

# Biomarkers in Drug Development

12th – 13th September 2007 London, UK



Driving innovation in the application of biomarkers to maximise clinical productivity

**ACI's inaugural Biomarkers in Drug Development Conference** will examine the latest uses of biomarkers in development, with a key focus on integrating biomarkers earlier in the clinical, and maximising their use as part of a personalised approach to treatment.

Hear from key industry leaders working in this innovative field of research and discover the challenges they are facing and solutions being applied to maximise the function of biomarkers as a vital research tool within your drug development strategy.

## THE AGENDA

Throughout the 2 days you will have the opportunity to hear from your industry peers and discover the hottest developments in the employment of biomarkers research:

- *Discover how to assess the true value of biomarkers*
- *Understand the practical challenges of applications*
- *Examine the development of more sensitive biomarkers of toxicity*
- *Hear cutting-edge case studies looking at real applications across a number of therapeutic areas*
- *Consider how the integration of markers earlier in development can maximise safety and accuracy of studies*

## AN INTERACTIVE 2 DAYS

ACI's meetings offer the perfect opportunity to discover the latest updates and to discuss your own research challenges and solutions with your peers through an interactive and informative 2 day programme.

- Hear from an outstanding line-up of the industry's leading researchers.
- Network informally with a relatively small, targeted group of senior-level researchers and decision-makers from the pharmaceutical and biotechnology industries.
- Learn more about your peers' research, network with key industry leaders and your industry colleagues.
- Discuss the latest challenges and developments in this rapidly changing and growing sector of the industry.
- Participate in roundtable sessions – giving you the chance to discuss the latest issues with your colleagues – and the speakers - in an open, informal and intimate setting.

## Who will attend?

All ACI's events attract a targeted group of senior level researchers and decision-makers from industry. **Our meetings are strictly end-user focussed.** Only a select group of companies are invited to sponsor the event – to ensure the emphasis is on the industry participants, and making sure our delegates have a valuable and positive experience.

Delegates will be drawn from pharmaceutical and biotechnology companies and include VPs, Directors and Managers of: Biomarkers, Translational/Experimental Medicine, Clinical Research/Development, Pharmacology, Toxicology and Safety Assessment, Clinical PK/PD, Discovery Medicine, Molecular Medicine/Diagnostics

## TESTIMONIALS FROM PREVIOUS ACI PHARMACEUTICAL EVENTS:

*"Complete overview. Interesting, exciting, relevant!"*

*"The event was excellent. The speakers were excellent, the organisation was excellent!"*

*"Excellent on every level"*

*"I look forward to next year's conference"*

## SPEAKERS INCLUDE:

**Dr. Nicholas Dracopoli**, Vice President, Clinical Discovery Technologies, Bristol-Myers Squibb

**Dr. Holly Soares**, Director, Translational Medicine, Pfizer

**Dr. Garret Hampton**, Senior Director, Biochemistry & Biomarker Development, Celgene

**Dr. Eric Blomme**, Project Leader, Cell and Molecular Toxicology, Abbott Laboratories

**Dr. Andrew Lockhart**, CPDM-Neurology Biomarker Group, GlaxoSmithKline

**Dr. Helen Young**, Senior Imaging Scientist, AstraZeneca

**Dr. Jingsong Wang**, Associate Director, Translational Medicine, Wyeth Research

**Dr. Gerald V Doyle**, Senior Director, Clinical Research, Immunicon Corp.

**Dr. Neil Gibson**, Research and Development Genetics, AstraZeneca

And many more....

For more information or to register for this exclusive event, contact ACI  
By calling +44 (0) 207 368 3360  
Emailing [delegations@acius.net](mailto:delegations@acius.net)  
Or visit the event website and register online: <http://www.acius.net/?cID=288>

Official sponsor:



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## DAY ONE: 12<sup>th</sup> September 2007

**08.00 Registration and Coffee**

**09.00 CHAIRMAN'S OPENING ADDRESS**

**09.10 KEYNOTE ADDRESS**

**Integrating Biomarkers in Early Clinical Development**

**Dr. Holly Soares**, Director, Translational Medicine, Pfizer

**09.50 CONFERENCE PRESENTATION**

**Determining the True Cost and Value of Biomarkers – Challenges in Identifying Biomarkers with Real Predictive Value**

**Dr. Garret Hampton**, Senior Director, Biochemistry & Biomarker Development, Celgene

**10.30 CONFERENCE PRESENTATION**

**Practical Challenges in Biomarker Applications**

**Dr. Johannes Lampe**, Director, Medical Development Specialized Therapeutics, Europe, Bayer Schering AG (invited)

**11.10 Morning Refreshments**

**11.40 CONFERENCE PRESENTATION**

**Translating Preclinical Biomarkers into Clinical Drug Development**

- Taking a more dynamic approach to quantification of responses

**Dr Ellen Bech Christensen**, Specialist, H. Lundbeck A/S

**12.20 CONFERENCE PRESENTATION**

**The Toxicology Challenge: Finding More Sensitive Biomarkers of Toxicity?**

- Finding safety biomarkers to predict toxicity earlier

**Dr. Eric Blomme**, Project Leader, Cell and Molecular Toxicology, Abbott Laboratories

**13.00 Lunch**

**14.20 CONFERENCE PRESENTATION**

**Biomarkers in Early Safety and Toxicity Assessment**

**Dr. Michael Zuehlisdorf**, Novartis (invited)

**15.00 CONFERENCE PRESENTATION**

**Transdermal Alzheimer Drug Development (ExelonR) Supported By Butyrylcholinesterase Biomarker**

**Dr. Silke Appel-Dingemanse**, Global Head, DMPK PK Neurosciences, Novartis Pharma AG

**15.40 Afternoon Refreshments**

**16.10 CONFERENCE PRESENTATION**

**Case Study: Using Drug-Specific Biomarkers to Enhance Development**

- Translating preclinical biomarker identification to the clinical setting
- Application of gene-based markers to predicting and detecting response

**Dr. David K. Bol**, Senior Vice President, Product and Pharmaceutical Development, Avalon Pharmaceuticals

**16.50 “Interactive” ROUNDTABLE DISCUSSIONS**

**Topics to be covered include:**

- Biomarker applications in cancer therapeutics
- Determining the value and ROI of biomarker applications
- Integrating biomarkers into studies earlier in development

**Roundtable Chairs include:**

**Dr. Gerald V Doyle**, Senior Director, Clinical Research, Immunicon Corp.

**17.50 Drinks Reception and End of Day One**

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## DAY TWO: 13<sup>th</sup> September 2007

08.30 Registration and Coffee

09.00 CHAIRMAN'S OPENING ADDRESS

09.10 KEYNOTE ADDRESS

**Biomarker Applications in Drug Development**

**Dr. Nicholas Dracopoli**, Vice President, Clinical Discovery Technologies, Bristol-Myers Squibb

09.50 CONFERENCE PRESENTATION

**Aligning Biomarker Studies within Clinical Trials: Incorporating Biomarkers into the Flow of Drug Development**

**Dr. Jingsong Wang**, Associate Director, Translational Medicine, Wyeth Research

10.30 CONFERENCE PRESENTATION

**Modifying Trial Design to Maximise Benefit of Integrating Biomarkers into Clinical Trials**

**Dr. Holly Posner**, Director, Clinical Research and Development, Eisai Medical Research Inc (invited)

11.10 Morning Refreshments

11.40 CONFERENCE PRESENTATION

**Validation for Successful Biomarker Measurement**

- Overview of Biomarker Assay "Issues" for the Laboratory
- AAPS Biomarker Committee
- Validation recommendations from the white paper
- Case Studies

**Dr. John L Allinson**, Director, Veeda Clinical Research Ltd.

12.20 CONFERENCE PRESENTATION

**Case Study: Major Pharmacogenetics Studies Using a Combination of Genome-Wide Tagging SNPs and High Density SNP Genotyping in Candidate Genes**

**Dr. Neil Gibson**, Research and Development Genetics, AstraZeneca

13.00 Lunch

14.20 CONFERENCE PRESENTATION

**Amyloid Imaging Agents as Non-specific Markers of Cerebral Amyloidosis**

- Identification of dementia patient populations to target with amyloid lowering therapies

**Dr. Andrew Lockhart**, CPDM-Neurology Biomarker Group, GlaxoSmithKline

15.00 CONFERENCE PRESENTATION

**Key Challenges in Developing Decisive Imaging Biomarkers**

- Current status of imaging biomarkers in drug development
- "Qualification" of imaging biomarkers for portfolio risk management
- Examples of imaging biomarkers in early drug development
- Overview of the Biomarker consortium and qualification of FDG-PET
- From "qualified" biomarker to surrogate for clinical outcome

**Dr. Helen Young**, Senior Imaging Scientist, AstraZeneca

15.40 Afternoon Refreshments

16.00 Closing remarks

**End of conference**

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## 5 EASY WAYS TO REGISTER

Tel: +44 20 7368 3360  
Fax: +44 20 7368 3365  
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Web: <http://www.acius.net>  
Mail: Vicarage House  
58/60 Kensington Church Street, London, W8 4DB

## TERMS AND CONDITIONS

### How to Register

Registrations must be received in writing or electronically at our secure web site. Please complete and mail or fax a copy of registration form with a cheque or credit card number. Fee includes program materials, continental breakfast, networking luncheon and refreshments.

### Payment

Payment must be received within five business days of returning the signed contract. After receiving payment a VAT receipt will be issued. If you do not receive a letter outlining details two weeks prior to the event, please contact the Conference Co-ordinator at ACI Europe Ltd.

**Discounts are available for multiple/group bookings. Please call +44 20 7368 3360 for more information**

### Cancellations

Substitutions are welcome up to 24 hours prior to the event. Cancellations must be received in writing no less than 3 weeks prior to the start of the conference; a full credit voucher towards a future ACI conference will be issued. Any cancellation received less than 3 weeks prior to the start of the event shall be deemed to be a breach of this contract by client, and accordingly, no credits will be given. By completing this registration form, the client hereby agrees that in case of dispute or cancellation ACI Europe Ltd will not be able to mitigate its losses for any less than 50% of the total contract value. Cancellations must be received in writing by mail or fax three weeks before the conference. Thereafter the full conference fee is payable. If for any reason ACI Europe Ltd decides to amend, cancel or postpone this conference, the conference fee will not be refunded. Furthermore, ACI Europe Ltd will not be responsible for covering airfare, hotel or other costs incurred by registrants. In the event that ACI Europe Ltd cancel or postpone the event, ACI Europe Ltd reserves the right to transfer this booking to another conference to be held in the following twelve months, or to provide a credit of an equivalent amount to another conference within the following twelve months. The construction, validity and performance of this agreement shall be governed in all respects by the laws of England to the exclusive jurisdiction of whose courts the Parties hereby agree to submit.

### About ACI

ACI, a UK owned company, have been running successful conferences for the last 8 years in the USA. Headquartered in Chicago with offices all around the States, they run forums in varied fields and are market leaders in Healthcare business conferences. Opening their European head office at the end of 2005, they have expanded rapidly and are launching a series of events covering emerging markets, the maritime industry and now the pharmaceutical industry.

### Venue:

Central London, UK. Details to be confirmed.

The cost of accommodation is not included in the event fee.

Preferential rates will be arranged with or near the event venue, and all confirmed delegates will be given details of how to book accommodation at this rate in due course.

### Prices and Payment Information

Conference (Includes Documentation Packet)	12 <sup>th</sup> – 13 <sup>th</sup> September 2007	£1,495 (+ VAT)
Documentation Packet	Copies of all conference proceedings	£295

### Documentation Packet Available

You can purchase the Biomarkers in Drug Development papers at just £295. Simply tick the box on the booking form, send it with payment and your copy will be on its way to you after the meeting. This important manual will be a source of invaluable reference for the future.

### Discounted Registrations

Members and customers of all supporting organisations are entitled to a 20% discount off their conference package. The deadline for discounted registrations is Wednesday 30<sup>th</sup> May 2007.

For more information please call +44 20 7368 3360.

### Media Partners:

