

in association with

Phacilitate  IBM Business Consulting Services

# R&D LEADERS' FORUM SPRING 2007

www.phacilitate.co.uk/leaders

5-7 March 2007,  
The Westin Philadelphia,  
Philadelphia, PA

Learn from, and network with, a speaker panel of more than 50 of the most influential industry and public sector thought-leaders – the individuals re-defining the life sciences R&D model for the coming decade and beyond:



- **Steven Paul, MD**, Executive Vice President, Science & Technology, Lilly Research Laboratories, [Eli Lilly and Company](#)
- **Professor Sir Michael Rawlins**, Chairman, [National Institute for Clinical Excellence](#)
- **Dr Maxine Gowen**, Senior Vice President & Head, Centre of Excellence for External Drug Discovery, [GlaxoSmithKline](#)
- **Felix W. Frueh, PhD**, Associate Director for Genomics, Office of Clinical Pharmacology, CDER, [FDA](#)
- **Ginger L. Gregory, PhD**, Global Human Resources Head, [Novartis Institutes for BioMedical Research](#)
- **Stuart T. Henderson**, Americas Life Sciences Pharma R&D Leader, [IBM Global Business Services](#)
- **Dr Anthony Ford-Hutchinson**, Executive Vice President, Worldwide Basic Research, [Merck Research Laboratories](#)
- **Daniel K. Burns, PhD**, Senior Vice President, Pharmacogenetics, [GlaxoSmithKline](#)
- **Jim Kelly**, Vice President, Global Investment Research - Pharmaceuticals, [Goldman Sachs](#)
- **Whaijen Soo, MD, PhD**, Senior Vice President, Medical Research, [Biogen Idec](#)
- **Dr Bruno Flamion**, Chair of the Scientific Advice Working Party, [EMEA](#)
- **Dr Alan Breier**, Chief Medical Officer & Vice President, Medical, [Eli Lilly and Company](#)
- **Mark Mynhier**, Director, Life Sciences Practice, [PRTM](#)
- **Dr Joseph B. Bolen**, Senior Vice President, Research & Drug Discovery, [Millennium Pharmaceuticals, Inc](#)
- **Professor Mikael Dolsten**, Global Head of Corporate Division, Pharma Research/Discovery, [Boehringer Ingelheim](#)
- **Dr Lee E. Babiss**, Vice President of Preclinical Research & Development, [Roche](#)
- **Dr Vanessa King**, Head of Strategy & Operations, [Novartis Institutes for BioMedical Research](#)
- **Dr Richard J. Heaslip**, Vice President, Project & Portfolio Management, [Wyeth Research](#)
- **Barbara Ryan**, Managing Director & Pharmaceutical Analyst, [Deutsche Bank Securities, Inc](#)
- **Dr Catherine M. Bonuccelli**, Vice President of External Scientific Affairs, [AstraZeneca](#)
- **Dr Mark Boguski**, Vice President & Global Head of Genome & Proteome Sciences, [Novartis Institutes for BioMedical Research](#)
- **Dr Nicholas Dracopoli**, Vice President, Clinical Discovery Technologies, [Bristol-Myers Squibb Pharmaceutical Research Institute](#)
- **Dr Bruce H. Littman**, Vice President, Global Translational Medicine, [Pfizer Global R&D](#)
- **Jerry Cacciotti**, Managing Director & Head of Life Sciences Practice, Strategic Decisions Group
- **Dr Christine J. Cioffe**, Vice President, R&D Portfolio Management, [Merck & Co, Inc](#)
- **Mary Jo Lamberti, PhD**, Senior Manager, Market Intelligence, [Thomson CenterWatch](#)
- **Nadine Cohen, PhD**, Head of Pharmacogenomics & Senior Research Fellow, [Johnson & Johnson Pharmaceutical R&D East Coast & Europe](#)
- **Dr Charles Morris**, Vice President of Clinical Development Projects (Oncology), [AstraZeneca R&D](#)
- **Dr William Z. Potter**, Vice President, Franchise Integrator, Neuroscience, [Merck Research Laboratories](#)
- **Christian Gabel, PhD**, Principal, Life Sciences Practice, [PRTM](#)
- **Henrik Rasmussen, MD, PhD**, Senior Vice President, Clinical Research, Medical & Regulatory Affairs, [Nabi Biopharmaceuticals](#)
- **Dr William D. Matthews**, Vice President, R&D Management Operations, [Centocor R&D, Inc](#)
- **Robert M. DeMarinis, PhD**, Assistant Vice President, Global Health Outcomes Assessment, [Wyeth Research](#)
- **Dr Jean-Francois Formela**, Partner, [Atlas Venture](#)
- **Kerry K. Reinertsen, PhD**, Vice President, Corporate & Business Development, [Vertex Pharmaceuticals Incorporated](#)
- **Marc Pfister, MD FCP**, Head of Strategic Modelling & Simulation, [Bristol-Myers Squibb](#)
- **Patrice M. Milos, PhD**, Executive Director, Molecular Profiling, Clinical Research & Development, [Pfizer Global R&D](#)
- **Helen Sherman, RPh, PharmD**, Director, Pharmacy Services, [The Regence Group](#)
- **Michael Krams, MD**, Assistant Vice President, Adaptive Trials Clinical Development, [Wyeth Research](#)
- **Dr Anthony Artuso**, Senior Director, Strategic Planning, Portfolio Management & Decision Analysis, [Bristol-Myers Squibb](#)
- **Andrew T. Chow, PhD**, Senior Director, Pharmacokinetics & Pharmacometrics, [Amgen Inc](#)
- **Dr Mel Sorensen**, President & CEO, [Ascenta Therapeutics](#)
- **Dr John Wagner**, Senior Director, Clinical Pharmacology, [Merck & Co, Inc](#)
- **David A. Mrzcek, MD, FRC, Psych**, Chair of the Department of Psychiatry & Psychology, [Mayo Clinic](#)
- **Manfred Kansy, PhD**, Head, Molecular Properties & Structure Property Correlation, Pharma Research Basel Discovery PRBD-C, [F. Hoffmann-La Roche Ltd](#)
- **Dr David Rosen**, Executive Director, Strategic Alliances, [Pfizer Global R&D](#)
- **Edwin A. Clark, PhD**, Executive Director of Oncology Biomarkers, Division of Clinical Discovery, [Bristol-Myers Squibb](#)
- **Dr Gervais Tougas**, Head, Translational Medicine (Gastroenterology), [Novartis](#)
- **John I. Howell III**, President, [Portfolio Decisions, Inc](#)
- **Dr Kiang-Kuo Gordon Lan**, Senior Director, Statistical Science, [Johnson & Johnson Pharmaceutical R&D](#)

SEE INSIDE FOR THE  
FULL PROGRAM!

REGISTER BEFORE 22nd DECEMBER 2006 TO SAVE \$200!

Silver sponsor:

PRTM

Management  
Consultants

Bronze sponsors:

SDG

Strategic Decisions Group

THOMSON



TM

## Morning plenary session

### Evaluating alternative approaches to the traditional R&D phases: When and how will they positively impact productivity?

**9.00 Chair's introduction**  
**How to change the timing and cost of delivering important drugs by 50%, not 5% - deciding where and how to focus one's optimization efforts**  
**Dr Catherine M. Bonuccelli**, Vice President of External Scientific Affairs, AstraZeneca

**9.10 Market analyst's perspective**  
**How are the financial markets evaluating R&D strategies?**

- How do the financial markets value changing R&D strategies? Is the pessimism of the past few years dissipating?
- Which investments (new technologies / platforms / organizational structure) are getting recognition from the financial market and how long until it recognizes those that aren't?
- How does the market evaluate an opportunity differently depending on whether it's from biotech, major pharmaceuticals or specialty pharmaceuticals?

**Jim Kelly**, Vice President, Global Investment Research - Pharmaceuticals, Goldman Sachs

**9.35 Questions & discussion**

**The changing face of R&D: Are the traditional phases redundant and are the "learn and confirm" paradigms more relevant to today's environment?**

**9.40 FDA viewpoint**  
**Update on the Critical Path and Personalized Medicine Initiative implementation**

- FDA's mission to a more personalized approach to medicine and why it is on the Critical Path to New Medical Products
- Assessing the rollout of related technologies and their impact on productivity
- The voluntary data submission program

- What are the regulatory requirements for evidence-based medicine?
  - Label updates, drug-test co-development
  - What are the responsibilities and achievements of the various consortia and public / private partnerships for stimulating pre-competitive data sharing, biomarker use and placebo testing?
  - The Predictive Safety Testing Consortium
- Felix W. Frueh, PhD**, Associate Director for Genomics, Office of Clinical Pharmacology, CDER, FDA

**10.05 Questions & discussion**

**10.10 European viewpoint**

- What can the US learn about the progress to date with the Innovative Medicine Initiative and public / private partnerships in Europe?
- What changes are anticipated to the traditional R&D model and how will they be achieved?
- How can conditional approval be reconciled with new paradigms in trial designs?
- How will the EMEA Scientific Advice system offer a more personalised and flexible approach?

**Dr Bruno Flamion**, Chair of the Scientific Advice Working Party, EMEA

**10.35 Questions & discussion**

**10.40 Morning coffee in the exhibition area**

**11.10 Keynote address**  
**Inside out: Can externalization of drug discovery impact productivity?**

- Maintaining or improving productivity in drug discovery remains the major challenge facing pharma R&D
- While there is a willingness to invest more in R&D there is a concern that building more of the same is not the answer
- Is there a way to dramatically increase the reach of a pharma R&D organization through a network of loosely connected independent companies?
- What is the benefit to the companies who partner in this way?

**Dr Maxine Gowen**, Senior Vice President & Head, Centre of Excellence for External Drug Discovery, GlaxoSmithKline

**11.40 Questions & discussion**

**11.45 Project and program leadership in a newly emerging pharmaceutical R&D model: (Re)defining the project leader role**

- The need for an expanded competency model, and a new generation of leaders
- The importance of integration skills: Strategy and tactics, science and business
- The impact of organizational context and culture

**Dr Richard J. Heaslip**, Vice President, Project & Portfolio Management, Wyeth Research

**12.10 Questions & discussion**

**12.15 A zero-based look at the pharma business model: How would someone from outside our industry discover, develop and market drugs?**

- What can be learned from other industries (automotives, energy, technology) that have gone through transformations similar to the one now taking place in pharma? What strategies did they pursue to transform, compete, and win?
- How might leading business thinkers diagnose the 'pharma problem' and what might their solutions look like?
- What would Toyota, Google, or GE be doing if they were competitors in pharma?

**Jerry Cacciotti**, Managing Director & Head of Life Sciences Practice, Strategic Decisions Group

**12.40 Questions & discussion**

**12.45 Buffet lunch in the exhibition area**

**FOLLOWED BY YOUR CHOICE OF 3 HIGHLY INTERACTIVE PARALLEL SESSIONS**

## Focus session 1

### Early-stage clinical trials: What progress is being made with phase zero trials and demonstrating early Proof of Concept in man?

**2.15 Chair's introduction**  
**Criteria for entry of novel mechanism compounds into human PoC studies**

- Validation state of animal models from known to be predictive to uncertain extrapolation from phenotype of mouse knock out or of novel target
- Availability of "target engagement tool" that translates from animals to humans to allow for testing of hypothesis that specified degree of hitting target is associated with a particular pharmacodynamic (and/or therapeutic) effect. Implicit in this is appropriate PK/PD modelling.
- Path for PoC study in relatively small human population based on any combination of enriched clinical population, perhaps through genetics, robust signal detection in terms of clinical measure and/or accessible marker of drug effect likely to predict drug effect

**Dr William Z. Potter**, Vice President, Franchise Integrator, Neuroscience, Merck Research Laboratories

**2.40 Questions & discussion**

**2.45 Case studies**  
**What is the value of phase zero?**

- Defining phase zero, getting on the same page
- Qualifying biomarkers and defining subject populations in phase zero
- What is the real decision-making value from these trials?
- Should they be thought of as acceleration tools or screening tools?
- How predictive is microdosing? Will it reduce attrition?

**Dr Bruce H. Littman**, Vice President, Global Translational Medicine, Pfizer Global R&D

**3.10 Questions & discussion**

**Demonstrating early proof of concept to reduce phase II attrition: Who has actually achieved it and how?**

- Latest metrics from big pharma
- What is an acceptable level of adverse events to move forward with a PoC short-term study?
- Can PoC studies be done with evidence of QTC effects?
- Working with the regulator to reach the clinic early
- Working with physicians to design protocols that are easier to administer - balancing this aim with using the opportunity to collect data for future studies
- "At Risk work" - managing the 'white space' between PoC and advancement

**3.15 Case study**  
**Accelerating drug development through enhanced preclinical and early clinical discovery efforts**

- How can preclinical studies aimed at better understanding the disease target(s) support optimal clinical candidate selection?
  - How can preclinical biomarkers be used in early clinical studies to understand the activity of clinical candidates?
  - How can novel biomarkers be identified and used in early clinical studies?
- Edwin A. Clark, PhD**, Executive Director of Oncology Biomarkers, Division of Clinical Discovery, Bristol-Myers Squibb

**3.40 Questions & discussion**

**3.45 Afternoon tea in the exhibition area**

**4.15 Case study**  
**Demonstrating early Proof of Concept to reduce phase II attrition**  
**Dr William D. Matthews**, Vice President, R&D Management Operations, Centocor R&D, Inc

**4.40 Questions & discussion**

**4.45 Panel discussion**  
**Managing the transition from preclinical to man: People, process, systems, pre-defined partner agreements - what are the key factors to consider?**

**5.15** End of focus session 1 - all delegates to reconvene for the afternoon plenary session

*" We believe this is the premier R&D leaders' event. It provides a comprehensive R&D landscape in a concise, interactive forum "*

**Christine Carberry**, Vice President, Program & Alliance Management, Biogen Idec

OR | Focus session 2

How is drug discovery research now being equipped and organized to rigorously qualify and deliver high quality clinical candidates?

- 2.15 Chair's introduction**  
**How do we use all the information available in the post-genomic era?**
- Where are we in the gene-to-drug agenda?
  - How do we feedback genetic information generated in drug development into discovery?
  - Experimental medicine: How is it helping to validate targets in man earlier and faster?
  - What's the progress on standardization of genotyping approaches?
- Nadine Cohen, PhD**, Head of Pharmacogenomics & Senior Research Fellow, Johnson & Johnson Pharmaceutical R&D East Coast & Europe
- 2.40 Questions & discussion**

How are the relatively fixed discovery dollars being spent today?

- 2.45 Report card on 'old' technologies: What has been their real impact on efficiency and cost?**
- Assuming that budgets have not increased to accommodate translational medicine and biomarkers, which technologies and platforms have been dropped and with what impact on productivity?
  - Are some technologies just making things more complex for no return?
  - How does your legacy footprint define you and what are the implications: When might it make sense to replace legacy infrastructure?
- Dr Lee E. Babiss**, Vice President of Preclinical Research & Development, Roche
- 3.10 Questions & discussion**

- 3.15 What's new in discovery chemistry?**
- What's been achieved to improve target selection and validation?
  - What successes are being achieved through nucleotide chemistry?
- Speaker to be confirmed

- 3.40 Questions & discussion**
- 3.45 Afternoon tea in the exhibition area**
- 4.15 Panel discussion**  
**How are organizations being energized to be increasingly exploratory and experimental, and more programmatic, in the early stages?**
- How have reorganization and re-engineering helped target selection and validation?
  - Academic centers: Analyzing GSK's thesis on the CEDD approach
  - Comparing translational research structural models
- Panelist:  
**Dr Anthony Ford-Hutchinson**, Executive Vice President, Worldwide Basic Research, Merck Research Laboratories
- 5.15 End of focus session 2 – all delegates to reconvene for the afternoon plenary session**

OR | Workshop

Developing robust decision criteria for the development and use of biomarkers: Learning from regulatory and industry experiences to date

Highly interactive session for a maximum of 30 participants

- 2.15 Moderator's introduction**  
**Clarifying the current regulatory position on the validation and standardization of biomarkers for approval and ongoing patient care**
- What purpose do voluntary submissions have?
  - What's the progress on standardization?
  - Short of full surrogacy, how can you qualify the information required, particularly for innovative medicines?
- Felix W. Frueh, PhD**, Associate Director for Genomics, Office of Clinical Pharmacology, CDER, FDA
- 2.40 Questions & discussion**

- 2.45 Delivering Big Science: The importance of public/private partnerships**
- What progress is being made with pre-competitive data sharing of genomic biomarkers?
  - Case study: The Genetic Association Information Network: GAIN - progress to date on a unique public/private partnership
  - Goal setting
  - Prioritizing which disease areas to work on
  - Executing the delivery of results
  - Access to data
  - Larger context for partnerships and consortium: What opportunities exist?
  - Example: Biomarkers Consortium
- Patrice M. Milos, PhD**, Executive Director, Molecular Profiling, Clinical Research & Development, Pfizer Global R&D
- 3.10 Questions & discussion**

**Case studies**  
**Have biomarkers provided compelling evidence that they can de-risk clinical development?**

- 3.15 Case study**  
**Using biomarkers for key decision-making in oncology development: Are we there yet?**
- Traditional drug development for oncology is less applicable to new agents
  - Early determination of biological activity is increasingly determined from biomarkers rather than clinical endpoints
  - Biomarker development and validation needs to occur early in the research process so we have biomarkers to support drug development
  - This talk will consider:
    - How effective is our use of biomarkers?
    - Are we ready to make critical decisions based on biomarkers alone?
    - Is our increasing dependency on biomarkers speeding up or slowing down drug development?
    - Will the increased cost and time in phase I and II be balanced by fewer late phase failures?
- Dr Charles Morris**, Vice President of Clinical Development Projects (Oncology), AstraZeneca R&D

- 3.40 Questions & discussion**
- 3.45 Afternoon tea in the exhibition area**

- 4.15 Case study**  
**Using biomarkers for key decision-making in diabetes development**
- Dr John Wagner**, Senior Director, Clinical Pharmacology, Merck & Co, Inc
- 4.40 Questions & discussion**
- 4.45 Panel discussion**  
**Establishing ground rules for developing and using biomarkers: Developing decision criteria to support various milestones, and to balance risk with investment**
- Scenario testing
  - How are biomarkers used in real time to impact decisions during clinical development?
  - Is it feasible to discover new biomarkers by phase II and validate them in phase III, or are new biomarkers only likely to be useful for follow-on and backup programs?
  - How is the ROI for biomarker research determined? What are the key criteria for determining ROI for novel biomarkers in drug development?
- Panelists:  
**Daniel K. Burns, PhD**, Senior Vice President, Pharmacogenetics, GlaxoSmithKline  
**Dr Nicholas Dracopoli**, Vice President, Clinical Discovery Technologies, Bristol-Myers Squibb Pharmaceutical Research Institute
- 5.15 End of workshop – all delegates to reconvene for the afternoon plenary session**

THEN | Afternoon plenary session

- 5.20 Panel discussion**  
**Linking commercialization with R&D: How have different organizational models for R&D impacted productivity, innovation and the development of real talent?**
- Feedback from ongoing research on how operational dimensions impact growth, innovation, and business performance at the leading biotech and pharmaceutical companies
  - Organizational design (functional integration, decision-making and geographic presence)
  - Product strategy (portfolio diversity, innovation strategy, asset creation and expansion)
  - Operational strategy (operational flexibility, external collaborations, eTechnology integration)

- What are the pros and cons of phase I trials being in the research group or the drug development group?
- To what extent should commercial be linked with discovery?
- What's the role of marketing / commercial and how should it integrate and interface with the changing face of R&D?
- Underlining changes in structure with accompanying changes in organization and decision rights in R&D
- What mechanisms / incentives are needed to ensure effective cooperation and alignment?
- What should the ultimate decision-making body be: At what level in the organization? And what oversight and direction should they be providing downward?
- What specific jobs/functions are needed to ensure alignment and cooperation?

- Moderator:  
**Mark Myhner**, Director, Life Sciences Practice, PRM
- Panelists:  
**Dr Maxine Gowen**, Senior Vice President & Head, Centre of Excellence for External Drug Discovery, GlaxoSmithKline  
**Dr Catherine M. Bonuccelli**, Vice President of External Scientific Affairs, AstraZeneca
- 6.00 Close of day one followed by a themed cocktail reception in the exhibition area**

## Morning plenary session

### Health economics and patient outcomes: What is R&D's current and future role in the demonstration of value and choice for patients, prescribers and payers?

#### 9.00 Co-chairs' introductions

**Daniel K. Burns, PhD**, Senior Vice President, Pharmacogenetics, GlaxoSmithKline  
**Robert M. DeMarinis, PhD**, Assistant Vice President, Global Health Outcomes Assessment, Wyeth Research

#### 9.05 Financial analyst perspective Healthcare and pharma economics are under assault

- Assessing the impact of parallel importation
- Pricing issues affecting the US market
- Certain disease areas are becoming less attractive
- Uniform pricing of drugs can't be far away: How will industry reconfigure when this happens?
- Pricing of targeted therapies: How much more can realistically be charged?
- Quantifying the threat from generics
- How will new product formulation/delivery mechanisms affect pharma economics, marketing and distribution? eg the new inhaled drugs, which have a device, drug and diluent are far more complex to manage, from production to warehousing to distribution to patient intake than are traditional oral solids

**Barbara Ryan**, Managing Director, Deutsche Bank Securities

#### 9.30 Questions & discussion

#### 9.35 Payer's perspective What demonstrates value with new medications?

- FDA approval requirements vs payers' needs for useable scientific evidence
- What is useable scientific evidence?
- What data is needed to demonstrate
- Effectiveness?
- Safety?
- Advantages?
- What technology platforms are needed to integrate R&D and evidence-based medicine?

**Helen Sherman, RPh, PharmD**, Director, Pharmacy Services, The Regence Group

#### 10.00 Questions & discussion

#### 10.05 Healthcare and pharmaceutical industry convergence: What are the benefits for pharma and the patient?

- Why is convergence happening now?
- What will be the outcome for the industry players and the patients?
- What new business models are emerging?
- Patient centric networks / health information exchanges
- The business model for replacing EDC with directly sourced EMR/EHR/PHR data
- The role for the trusted third party
- Case studies illustrating the different levels of interoperability towards the converged environment
- What are the challenges and hurdles for pharmaceutical companies seeking to lead the convergence (eg standards, EMR penetration, trust etc)?
- What action should we be taking today?

**Stuart T. Henderson**, Americas Life Sciences Pharma R&D Leader, IBM Global Business Services

#### 10.30 Morning coffee in the exhibition area

#### 10.50 US government perspective Finding new ways to better describe value and provide choice for patients

- Update on the creation and progress of HHS' cross-agency team to integrate genomic data and electronic medical records.

**Dr Mike Leavitt**, Secretary, Health & Human Services Secretary (invited)

#### 11.15 Questions & discussion

#### 11.20 Physician's perspective Understanding changing prescribing habits and how they might impact R&D

- With many drugs now being developed for multiple indications, how will marketing to physicians evolve?
- The implications of clinical pharmacogenomic genotyping for the emergence of personalized medicine

- The implications of electronic medical records for involvement in R&D opportunities
- Confidentiality issues: Implications for physicians and pharma R&D

**David A. Mrazek, MD, FRC, Psych**, Chair of the Department of Psychiatry & Psychology, Mayo Clinic

#### 11.45 Questions & discussion

#### 11.50 Keynote address Responding to the changing economics of the healthcare environment: Thinking creatively about R&D productivity, patient outcomes, and the drive towards personalized medicine

**Dr Steven Paul**, Executive Vice President, Science & Technology, President, Lilly Research Laboratories, Eli Lilly and Company

#### 12.15 Questions & discussion

#### 12.20 Panel discussion R&D in the information age: Will the explosion of information capture and analysis be our demise or our nirvana?

- Ensuring that the available tools add value and improve outcomes

Panelist:

**Dr Mark Boguski**, Vice President & Global Head of Genome & Proteome Sciences, Novartis Institutes for BioMedical Research

#### 1.00 Buffet lunch in the exhibition area

**FOLLOWED BY YOUR CHOICE OF 3 HIGHLY INTERACTIVE PARALLEL SESSIONS**

## Focus session 1

### Assessing progress with innovation in late stage clinical trials and managing the evolution to phase IV 'lifecycle trials'

#### 2.30 Chair's introduction

#### Case studies

#### Practical experiences with adaptive trial design: Regulatory and operational considerations

#### 2.35 Case study Adaptive designs in phase III clinical trials

- Multiple endpoints: Choice of the primary endpoint may not be perfect
  - The alpha level: We still don't know how to control it accurately
  - The use of prior information: Reaching consensus on how to incorporate the information into the pivotal study
  - Improving communication between DSMB and sponsor: Not enough under the current system
- Dr Kiang-Kuo Gordon Lan**, Senior Director, Biometrics & Clinical Informatics, Johnson & Johnson Pharmaceutical R&D

#### 2.55 Questions & discussion

#### 3.00 Adaptive designs as an enabler for teamwork: Two case studies on dose-response finding

- From concept sheet to scenario analysis to simulation report
- Translational medicine and adaptive designs

- Implementation: IT, drug supply management
- Team dynamics

**Michael Krams, MD**, Assistant Vice President, Adaptive Trials Clinical Development, Wyeth Research

#### 3.20 Questions & discussion

#### 3.25 How can adaptive designs and randomized discontinuation designs improve clinical development and lifecycle management trials?

- Case studies, illustrating operational and technical experiences
- When can/can't you use these approaches: What does it save you?
- Will randomized discontinuation design ever be used for definitive clinical trials?

**Dr Gervais Tougas**, Head, Translational Medicine (Gastroenterology), Novartis

#### 3.45 Questions & discussion

#### 3.50 Afternoon tea in the exhibition area

#### 4.20 Case study Making the decision to proceed into phase IV: What are the timing and operational considerations?

- How is the greatest value derived from phase IV trials?
- How may phase IV play a more important role in the regulatory process?

- How will benefit/risk be enhanced through phase IV trials?
- What are innovative approaches to conducting phase IV trials?

**Dr Alan Breier**, Chief Medical Officer & Vice President, Medical, Eli Lilly and Company

#### 4.40 Questions & discussion

#### 4.45 Panel discussion Managing the transition from phase III to IV and post-marketing commitments: What impact will they have on R&D and lifecycle management?

- Will the advent of post-marketing commitments require a different R&D structure? Traditionally these studies have been undertaken by marketing, but should they now be lead by R&D?
- Is true lifecycle management back in fashion? Will phase IV be used to look at ever expanding indications and opportunities to expand value?
- What are the data gathering implications for R&D?
- Quantifying the economic impact of phase IV trials - where will the budget and other resources come from? Will it take away from the investment in getting new drugs to market?

#### 5.20 End of focus session 1 - all delegates to reconvene for the afternoon plenary session

OR | Focus session 2

Justifying investment in modelling and simulation: How and where are they adding significant value to the R&D process?

- 2.30 **Chair's introduction**  
**Measuring the value added by simulation and modelling, especially in the early stages of R&D**
  - How can we use modelling and simulation in the exploratory phase to terminate compounds (or programs) earlier?
  - How can we use them prospectively for dose selection and clinical development planning?

**Marc Pfister, MD FCP**, Head of Strategic Modelling & Simulation, Bristol-Myers Squibb
- 2.55 Questions & discussion
- 3.00 **What is the progress with the FDA's application of drug/disease modelling and simulation?**
  - When might they be used by industry to simulate and design clinical trials?
  - What is the progress with building and sharing a knowledge repository of drug/disease interactions for particular diseases?
  - What impact has FDA's modelling and simulation technology had on dosing regimes and post-market trial commitments?

Speaker to be announced
- 3.25 Questions & discussion
- 3.25 **PK/PD model based drug development, a defined role and responsibility in R&D**
  - Vision, mission & application strategy at different stages of development

- Organizational readiness
- Therapeutic area-based modeling & simulation: A critical success path moving forward  
**Andrew T. Chow, PhD**, Senior Director, Pharmacokinetics & Pharmacometrics, Amgen Inc
- 3.45 Questions & discussion
- 3.50 Afternoon tea in the exhibition area
- 4.20 **Examining the impact of *in silico* techniques on the R & D process: Current status and possible future perspectives**
  - Application of *in silico* techniques along the value chain
  - What progress is being made and what future possibilities are forecast?
  - What has been the impact on safety, attrition rates, productivity?
  - Wet lab experiments, databases, predictions
  - What are the interrelationships?
  - Can *in silico* predictions tools reduce wet lab experiments?
  - Expression profiling, pathway analysis, disease modelling
  - Bottom-up versus top-down approach
  - Possible consequences for R&D

**Manfred Kansy, PhD**, Head, Molecular Properties & Structure Property Correlation, Pharma Research Basel Discovery PRBD-C, F. Hoffmann-La Roche Ltd
- 4.40 Questions & discussion

- 4.45 **Panel discussion**  
**Deeper human disease modelling versus better animal models: Where should you invest to improve confidence in novel drug targets?**
  - When to validate targets directly in humans
  - What population or subpopulation of patients represents the best test of the drug target hypothesis? Defining a "molecularly correct subpopulation"
  - What is a predictive animal model for an unprecedented mechanism, how can you be certain, what are the criteria?
  - How much confidence is needed in an outcome to kill an unprecedented drug target? Design of "a proof of non-viability" human study

Panelist:  
**Dr Bruce H. Littman**, Vice President, Global Translational Medicine, Pfizer Global R&D
- 5.20 End of focus session 2 -- all delegates to reconvene for the afternoon plenary session

"Overall an excellent forum. Engaging and informative discussion, great presenters who are leaders in their fields, well organized, and a great location!"

**Mike Pegler, Principal,**  
**PRTM Management Consultants**

OR | Workshop

Valuing and managing assets and factoring in risk throughout their lifecycle to optimize portfolio management

Highly interactive session for a maximum of 30 participants

- 2.30 **Moderator's introduction**  
**How do you determine the value of an asset?**
  - Whose input do you need to determine the value of an asset now that payers are defining value, not always clearly or transparently?
  - When do you start looking at the profile of an asset to make it through to a patient? How do you do that without disempowering people?
  - When you see early signs of success, how aggressively should you extrapolate value? At what point in the product development cycle do you have enough information to step up?
  - How will the shift to narrower indications and targeted populations impact asset valuation?
  - Organizational issues: If you have a very focused research center and a very focused development center how can you combine them for the best asset strategy?

**Dr Anthony Artuso**, Senior Director, Strategic Planning, Portfolio Management & Decision Analysis, Bristol-Myers Squibb
- 2.55 Questions & discussion
- 3.00 **Case study - technology mapping**  
**Taking a fundamental core asset, such as knowledge of a particular pathway,**

- and calculating the value it could realize and when**  
Speaker to be announced
- 3.20 Questions & discussion
- 3.25 **Defining benefit/risk assessments along the product lifecycle chain: Qualitative or quantitative?**
  - How to best integrate subjective and objective approaches in decision-making and governance processes
  - Approaches to consistently factoring in risk throughout the lifecycle of an asset
  - Building in more prospective planning to improve quality

**Dr Christine J. Cioffe**, Vice President, R&D Portfolio Management, Merck & Co, Inc
- 3.45 Questions & discussion
- 3.50 Afternoon tea in the exhibition area
- 4.20 **Delivering predictable results in an unpredictable business environment: A petroleum industry benchmarking example of balancing risk and reward**
  - Managing diverse assets that have different risks, dependencies and constraints and business structures across their lifecycle

- Understanding business risks and benefits of alternate business scenarios using portfolio management tools
- Using portfolio options to facilitate executive's strategic decisions  
**John I. Howell III**, President, Portfolio Decisions, Inc
- 4.40 Questions & discussion
- 4.45 **Panel discussion**  
**Will portfolio management techniques preserve the standard R&D business model?**
  - Will portfolio management deliver stability?
  - Has there been progress in reducing attrition?
  - How is portfolio management being integrated with benefit:risk and with what results?
  - In spite of all the sophisticated data, leadership still relies on "gut feel". Why is that and what can Portfolio Managers do to make their data and processes more relevant?
- 5.20 End of workshop – all delegates to reconvene for the afternoon plenary session

THEN | Afternoon plenary session

- 5.25 **Panel discussion**  
**What is the role of clinical research in society? How can its status be improved?**
  - Increasingly drug development operates as an appendage to healthcare and, therefore, doesn't benefit from same pace of progress that the rest of medicine enjoys: How is this being addressed?
  - The US public doesn't want to participate in trials and the clinical infrastructure is fragmented: What can be done?

- Is the issue of public trust starting to turn the corner? What have we learned so far; what difference has been made?
- Increasing efforts to focus on outcomes and ensure functional endpoints that are meaningful for the patient at a practical level
- Preparing patients for unexpected events
- Publication of clinical trials data is becoming increasingly contentious: Debating whether the results of all clinical trials should be in the public domain
- Ethical issues related to pediatric research and the new efforts to expand the use of prisoners in trials

- Changing strategies reflected in metrics
  - Development strategies being adopted by the industry including increased use of outsourcing, increased use of emerging markets in which to conduct clinical trials, the role that EDC plays, and more effective patient recruitment and retention strategies
- Panelist:  
**Mary Jo Lamberti, PhD**, Senior Manager, Market Intelligence, Thomson CenterWatch
- 6.00 Close of day two followed by a themed cocktail reception in the exhibition area

## Morning plenary session

### Sourcing new opportunities for pharma R&D: Developing the portfolio via investment in biotech, networking externally, and focusing innovation on areas of unmet need

- 9.00 Chair's introduction**  
**What do you do to meet your growth objectives when there is a paucity of product opportunity?**
- Open innovation: Finding growth and value opportunities from external sources along the operational value chain
  - Strategic partnering: Defining an operational strategy to guide alliance choices
  - Portfolio strategy: Valuation, metrics and prioritization of external and internal products
- Christian Gabel, PhD**, Principal, Life Sciences Practice, PRTM

- 9.20 Keynote address**  
**Pharmaceutical innovation: Balancing price, cost and need**
- The resource problem facing developed countries
  - The demographic time-bomb
  - Unmet clinical need
  - The price and cost of innovative technologies
  - Appropriate responses of healthcare providers
  - Appropriate responses of the pharmaceutical industry
- Professor Sir Michael Rawlins**, Chairman, National Institute for Clinical Excellence

- 9.45** Questions & discussion

- 9.50 Financial viewpoint**  
**Examining the state of the biotech industry**
- What evidence is there to support the perceived Proof of Concept gap?
  - Looking into the future of innovation and partnering in research and discovery, as partnering deals for compounds are shifting earlier and earlier, and cost more and more
  - Overview of current deal structures
  - Decline of IPOs
  - Reverse mergers are increasing significantly

- How are exit strategies changing for VCs and with what impact on biotech and pharma?
  - What recent examples are there of non-traditional agreements?
- Speaker to be announced

- 10.15** Questions & discussion

- 10.20 Mergers & acquisitions debate**  
**What role does / should M&A play in promoting innovation, and what are the IP implications?**
- How expensive have recent deals been and with what outcomes? What models have been favored?
  - What impact has the levels of VC funding had on recent deals?
  - What is the ideal timing: At what stage in its development should a technology platform be the subject of an M&A?
  - How destructive – or constructive – are M&As to research and innovation?
  - What can be done to reverse short-term strategy?
  - With acquisitions becoming the preferred option, access to the asset becomes key, people and innovation capability become less important
  - What are the trends for IP and maintaining exclusivity that pharma/biotech leadership should be aware of?
  - Off label use of your product
  - IP issues with biologics
  - How and when to integrate IP into research: Which elements of IP should be done in each research disease area versus by the investigators and when?
- Panelists:
- Dr Vanessa King**, Head of Strategy & Operations, Novartis Institutes for BioMedical Research
- Kerry K. Reinertsen, PhD**, Vice President, Corporate & Business Development, Vertex Pharmaceuticals Incorporated
- Dr David Rosen**, Executive Director, Strategic Alliances, Pfizer Global R&D

- 10.50 Panel discussion**  
**How will the pharma portfolio develop to capitalize on remaining areas of unmet need?**
- Looking at the combined modality of small molecules and biologics in pipeline strategies: Is there only room for companies providing either small or large molecules or does everyone need a more comprehensive portfolio?
  - How much of your strategy should be radical innovation versus incremental improvements?
  - Are combination products stifling innovation or providing added value?
  - How much of your portfolio strategy should be focused on targeted and personalized medicine?
  - What impact will the ageing population and the metabolic disease time epidemic have on R&D? What will be the additional therapeutic areas of focus?
  - Tapping into funding from not-for-profit organizations for neglected diseases: Marrying profit and corporate social responsibility
  - What can be learned from the resurgence in vaccines and pandemic activity?
- Panelists:
- Professor Mikael Dolsten**, Global Head of Corporate Division, Pharma Research / Discovery, Boehringer Ingelheim
- Dr Joseph B. Bolen**, Senior Vice President, Research & Drug Discovery, Millennium Pharmaceuticals, Inc
- Dr Jean-Francois Formela**, Partner, Atlas Venture
- Henrik Rasmussen, MD, PhD**, Senior Vice President, Clinical Research, Medical & Regulatory Affairs, Nabi Biopharmaceuticals

- 11.30** Morning coffee in the exhibition area

**FOLLOWED BY YOUR CHOICE OF 2 HIGHLY INTERACTIVE PARALLEL SESSIONS**

## Focus session 1

### Strategically planning the clinical capabilities of biotech and determining the criteria for success

- Practical experiences from those tackling the research talent gap through offshoring

- 12.00 Chair's introduction**
- 12.05 Getting your development program started in a timely fashion**
- Improving clinical input for efficient preIND activities and IND filing
  - Seamless planning from clinical candidate to go/no decision after Proof of Concept studies
- Whajjen Soo, MD, PhD**, Senior Vice President, Medical Research, Biogen Idec
- 12.30** Questions & discussion

- 12.35 Analyzing the trend for smaller biotechs to ramp up their clinical capabilities: What's the impact on big and small companies?**
- Henrik Rasmussen, MD, PhD**, Senior Vice President, Clinical Research, Medical & Regulatory Affairs, Nabi Biopharmaceuticals
- 1.00** Questions & discussion
- 1.05 Case study from a biotech offshoring late stage clinical trials**
- What is driving biotech to offshore late stage clinical trials?
  - Experiences from different regions
  - Conducting pivotal trials for drugs intended for western markets: What are the limitations of different regions / countries?

- What business models are being used to establish a footing in these countries?
  - Lessons learned from managing cultural differences
- Speaker to be announced
- 1.30** Questions & discussion
- 1.35 Panel discussion**  
**Debating which clinical development models are most appropriate for biotech now and determining the criteria for success**
- 2.00** Lunch & close of the R&D Leaders' Forum Spring 2007

## Sponsorship and Exhibition Opportunities

Confirmed sponsors and exhibitors include: Beckman Coulter • Current BioData • i3 • InnoCentive • ProModel Corporation • PRTM • Strategic Decisions Group • Thomson Scientific.

R&D Leaders' Forums provide the perfect opportunity for companies to raise their profile with an unparalleled group of senior level R&D and business executives, as well as with senior policy makers.

designed to be highly conducive to informal discussions around the booths themselves.

We are pleased to offer a range of options to companies who would like to associate themselves with the event of the year for top-level R&D industry figures, from sponsoring the forum as a whole, through hosting briefing sessions to a number of exhibition-based options. Opportunities

are strictly limited to ensure maximum exposure for those companies who participate.

**For more information on how you can become involved, please contact Nicola McCall at Phacilitate**  
Tel: +44 (0)20 7839 6137  
Email: [nicola@phacilitate.co.uk](mailto:nicola@phacilitate.co.uk)

The exhibition area will provide the location for the vast majority of the networking activities at the R&D Leaders' Forum Spring 2007 and is being

OR | Focus session 2  
How far and how fast is globalization impacting research and innovation?

12.00 Chair's introduction

**Dr Joseph B. Bolen**, Senior Vice President, Research & Drug Discovery, Millennium Pharmaceuticals, Inc

12.05 Tapping the global talent pool for innovation in drug discovery

- Where is the scientific talent coming from?
- Where does the talent want to work?
- How can we increase knowledge transfer and sharing among global sites?
- Are we moving to a 24-7 model of global innovation?
- Maximizing efficiency and minimizing travel

**Ginger L. Gregory, PhD**, Global Human Resources Head, Novartis Institutes for BioMedical Research

12.30 Questions & discussion

In 5-10 years time, where will research be centered geographically?

12.35 Case study

**Offshoring research: The pharma perspective**

- Establishing research sites in India and China: What were the business drivers and operational considerations?
- How long will it take for these sites to reach western standards?
- Key considerations for making ex-US sites successful when conducting research targeted for the US market
  - Site selection and infrastructure
  - Contracts
  - Data capture/review/cleaning/etc

1.00 Questions & discussion

1.05 Case study

**Biotech R&D across borders: the Ascenta experience**

- Biotech science is global and opportunities are not confined to US/EU/ Japan anymore

- What is driving biotech to offshore lab research?
  - Highly cost-efficient lead optimization and preclinical development
  - Excellent education and quality of chemistry and biology
  - Local opportunities for academic/contract collaborations
  - High unmet need and large patient populations
- Mel Sorensen**, President & CEO, Ascenta Therapeutics, Inc

1.30 Questions & discussion

1.35 Panel discussion

**What make one discovery great, another mediocre and another fail? How might globalization impact this question through accessing new research talent?**

2.00 Lunch & close of the R&D Leaders' Forum Spring 2007

Co-organizers



IBM Business Consulting Services

IBM Business Consulting Services is the world's largest consulting organization with consultants and professionals in more than 160 countries. IBM Business Consulting Services is committed to every client's success through our expertise in building innovative solutions, our capabilities for unlocking value in business performance, and our approach to client agreements that hold us accountable for tangible business results. From consulting to onsite deployment to outsourcing, IBM is a partner that can deliver the full equation. For more information, **please visit** <http://www.ibm.com/services/bcs>

IBM Healthcare and Life Sciences

IBM Healthcare and Life Sciences enables our clients to transform drug discovery and development and delivery of medical care by combining deep industry insight, business process expertise, and leading technology. IBM and its global network of Business Partners offer innovative Life Sciences R&D solutions to help clients integrate disparate data sources, streamline research and business processes, share information and collaborate on findings, and facilitate regulatory compliance. For more information on how IBM can help you meet the unique challenges in discovering, developing, and delivering new diagnostics and therapeutics, **please visit** <http://www.ibm.com/industries/healthcare/>



Phacilitate is a specialist in the organization of exclusive events for leaders from the pharma, vaccine and biotech communities. Our philosophy is simple – to deliver the ultimate in strategic knowledge exchange and networking through flawless, personalized service.

Our team is focused on just six events a year – our Spring and Winter Vaccine Forums, our Autumn and Spring R&D Leaders' Forums, our Cell & Gene Therapy Forum and our Oncology Leaders' Forum. This level of specialization means that we have closer links with, and spend more time listening to, the industry we serve than any other conference organizer, aided by input from our Advisory Boards. [www.phacilitate.co.uk](http://www.phacilitate.co.uk)

Silver sponsor



Management Consultants

Since 1976, PRTM has created a competitive advantage for its clients by changing the way companies operate. PRTM management consultants work with senior executives to develop and implement innovative operational strategies that deliver breakthrough results. The firm is a leader in operational strategy, supply chain, product development, and customer management. PRTM has 16 offices worldwide and serves major industry and government sectors. [www.prtm.com](http://www.prtm.com)

Bronze sponsors



Strategic Decisions Group

Strategic Decisions Group has worked with global biopharmaceutical companies since 1981, helping them formulate robust strategies to meet increasingly competitive challenges. SDG is widely recognized as having added billions of dollars in shareholder value for world-leading corporations. Our work has transformed how the industry values and manages R&D, and how it implements portfolio investment, product strategy and therapeutic area strategy decisions. As the industry advances into increasingly radical change, SDG stands ready to help clients reach new levels of success. [www.sdg.com](http://www.sdg.com)



Thomson Scientific, part of the Thomson Corporation, is a global leader in providing information solutions to R&D professionals working in drug discovery, development, regulatory affairs and generics. We provide focused, authoritative content, powerful functionality and unrivalled expertise to the pharmaceutical and biotechnology markets. Thomson Pharma<sup>SM</sup> integrates the best of this content into a single workflow tool that can be configured to suit your specific information needs. For further information, visit: [www.scientific.thomson.com](http://www.scientific.thomson.com)

Media partners

