Europe
18th - 19th January 2017, London, UK

FEBRUARY

Parallel Trade
6th - 7th February 2017, London, UK

3D Cell Culture
22nd - 23rd February 2017, London, UK

RNAi Therapeutics
22nd - 23rd February 2017, London, UK

MARCH

Superbugs & Superdrugs - A Focus on Antibacterials
20th - 21st March 2017, London, UK

Paediatric Clinical Trials
20th - 21st March 2017, London, UK

Drug Discovery
27th - 28th March 2017, London, UK

Asthma & COPD
29th - 30th March 2017, London, UK

APRIL

Controlled Release
3rd - 4th April 2017, London, UK

Adaptive Designs
3rd - 4th April 2017, London, UK

Pre-Filled Syringes East Coast
26th - 27th April 2017, Boston, USA

MAY

Lyophilisation
8th - 9th May 2017, London, UK

Orphan Drugs Europe
15th - 16th May 2017, Berlin, Germany

Clinical Trial Logistics
18th - 19th May 2017, London, UK

Pain Therapeutics
22nd - 23rd May 2017, London, UK

ADC Summit
22nd - 23rd May 2017, London, UK

JUNE

Pre-Filled Syringes West Coast
5th - 6th June 2017, San Diego, USA

Microbiology USA
8th - 9th June 2017, San Diego, USA

ADMET
12th - 13th June 2017, London, UK

Immunogenicity
12th - 13th June 2017, London, UK

BioBanking
14th - 15th June 2017, London, UK

JULY

Allergies
6th - 7th July 2017, London, UK

Peptides
6th - 7th July 2017, London, UK

SPONSORSHIP AND EXHIBITION OPPORTUNITIES

SMi offer sponsorship, exhibition, advertising and branding packages, uniquely tailored to complement your company's marketing strategy. Prime networking opportunities exist to entertain, enhance and expand your client base within the context of an independent discussion specific to your industry. Should you wish to join the increasing number of companies benefiting from sponsoring our conferences please call:
Alia Malick on +44 (0) 20 7827 6168 or
email: amalick@smi-online.co.uk

ADAPTIVE DESIGNS IN CLINICAL TRIALS

Conference: 3rd-4th April 2017, Copthorne Tara Hotel, Kensington, London, UK Workshop: 5th April 2017, London

4 WAYS TO REGISTER

ONLINE at www.adaptivedesigns.co.uk

FAX your booking form to +44 (0) 870 9090 712

PHONE on +44 (0) 870 9090 711

POST your booking form to: Events Team, SMi Group Ltd, Ground & First Floor, 1 Westminster Bridge Road London, SE1 7XQ

Unique Reference Number	
Our Reference	**P-202**

DELEGATE DETAILS

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

Title: **Forename:**

Surname:

Job Title:

Department/Division:

Company/Organisation:

Email:

Company VAT Number:

Address:

Town/City:

Post/Zip Code: **Country:**

Direct Tel: **Direct Fax:**

Mobile:

Switchboard:

Signature: **Date:**

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

ACCOUNTS DEPT

Title: **Forename:**

Surname:

Email:

Address (if different from above):

Town/City:

Post/Zip Code: **Country:**

Direct Tel: **Direct Fax:**

VENUE Copthorne Tara Hotel, Kensington, London, UK

☐ **Please contact me to book my hotel**

Alternatively call us on +44 (0) 870 9090 711, email: events@smi-online.co.uk or fax +44 (0) 870 9090 712

Terms and Conditions of Booking

Payment: If payment is not made at the time of booking, then an invoice will be issued and must be paid immediately and prior to the start of the event. If payment has not been received then credit card details will be requested and payment taken before entry to the event. Bookings within 7 days of event require payment on booking. Access to the Document Portal will not be given until payment has been received.

Substitutions/Name Changes: If you are unable to attend you may nominate, in writing, another delegate to take your place at any time prior to the start of the event. Two or more delegates may not 'share' a place at an event. Please make separate bookings for each delegate.

Cancellation: If you wish to cancel your attendance at an event and you are unable to send a substitute, then we will refund/credit 50% of the due fee less a £50 administration charge, providing that cancellation is made in writing and received at least 28 days prior to the start of the event. Regretfully cancellation after this time cannot be accepted. We will however provide the conferences documentation via the Document Portal to any delegate who has paid but is unable to attend for any reason. Due to the interactive nature of the Briefings we are not normally able to provide documentation in these circumstances. We cannot accept cancellations of orders placed for Documentation or the Document Portal as these are reproduced specifically to order. If we have to cancel the event for any reason, then we will make a full refund immediately, but disclaim any further liability.

Alterations: It may become necessary for us to make alterations to the content, speakers, timing, venue or date of the event compared to the advertised programme.

Data Protection: The SMi Group gathers personal data in accordance with the UK Data Protection Act 1998 and we may use this to contact you by telephone, fax, post or email to tell you about other products and services. Unless you tick here ☐ we may also share your data with third parties offering complementary products or services. If you have any queries or want to update any of the data that we hold then please contact our Database Manager databasemanager@smi-online.co.uk or visit our website www.smi-online.co.uk/updates quoting the URN as detailed above your address on the attached letter.

EARLY BIRD DISCOUNT

- ☐ **Book by 16th December to receive £400 off the conference price**
- ☐ **Book by 31st January to receive £200 off the conference price**
- ☐ **Book by 28th February to receive £100 off the conference price**

CONFERENCE PRICES

GROUP DISCOUNTS AVAILABLE

I would like to attend: (Please tick as appropriate)	**Fee**		**TOTAL**
☐ Conference & Workshop	**£2098.00**	**+ VAT**	**£2517.60**
☐ Conference only	**£1499.00**	**+ VAT**	**£1798.80**
☐ Workshop only	**£599.00**	**+ VAT**	**£718.80**

PROMOTIONAL LITERATURE DISTRIBUTION

☐ Distribution of your company's promotional literature to all conference attendees	**£999.00**	**+ VAT**	**£1198.80**

The conference fee includes refreshments, lunch, conference papers, and access to the Document Portal. Presentations that are available for download will be subject to distribution rights by speakers. Please note that some presentations may not be available for download. Access information for the document portal will be sent to the e-mail address provided during registration. Details are sent within 24 hours post conference.

DOCUMENTATION

I cannot attend but would like to Purchase access to the following Document Portal/ Paper Copy documentation.	**Price**		**Total**
☐ Access to the conference documentation on the Document Portal	**£499.00**	**+ VAT**	**£598.80**
☐ The Conference Presentations – paper copy (or only £300 if ordered with the Document Portal)	**£499.00**	**-**	**£499.00**

PAYMENT

Payment must be made to **SMi Group Ltd**, and received before the event, by one of the following methods **quoting reference P-202 and the delegate's name. Bookings made within 7 days of the event require payment on booking, methods of payment are below. Please indicate method of payment:**

☐ **UK BACS** Sort Code **300009**, Account **00936418**

☐ **Wire Transfer** Lloyds TSB Bank plc, 39 Threadneedle Street, London, EC2R 8AU
Swift (BIC): **LOYDGB21013**, Account **00936418**
IBAN **GB48 LOYD 3000 0900 9364 18**

☐ **Cheque** We can only accept Sterling cheques drawn on a UK bank.

☐ **Credit Card** ☐ Visa ☐ MasterCard ☐ American Express

All credit card payments will be subject to standard credit card charges.

Card No: ☐☐☐☐ ☐☐☐☐ ☐☐☐☐ ☐☐☐☐

Valid From ☐☐/☐☐ Expiry Date ☐☐/☐☐

CVV Number ☐☐☐ 3 digit security on reverse of card, 4 digits for AMEX card

Cardholder's Name:

Signature: **Date:**

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

Card Billing Address (If different from above):

VAT

VAT at 20% is charged on the attendance fees for all delegates. VAT is also charged on Document portal and literature distribution for all UK customers and for those EU Customers not supplying a registration number for their own country here

If you have any further queries please call the Events Team on tel +44 (0) 870 9090 711 or you can email them at events@smi-online.co.uk