



Oncology Drug Development World Europe

14 – 16 October 2008, The Hilton London Euston Hotel, London, United Kingdom

Progression from clinic to patient

Key speakers include



Dr Roy Baynes
Vice President,
Therapeutic Area
Head, Oncology
Amgen



Dr Clive Morris
Director, Late Stage
Oncology Clinical
Development
AstraZeneca



Dr Haren Rupani
Executive Director
& Global Head
of Oncology,
Clinical Imaging
Novartis



Dr Bahija Jallal
Vice President,
Translational Science
& Head Oncology
MedImmune



Dr Simon Day
Statistical Expert
Roche



Dr Donald Bergstrom
Director and Oncology
Franchise Lead,
Experimental Medicine
Merck & Co



Ms Colleen Mockbee
Associate Director,
US Regulatory Affairs
Eli Lilly & Co



Dr Jean-Yves Bonnefoy
Vice President, Research
& Development
Transgene

Critical issues to be addressed:

- Directional strategies for oncology therapeutics
- The value of oncology drugs
- Review of regulatory requirements
- Biomarkers to aid drug development and stratification
- Patient selection to enhance proof of concept
- Adaptive trial design for seamless development
- Partnering in oncology drug development
- Clinical case studies from leading pharmaceutical and biotechnology companies

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Progression from clinic to patient

Strategic, clinical and regulatory solutions for the critical issues in oncology drug development

The World market for cancer therapeutics is growing at a brisk double digit pace with revenues surpassing \$40 billion a year. The industry is investing 20% of its global R&D and in the past decade it has now become the most significant area of drug development.

The success rate for developing an oncology drug is only 5% with an average development time of 9 to 12 years, of this 50% spent in phase II and III trials.

The 2nd annual *Oncology Drug Development World Europe* brings together top pharmaceutical, biotechnology and regulatory representatives in a forum that addresses the key issues. The varied agenda approaches the major challenges that affect the development of oncology therapeutics through addressing the following topics:

- How can biomarkers be used to improve predictivity in early research?
- Are therapeutic cancer vaccines the perfect drug?
- Who pays for innovation?
- How can translational development be used to optimise proof of concept?
- Partnering and licensing to optimise your oncology portfolio



Meet key oncology professionals

Who will attend?

This event will be attended by heads and managers working in the pharmaceutical and biotechnology industry in the following departments:



Discussing the future direction of oncology drug development and the challenges in bringing a product to market.

At *Oncology Drug Development World Europe* there will be a panel of the world's most eminent drug development scientists and strategists who will be coming together to discuss the future of oncology drug development and the hurdles of bringing a product to market.

Read the reviews of delegates who attended the 2007 European event:

“ **Beneficial; a good overview to oncology** ”

Lynn Wilson,
Clinical Scientist, **Biogen Idec**

“ **Very good clinical aspect** ”

Dr Shabir Hasham,
Medical Affairs, **Novartis**

“ **Good topics, useful regulatory section and good case studies** ”

Dr Rob Williams,
Head of Drug Development, **Cancer Research**

healthnetwork Health Network Communications COMMUNICATIONS is an international events company dedicated to providing conferences, training courses and seminars for the life sciences community. Through our network of advisors in industry, academia and the regulatory authorities, we are able to develop quality events that discuss and find solutions to some of the most pressing issues in the life sciences sector today. For further information please visit www.healthnetworkcommunications.com.

With cutting edge presentations from industry leaders, breakout discussion and networking sessions, there can be no better way of staying abreast of the latest developments in oncology drug development.

The earlier you book the more you save.

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Progression from clinic to patient

08:30 Registration & coffee**08:50 Opening remarks from the chair****09:00 Directional strategies for oncology therapeutics**

- Current state of oncology drug development and reasons for failure
- Proposed alternatives for improving success in oncology drug development
- Examples of oncology drug development strategies for early decision-making and maximisation of probability of success

Dr Donald Bergstrom, Director and Oncology Franchise Lead, Experimental Medicine, **Merck & Co**

09:30 The value of oncology drugs in development

- Review of recent deals by stages of development
- Is there space in the market for so many new products?
- Reimbursement issues
- Deal valuation

Brian Lovatt, Managing Director, **Cancer Deals**

10:00 Morning tea

Make the most of the extended refreshment breaks

10:30 European regulatory perspective: an independent personal view

- Importance of survival and progression
- Translating endpoints into benefits
- Standardising biomarkers
- Conditional approval

Dr John Warren, Expert Medical Assessor, **MHRA**

11:00 US regulatory perspective

This presentation will:

- Provide a perspective on the regulatory mechanisms for accelerating anticancer agent development and approval in the U.S. and the necessity of a comprehensive development plan
- Discuss the endpoints for oncology registration studies including potential FDA review issues and how proper planning can reduce the potential for ambiguity as an outcome
- Assess the regulatory challenges of targeted therapies on design of global registration studies

Dr Colleen Mockbee, Associate Director, US Regulatory Affairs, **Eli Lilly & Co**

11:30 Improving decision making in early clinical trials

- Limitations of extrapolations of early development
- Appropriate deployment of biomarkers
- Choice of study populations

Dr Glen Clack, Associate Director, Discovery Medicine, **AstraZeneca**

12:00 Use of adaptive designs for developing oncology compounds

- Possible novel / adaptive designs to consider
- Strategies for implementation
- Addressing (and taking) scientific risks
- Addressing regulatory concerns

Dr Simon Day, Statistical Expert, **Roche Products Limited**

12:30 Lunch**13:30 Predictive biomarkers in oncology drug development**

- Understanding the disease, target and therapy
- Preclinical models for the discovery of predictive biomarkers
- The interplay between positive and negative predictors

Dr Richard Wooster, Director, Translational Medicine, **GlaxoSmithKline**

14:00 A look at the laboratory aspects of biomarker analysis for quantitative assays

- Overview of biomarker assay issues
- Choice of laboratory & scientific consensus
- AAPS - LBABFG biomarker committee
- Validation recommendations
- Case studies

John Allinson, Director, **Veeda Oncology**

14:30

This is a revolutionary, exciting and quick way to meet fellow delegates and industry peers in a 45 minute session. These meetings are the starting point for networking throughout the event. Make sure you bring plenty of business cards!



Meet...move on...meet...move on...meet!

15:15 Afternoon tea**15:30 Exploratory imaging in oncology drug development**

- What is exploratory imaging?
- What clinical questions can be answered and is the cost justified?
- Challenges with imaging when implementing multinational, multicentre oncology trials

Dr Haren Rupani, Executive Director & Global Head of Oncology Clinical Imaging, **Novartis**

16:00 Strategies to optimise phase III oncology trials

- Improving patient selection and retention
- Strategies to optimise the use of targeted agents

Dr Jay Mei, Director, Oncology Clinical Development, **Novartis**

16:30 Model simulated design for cancer therapies

- Integration of systems biology, modelling and simulation
- Illustrating the applications of these tools in increasing the efficacy and productivity
- Case study

Dr Ulrik Nielsen, Vice President, Research, **Merrimack Pharmaceuticals**

17:00 Chairman's closing remarks**17:10****Networking drinks reception**

The networking drinks reception will be the evening highlight of *Oncology Drug Development World Europe*. Develop new contacts or strengthen relationships you have previously made in a relaxed and informal setting.

Progression from clinic to patient

08:30 Registration & coffee

08:50 Opening remarks from the chair

09:00 European perspective; who pays for innovation?

- New targeted therapies / treatments that are hitting the market
- Gaining market access
- Cost of new treatment; who pays?
- European healthcare providers expectations from industry

John de Wit, Business Unit Director, **Amgen**

09:30 Strategies for developing successful oncology therapies

- Targets: mixing the chemists with the molecular biologists
- Markers: mixing the pathologists with the imaging experts
- Phase 0,1,2: mixing the academic clinicians with the preclinical teams
- Patients: mixing with the ethicists, advocates, and all the above.
- Funders: mixing industry (large and small) with academia, not-for-profits, civil servants and patients

Prof Gordon McVie, Director, **Cancer Intelligence**

10:00 Morning tea

10:30 Partnering in oncology drug development; what are big pharmaceutical companies looking for?

- Forces reshaping the pharmaceutical Industry
- Oncology: success and its consequences
- What is Roche looking for in oncology innovation and partnerships?

Warwick Bedwell, Vice President and Global Head of Business Development, **Roche**

11:00 Case study: partnering in oncology drug development

- Clinical development partnership programme
- Innovative new ways to progress new drug candidates
- Case study: AZD0424

Dr Victoria John, Head of Clinical Partnerships, **Cancer Research UK**



Ask questions to the panel of expert speakers

11:30 Optimising strategies to fully capitalise on opportunities

- The importance of internal co-ordination and organisation
- The importance of communication and relationship building with potential partners
- Successes in building up an oncology pipeline

Dr Margaret Beer, Senior Director and Head, Licensing and External Research, Europe, **Merck Sharp & Dohme**

12:00 Panel discussion: discussing the future direction for oncology drug development and overcoming challenges

12:45 Lunch

13:45 Are therapeutic Cancer vaccines the perfect drug?

- Scientific rationale
- Synergy with other cancer treatments
- Clinical results
- Biomarker signatures

Dr Jean-Yves Bonnefoy, Vice President, Research and Development, **Transgene**

14:15 Key principles for Amgen's targeted oncology pipeline

- Innovative interdiction of important targets in the treatment and supportive care of the Cancer patient
- Optimising the therapeutic modality for the given target
- Having a science and biology focus to the development strategy
- Employing informative biomarkers where possible for appropriate patient selection

Dr Roy Baynes, Vice President, Therapeutic Area Head, Oncology, **Amgen**

14:45 Afternoon tea



Use the contact system to book meetings prior to the event

15:15 Challenges in the development of a targeted therapy: gefitinib

- Early clinical data
- Results of pivotal studies and efforts to delineate subgroups of increased sensitivity
- Learning for development of future targeted therapies

Dr Clive Morris, Director, Late Stage Oncology Clinical Development, **AstraZeneca**

15:45 Gaining approval of Tykerb (lapinib) a first in class therapy for breast Cancer

- The role of targeted therapies
- Clinical development of new targeted agent
- New era of tailored treatments

Dr Cristina Oliva, Clinical Director, Oncology, **GlaxoSmithKline**

16:15 Therapeutic antibodies in oncology: enhancing anti-tumor activity through antibody engineering

- Overview of therapeutic antibodies in oncology
- Antibody engineering and technologies to modify activities and effector function
- Brief review of two specific examples: CD19 and CEA-Bite

Dr Bahija Jallal, Vice President Translational Science & Head of Oncology, **MedImmune**

16:45 Closing remarks from the chair

The definitive event for oncology drug development

Fax back the registration form to +44 (0) 207 608 7050 or visit www.healthnetworkcommunications.com

Tuesday 14 October 2008

Pre-conference workshop

Biomarker assay development and validation

Tuesday 14 October, The Hilton London Euston Hotel, UK

This practical and interactive tutorial will focus on the recommendations for the best practices in the development and validation of bio-marker assay development, method validation and sample analysis, with special emphasis on assays where a reference standard material is available.

The workshop will begin at 10:00 and will end at 15:30.
Lunch and refreshments will be provided.

Agenda:

- Introduction – Nomenclature, types of biomarker methods/assays, biomarker method development & validation road-map, fundamental validity, similarity to PK assays & difference from diagnostic application.
- Pre-analytical and Bioanalytical elements: Target range, standards, validation & QC samples, stability, matrix effect, and relative selectivity.
- Calibration curve model selection, evaluation, and weighting.
- Method feasibility and optimisation with precision profiles.
- Evaluation of some pre-study validation characteristics such as precision, bias, sensitivity and quantification limits.
- Illustrations of pre-study validation and in-study validation (sample analysis).

Your workshop leader:

John Allinson, is a Fellow of the Institute of Biomedical Sciences (FIBMS) and, having spent 22 years in diagnostic laboratories in the National Health Service, has experience in all major fields of clinical pathology. He has managed and developed specialist laboratory services for drug monitoring, trace metals, and immunoassays. During his tenure in a large CRO, he developed analytical services for a large central clinical laboratory conducting all phases of pre-clinical and clinical trials. This work necessitated the validation of more than 100 immunoassays on a variety of analytical platforms.

Your workshop sponsor:

Veeda Oncology is a global oncology CRO – part of the Veeda CR family. We undertake Phase I-IV cancer clinical trials in Western, Central and Eastern Europe, the United States and India, using our teams of experienced oncology professionals. In the US and India we have exclusive relationships with oncology networks, enabling access to large cancer patient populations and excellent enrolment capabilities. At Veeda Oncology we offer our clients cancer study expertise, rapid and reliable enrolment, and a high quality, cost-effective service.

Networking

contact

Our online “contact” system allows you to make initial contact, arrange meetings and begin networking with your fellow delegates prior to the event. It allows you to take full advantage of the extended breaks and dedicated networking time by planning in advance the meetings that will drive your business forward. The system will be live 3 weeks before the event.



This is a revolutionary, exciting, quick and non-pressurised way to meet fellow delegates and industry peers in one 45 minute session. These brief meetings are the starting point for conversation and networking throughout the conference. **Make sure you bring along plenty of business cards for this session** which is where long lasting and fruitful relationships begin.

- The best 45 minute networking session you’ve ever experienced!
- Meet ... move on ... meet ... move on ... meet!
- Exchange business cards with fellow delegates, speakers and moderators



The conference program includes several panel sessions. These are chat show style sessions creating an interactive environment rather than a lecture. The panelists are chosen for their views and lively debate is encouraged. This is your chance to interact and put your questions to the panel to ensure that the experts can answer the questions that are relevant to your business.



Health Network’s evening drinks receptions allow you to continue the conversations you began during the congress. Join us to relax with your peers and experience toasting the developments in your industry.

The venue

Hilton London Euston hotel

Chic and central, the Hilton London Euston hotel is only 5 minutes from Euston Station and within a mile of The City. Set in a stunning Victorian building, the hotel boasts 11 meeting rooms, a gym and sauna. Enjoy fine dining in the smart conservatory of Woburn Place Dining Room or host a banquet on its terrace.

www.hilton.co.uk/Euston

To register for the pre-conference workshop or to make an enquiry call +44 (0) 207 608 7055 register online at www.healthnetworkcommunications.com

Speaker highlights

Challenges in the development of a targeted therapy: gefitinib



Dr Clive Morris

Director, Late Stage Oncology Clinical Development
AstraZeneca

Dr Morris is currently the Director for Late Stage Oncology within Clinical Development at AstraZeneca. Dr Morris has held roles across the spectrum of drug development in Oncology from interaction with drug discovery to maximising brand value. Prior to joining AstraZeneca, he trained in surgery leading to accreditation by the Royal College of Surgeons of England, and subsequently gained a Doctorate of Medicine research degree

Partnering in oncology drug development, what are big pharmaceutical companies looking for?



Mr Warwick Bedwell

Vice President,
Global Head of Business Development Pharma Partnering
Roche Pharmaceuticals

Mr Bedwell leads the Business Development team, which spearheads Roche's external search and for potential partners. Prior to Roche, Warwick held positions of increasing responsibility at Schering-Plough in Australia and Asia and other healthcare-related companies. In March 2007 he was elected a member of the Board of the New York Pharma Forum. Warwick has a PharmD from the University of Sydney and a Masters in Business Administration and a Post-Graduate Diploma in Marketing.

Use of adaptive designs for developing oncology compounds



Dr Simon Day

Statistical Expert
Roche Products Limited

In 1990 Dr Day joined Eli Lilly heading a group of Statisticians and Data Managers. In 1994 he moved to Leo Pharmaceuticals heading a similar group. In 2002 he joined the Medicines Control Agency (now MHRA), initially as Statistics Unit Manager and later he managed the assessment of all gastrointestinal, nutritional and blood therapies. He was Vice-Chairman of the CHMP Scientific Advice Working Party. In 2006 he joined Roche as a Statistical Expert.

Direction and strategies for oncology treatments



Dr Donald Bergstrom

Director and Oncology Franchise Lead,
Experimental Medicine
Merck & Co

Since February 2007 Dr Bergstrom has been Director and Oncology Franchise Lead in the Experimental Medicine department at Merck. This department is focused on improving the probability of success of development of novel targeted oncology drugs. Prior to joining Merck he trained in Laboratory Medicine and was a Post-Doctoral Associate at the Fred Hutchinson Cancer Research Centre. Dr. Bergstrom received his PhD and MD degrees at the University of Washington.

Key principles for Amgen's targeted oncology pipeline



Dr Roy Baynes

Vice President, Therapeutic Area Head for Oncology
Amgen Inc

Dr Baynes previous roles at Amgen have included GDL for Neulasta, GDL for Panitumumab, and TA Head for Medical Affairs Oncology. Before joining Amgen, he was Director of the Bone Marrow Transplant Program, the Stem Cell Biology Program, the JP McCarthy Umbilical Cord Stem Cell Bank and the Haematological Malignancies Multidisciplinary Clinic at the Barbara Ann Karmanos Cancer Institute.

Are therapeutic Cancer vaccines the perfect drug?



Dr Jean-Yves Bonnefoy

Vice President, Research and Development
Transgene

Dr Jean-Yves Bonnefoy, is in charge of Research, Clinical Development, Regulatory Affairs and Intellectual Property. Prior to joining Transgene, he was Head of the Canceropôle Lyon Rhône-Alpes. From 1997 to 2002, he was Director of the Immunology Centre of the Pierre Fabre Group, France. He previously was responsible for the Immunology Department of the Biomedical Research Institute of the Glaxo-Wellcome Group, Switzerland. Jean-Yves Bonnefoy holds a PhD in Immunology from the Lyons Claude Bernard University.

Therapeutic antibodies in oncology: enhancing anti-tumor activity through antibody engineering



Dr Bahija Jallal

Vice President, Translational Science & Head Oncology
MedImmune

Dr Jallal joined MedImmune as Vice President, Translational Sciences, in March 2006. In this role, Dr Jallal is developing the translational sciences group to assess biomarkers. In 2007, she was appointed Head, Preclinical Oncology. Previously, Dr. Jallal worked with Chiron Corporation where she served as Vice President, Drug Assessment and Development. Prior to Chiron, she worked at Sugen, Inc. where she held positions of increasing responsibility.

Exploratory imaging in oncology drug development



Dr Haren Rupani

Executive Director &
Global Head of Oncology Clinical Imaging
Novartis

Dr Rupani joined the pharmaceutical industry beginning with Bracco Diagnostics Inc, as a Director in Medical Affairs. Dr Rupani then joined Corixa / GlaxoSmithKline, as the Senior Director in Oncology responsible for Bexxar and Imaging in Oncology Drug Development. Dr Rupani is currently an Executive Director and Global Head of Oncology Clinical Imaging at Novartis, overseeing 40 trials involving 14 compounds from Pre-clinical to Phase IV.

US regulatory perspective for oncology drug development



Ms Colleen Mockbee

Associate Director of US Regulatory Affairs
Eli Lilly & Co

Ms. Mockbee specialises in the field of regulatory oncology drug development. She has over 10 years of drug development experience including preparing teams for FDA and advisory committee meetings as well as successful registration of new indications for commercial products. She is a pharmacist by training. Prior to joining Eli Lilly she worked as a pharmacist in the Veteran's Administration hospital and clinics, and as a sales representative for Merck & Co.

Optimising strategies to fully capitalise on opportunities



Dr Margaret Beer

Senior Director and Head, Licensing and
External Research, Europe,
Merck Sharp & Dohme

Dr Beer studied at the University of Reading and the University of London. Margaret joined the Worldwide Licensing and External Research Europe group, under the leadership of Dr Ray Hill, in 2003. This group was established in 2002 specifically in recognition of the scientific excellence in Europe and the wealth of potential licensing opportunities. Margaret assumed leadership of the group in 2008.

Sponsorship and exhibition opportunities at *Oncology Drug Development World Europe 2008*

Oncology Drug Development World Europe is where your clients will come to look for solutions you can provide.

Your direct route to market

Oncology Drug Development World Europe is the number one platform for world class vendors and solution providers to showcase products and expertise to a targeted audience. This is your chance to be part of the most cost effective marketing solution in drug development. Reduce the time taken to meet new customers, reduce the costs of advertising and maximise the return on your investment.

Simple questions to determine your participation

- Do you want to do business with senior decision makers from the leading pharmaceutical, biotechnology and research institutions from the oncology arena?
- Are you able to help companies further their oncology clinical research?
- Do you want a fast track to gaining competitive advantage and increased market share?

If your answer is yes to these questions then you should be participating at this event.

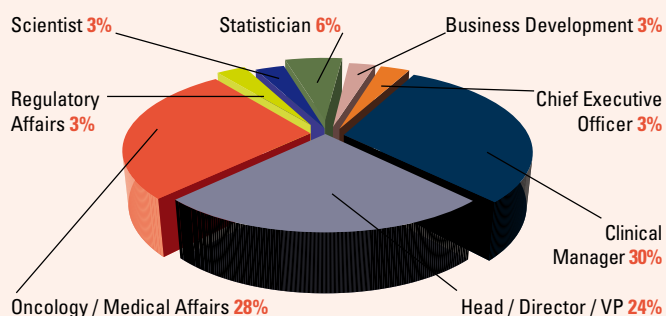
Delivering real results

No other event can give you exclusive access to senior decision makers from key pharmaceutical and biotech companies. Sponsoring or exhibiting is an exceptional opportunity to be part of a marketing campaign that guarantees a quality audience and also keeps your target markets informed about you.

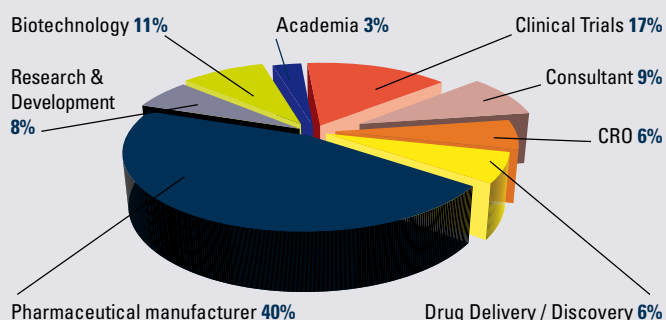
Meet the people that matter to your business

Look at who attended in 2007 so you can be sure that you will meet your prospects there:

Organisation by job function



Organisation by industry type



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Veeda Oncology is a global oncology CRO – part of the Veeda CR family. We undertake Phase I-IV cancer clinical trials in Western, Central and Eastern Europe, the United States and India, using our teams of experienced oncology professionals. In the US and India we have exclusive relationships with oncology networks, enabling access to large cancer patient populations and excellent enrolment capabilities. At Veeda Oncology we offer our clients cancer study expertise, rapid and reliable enrolment, and a high quality, cost-effective service.



ORION Clinical Services is a full service clinical development organisation performing all aspects of clinical trials. We are a dynamic, proactive multicultural CRO, offering a high quality, customised and flexible service. With offices in the UK, France, Germany, the USA and Australia, along with supporting networks of regionally-based CRAs in Central and Eastern Europe, Africa, South America and Asia, we can offer a truly seamless approach to global drug development. Our philosophy is to provide a high quality, customer focused service at a fair price.

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<input type="checkbox"/> 2 day conference	15 – 16 September 2008	£1,098 + VAT £192.15 = £1,290.15	£1,160 + VAT £203 = £1,363	£1,190 + VAT £208.25 = £1,398.25	£1,220 + VAT £213.50 = £1,433.50

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Venue and hotel accommodation

Venue: Hilton London Euston Hotel, 17-18 Upper Woburn Place
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Hotel accommodation: The conference fee does not include accommodation. Health Network Communications has obtained specially discounted rates for all attendees. A hotel booking form will be sent to all registered attendees. Please book your accommodation early to avoid disappointment.

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- Alternatively, you may choose a credit note for the full value of the registration price (valid for 1 year), which may be put towards another Health Network event.
- The company regrets that no cancellations will be accepted within 30 days of the conference start date. Prepayments will not be refunded and invoiced sums will be payable in full, except in cases where it has been possible to mitigate loss.
- Course documentation will, however be made available to the delegate. Health Network Communications reserves the right to alter the program without notice.

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