SMi present their 3rd Annual Conference...

Preclinical Models & Biomarkers

Bridging the gap in drug discovery

15th & 16th March 2006, Millennium Gloucester Hotel, London

An exclusive opportunity to learn from prominent industry professionals including:

- **Dr Harsukh Parmar**, Executive Director, Global Discovery Medicine, Respiratory & Inflammation, AstraZeneca
- **Dr Giles Campion**, Head, Global Medical Research, GE Healthcare
- **Dr Hans Winkler**, Senior Director & Head, Functional Genomics, Johnson & Johnson
- **Dr Zorina Galis**, Research Fellow, Atherosclerosis/Metabolic Syndrome Drug Hunting Team, Cardiovascular Discovery, Eli Lilly
- **Dr Jarko Kochan**, Director, Biomarkers, Metabolic & Vascular Diseases, F. Hoffmann-La Roche
- **Dr Sudeep Chandra**, Director, Imaging Sciences, Millennium
- **Dr Huw Davies**, Manager, European Biomarker Discovery Centre, Ciphergen
- **Professor Karol Sikora**, Professor of Cancer Medicine, Imperial College London, & Scientific Director, Medical Solutions

An in-depth conference encompassing:

- **TRANSLATIONAL COMMUNICATION**: Discuss the appropriate use of preclinical and biomarker results in the development of clinical trials through to end-user products
- **THE HUMANISING OF DRUG DISCOVERY**: Discover why high quality target validation is critical to the choice and selection of targets, and how key functional validation experiments in vitro and in vivo can help prioritise these targets
- **LEARNING FROM THE CLINIC**: Identify the unmet medical needs in model selection criteria for preclinical surrogates to clinical endpoints. How do these designs/endpoints translate across species?
- **PRACTICAL CASE STUDIES**: Learn about the latest developments from acclaimed experts in areas from cancer drug targeting, Alzheimer’s Disease through to cardiac toxicity
- **BIOMARKER TECHNOLOGIES**: Examine the development of biomarkers from discovery to application, taking a range of differing technologies and therapies into consideration
- **VIRTUAL LEAD OPTIMISATION**: Comprehend the validation of methodologies through case history by addressing the need to balance potency, safety and ADME properties from first principles
- **INFORMATION INTERCHANGE**: Interact and debate with some of the industry’s key experts and individuals at a mercantile yet scholastic convention

Supported by

**DrugResearcher.com**

PLUS A HALF-DAY POST-CONFERENCE EXECUTIVE BRIEFING

Project Management for Drug Discovery

17th March 2006, Millennium Gloucester Hotel, London

In association with: Bodiam Consulting Limited

Special Price for Academic Researchers Available

Register online at

www.smi-online.co.uk/preclinmb.asp

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

GROUP DISCOUNTS AVAILABLE
Day One
15th March 2006

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GROUP DISCOUNTS AVAILABLE

8.30 Registration & Coffee

9.00 Chairman’s Opening Remarks
Dr Alan Lewis, President, Celgene

OPTIMISING THE COMMUNICATION BETWEEN PRECLINICAL AND CLINICAL RESEARCH

9.10 The appropriate use of biomarkers
Dr Giles Campion, Head, Global Medical Research, GE Healthcare*

THE USE OF BIOMARKERS AND TARGET VALIDATION

9.50 Humanising drug discovery
• High quality target validation is critical to the choice and selection of targets
• Translational science and biomarkers across the R&D spectrum are important for earlier validation
• Key functional validation experiments in in vitro and in vivo can help prioritise targets
• Use of small and large molecule therapeutics in humans can validate important biological pathways
Dr Harsukh Parmar, Executive Director, Global Discovery Medicine, Respiratory & Inflammation, AstraZeneca

10.30 Morning Coffee

BIOMARKER DISCOVERY AND DEVELOPMENT FOR THE HISTONE DEACETYLASE INHIBITOR MS-275

11.00 Interaction between preclinical and clinical research
• MS-275: a short introduction
• Analysis of kinetics of hyperacetylation in PBMCs and tumours
• Investigation of treatment effects on the serum proteome of an animal model
• Metabolomic analysis showing effects of MS-275 treatment in rat serum
Dr Oliver Politz, Research Scientist, Schering

PRECLINICAL RESEARCH

11.40 Identifying the unmet medical need
• Criteria for model selection
• Preclinical surrogates for clinical endpoints
• Designs/endpoints that translate across species
• Disease models and biomarker models
• Mechanistic intermediates and empirical validation
Dr Zorina Galis, Research Fellow, Atherosclerosis/Metabolic Syndrome Drug Hunting Team, Cardiovascular Discovery, Eli Lilly

12.20 Networking Lunch

BALANCING COMPOUND PROPERTIES FROM CONCEPT TO PRACTICE

1.50 Charting your course for success
• Addressing the need to balance potency, safety and ADME properties from first principles
• Integrating in silico models and in vitro data into design and decision tools for discovery projects
• Virtual lead optimisation: validation of methodologies through case history
• Future trends
Dr Matthew Segall, Head, Admensa Business, Inpharmatica

PRECLINICAL PHARMACOLOGY

2.30 PK/PD modelling in inflammation
• How to model inflammatory diseases in pharmacology
• PD assessment in pharmacology
• PD assessments in early clinical trials
• Different challenges for biologicals and small molecules
Dr Neil Gozzard, Director, Pharmacology, UCB Celltech

3.10 Afternoon Tea

TRANSLATIONAL RESEARCH IN ALZHEIMER’S DISEASE

3.40 From preclinical and clinical studies for biomarker discovery
• Identifying biomarkers of disease, drug efficacy and toxicity in preclinical studies
• Biomarkers of disease, disease progression and response to drug in Alzheimer’s patients
• Proteins that correlate with drug response in a cross-sectional study of hypertension
• Discriminating drug effects within a class and between classes
• Proteins that give insight into mechanism of action and off-target effects
Dr Daniel Chelsky, Chief Scientific Officer, Caprion

4.20 Translating disease-based proteomic biomarkers discoveries to assays for implementation in clinical trials
• Multi-institutional study design and sample handling considerations
• Proteomic interrogation of clinical samples to mine for novel biomarkers
• Univariate and multivariate data analysis techniques
• Biomarkers of disease severity as potential surrogates for monitoring drug efficacy
• Assay development and implementation in preclinical models and clinical trials
Dr Huw Davies, Manager, European Biomarker Discover Centre, Ciphergen

5.00 Chairman’s Closing Remarks and Close of Day One

* Presentation details subject to final confirmation

SPONSORSHIP AND EXHIBITION OPPORTUNITIES

SMi offers sponsorship, exhibition 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: Adrian Johnston, SMi Sponsorship on +44 (0) 20 7827 6074 or email: ajohnston@smi-online.co.uk

Want to know how you can get involved? Interested in promoting your financial services to this market? Contact Margaret Kiyimba, SMi Marketing on +44 (0) 20 7827 6072 or email: mkiyimba@smi-online.co.uk

Case Study
Day Two
16th March 2006

Register online at www.smi-online.co.uk/preclinmb.asp
Alternatively fax your registration to +44 (0) 870 9090 712 or call +44 (0) 870 9090 711
GROUP DISCOUNTS AVAILABLE

8.30 Re-registration & Coffee

9.00 Chairman’s Opening Remarks
Dr Harsukh Parmar, Executive Director, Global Discovery Medicine, Respiratory & Inflammation, AstraZeneca

NOVEL BIOMARKER DEVELOPMENT

BIOMARKERS
9.10 From discovery to application
• Discovery technologies
• Issues of evaluation
• Application of biomarkers now and in the future
Dr Hans Winkler, Senior Director & Head, Functional Genomics, Johnson & Johnson

METABOLIC APPLICATIONS OF BIOMARKERS
9.50 Preclinical discovery and planning
• What types of metabolic biomarkers are available?
• Strategies for metabolic biomarker discovery
• Development of assays for metabolic biomarkers
• Applying metabolic biomarkers in research and early clinical studies
Dr Jarko Kochan, Director Biomarkers, Metabolic & Vascular Diseases, F. Hoffmann-La Roche

VALIDATION FOR SUCCESSFUL BIOMARKER MEASUREMENT
11.00 Fit-for-purpose method development
• An overview of the recently published paper of the AAPS LBA/BFG Biomarker Committee
• The history behind the committee’s formation, it’s members and proceedings, summarising the outcomes covered in the paper and how the major recommendations were conceived
• All aspects of assay validation, including how and why some validation experiments differ from both PK and diagnostic assays
• Potential pitfalls in biomarker analysis
• Case studies
John Allinson, Laboratory Director, Bioanalytical Systems

TRANSFERRING DATA TO THE CLINICAL PHASE

TRANSLATIONAL RESEARCH AT THE MOLECULAR LEVEL
11.40 Understanding disease mechanisms
• Coupling model systems to human biology
• In vitro studies to experiments in vivo
• Developing more predictable assays
• Improving confidence in project selection
Dr Anders Åberg, Chief Scientific Officer, Sidec Technologies

IMAGING BIOMARKERS
1.50 Utility of imaging at the interface of discovery and development
• In vivo imaging techniques (MRI, CT and PET) as translational possibilities
• Imaging to explore novel clinically relevant read-outs
• Imaging for establishing linkage of pathway and read-outs
• Impact of drug discovery
Dr Sudeep Chandra, Director, Imaging Sciences, Millennium

EGFR AS A CANCER DRUG TARGET
2.30 A case study
• Over 50 small molecule kinase inhibitors or monoclonal antibodies to this target are currently in clinical development for cancer and three are now on the market
• Downstream biomarker identification and quantitation enables logical decision-making and downstream comparisons of efficacy
• Molecular signatures that predict response are essential to personalise therapy
• Phosphoprotein mapping by immunohistochemistry and proteomics are likely to uncover novel biomarkers that can be used as response surrogates
• The use of biomarkers and surrogates will enhance of EGFR inhibitor development, speed to market, life-cycle management through identification of likely target diseases
Professor Karol Sikora, Professor of Cancer Medicine, Imperial College London, & Scientific Director, Medical Solutions

CYTOMETRIC EVALUATION OF CELL-BASED BIOMARKERS
3.40 Phase 0 and Phase I clinical investigations
• Utility of cytometric platforms for biomarker discovery and application in clinical studies
• Fit-for-purpose validation and benchmarking
• What types of biomarkers are best measured by flow cytometry/laser scanning cytometry?
• Case studies
Dr John Ferbas, Principle Scientist, Clinical Immunology, Amgen

PREDICTIVE BIOMARKERS AND USEFUL MODELS TO ASSESS CARDIAC TOXICITY
4.20 A case study
• Review of serum biomarkers for cardiac toxicity
• Review of gene microarray databases for cardiac toxicity
• Useful models to assess cardiac toxicity
• Presentation of case study
Dr Laurie Iciek, Senior Research Toxicologist, Abbott

5.00 Chairman’s Closing Remarks and Close of Conference

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About the SMi Pharmaceutical Team

SMi have been involved in the Pharmaceutical industry since 1993 and have developed a series of informative and niche events, covering the latest issues and developments surrounding the industry.

Events bring together senior industry professionals and serving companies who have a focus on being at the forefront of developments in this area. SMi aim to generate informed and topical discussion through the medium of both Conferences and Executive Briefings.

Our Pharmaceutical events are research-based and content driven with regular contact with major industry personnel and cover a wide range of industry sectors. For more information please visit www.smi-online.co.uk/pharma.asp

Pharmaceutical Forward Planner

JANUARY 2006
23/24 High Throughput Screening
25/26 Innovating Clinical Drug Development
30/31 Therapeutic Antibodies

FEBRUARY 2006
6/7 Market Opportunities & Technology Trends in Point of Care Diagnostics
13/14 Controlled Release
15/16 A Risk-Based Approach to Computer Systems Validation
22/23 Packaging & Labelling for the Pharmaceutical Industry
27/28 Drug Design V

MARCH 2006
13/14 Imaging in Oncology
15/16 Preclinical Models & Biomarkers
20/21 Pricing & Reimbursement in North America
27/28 Accelerating Patient Recruitment in Clinical Trials

APRIL 2006
5/6 Generics, Supergenerics & Patent Strategies
24/25 Superbugs & Superdrugs: A Focus on Antibacterials
24/25 Reporting Adverse Events
26/27 Asthma & COPD
About the executive briefing:
The Executive Briefing will outline the importance of project management to drug discovery. The briefing will cover why you should either introduce project management, if it does not exist, or refresh project management if you have already adopted it. The focus will be on what you need to consider for your organisation to improve its success and competitive position. It will involve both presentations and interactive sessions.

8.30 Registration & Coffee

9:00 Project management in discovery
- Why?

9:10 Designing and implementing a project management office (PMO) for an R&D organisation
- Developing the business case
- Best practices in developing a PMO
- Allocating project management resources
- Proactively managing a PMO

10.00 Project management at the beginning of drug development
- The project objective
- Work breakdown structure and responsibility matrix
- Scheduling and budgeting
- Project planning

10:45 Interactive session
- What do you want from project management?

11:00 Morning Coffee

11:15 Project Management in a global setting
- Project strategy
- Control and coaching
- Project culture

11:50 Interactive session
- Current practice

12:00 Effective project management methods across discovery and development
- Ensuring effective drug candidate feasibility assessments
- Facilitating the discovery to development hand over
- Developing high performance strategic relationships
- Examining risks and benefits

12:10 Discussion and questions – review of the session

12:30 Close of Executive Briefing

About your Briefing Leader:
Keith Rodgers is CEO of Bodiam Consulting Limited. Prior to his present position Keith was a Project Leader at Xenova and has worked as a director of Technical and Business Development for a packaging organisation. He spent over 20 years working for Wellcome and Glaxowellcome in a variety of roles including project manager in R&D where he worked on pharmaceutical, technology and scientific IT projects. He also played a key role as an internal consultant working on a business process redesign initiative. He holds a MBA, Diploma in Company Direction, MSc and an Honours degree.

About the Company:
Bodiam Consulting has provided project management support to assist a company progress from preclinical to Phase I clinical trials, led and managed a virtual project team, designed and delivered a project management training programme for a European biopharmaceutical company. In addition to providing virtual drug development services to the pharmaceutical, biotechnology and medical device sectors, Bodiam Consulting can also provide other bespoke services including: Scenario planning, strategic analysis and creative & innovative approaches to, for example, change initiatives.
# Preclinical Models & Biomarkers

15th & 16th March 2006, Millennium Gloucester Hotel, London  
Executive Briefing: 17th March 2006

## 4 Ways to Register

### Online

Post your booking form to: Events Team, SMi Group Ltd, Great Guildford Business Square, 30 Great Guildford Street, London SE1 0HS, United Kingdom

Phone on +44 (0) 870 9090 712

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

**Email**: sales@smi-online.co.uk

**Website**: www.smi-online.co.uk/preclinmb.asp

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### Early Bird Discount

Register before 23rd December 2005 and receive a £100 discount

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### Conference Prices

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<thead>
<tr>
<th>Description</th>
<th>Price</th>
<th>Total</th>
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<tr>
<td>Conference &amp; Executive Briefing</td>
<td>£1778.00 + VAT</td>
<td>£2089.15</td>
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<tr>
<td>Conference only</td>
<td>£1279.00 + VAT</td>
<td>£1502.83</td>
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<tr>
<td>Executive Briefing only</td>
<td>£499.00 + VAT</td>
<td>£586.33</td>
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<td><strong>ACADEMIC FEE</strong></td>
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<tr>
<td>Conference &amp; Executive Briefing</td>
<td>£1198.00 + VAT</td>
<td>£1407.65</td>
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<tr>
<td>Conference only</td>
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<tr>
<td>Distribution of your company's promotional literature to all conference attendees</td>
<td>£999.00 + VAT</td>
<td>£1173.83</td>
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### CD ROMs/Documentation

- The Conference Presentations - paper copy
- The Conference Presentations - audio on CD ROM

- Distribution of your company's promotional literature to all conference attendees

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### Payment

Payment must be made to SMi Group Ltd, and received before the event, by one of the following methods quoting reference T22 and the delegate’s name. Please indicate method of payment:

- UK BACS: Sort Code 40-06-21, Account 91618695
- Wire Transfer: HSBC Bank plc, 28 Borough High Street, London, SE1 1YB
  - Swift (BIC): MILDLGB2, Account 91618695
  - IBAN: GB09MIDL40062191616869

- Cheque: We can only accept Sterling cheques drawn on a UK bank.
- Credit Card: Visa, MasterCard, Diners Club, American Express

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### Venue

Millennium Gloucester Hotel, 4-18 Harrington Gardens, London SW7 4LH

Book your accommodation at SMi discounted rates by calling us on +44 (0) 870 9090 713 or emailing hotels@smi-online.co.uk or send your fax to +44 (0) 870 9090 714

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**Fax**: +44 (0) 870 9090 712

**Email**: pca@smi-online.co.uk

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### Data Protection

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