

ICPM 2008

7-10 September 2008

news

ICPM
2008
AMSTERDAM

The 15th International
Conference on Pharmaceutical
Medicine in
Amsterdam The Netherlands

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Okura Hotel Amsterdam
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Hosted by:



“Gratis”, a typical Dutch word? Free courses at a value of 3000 €!!!

During the ICPM 2008 in Amsterdam we offer three short courses.

1. **Statistics for non interventional studies** by **Richard Kay (RK Statistics)**
2. **Update in Risk Benefit Analysis** by **Graeme Ladds (Pharsafer)**
3. **Media Training** by **Ingo Heijnen (Hill & Knowlton)**

Each of these courses by these high class lecturers would normally cost you around 1000 €. If you come to the ICPM2008 they are for FREE! If you subscribe on time! You can follow two of the courses because all courses will be given on Monday as well as Tuesday.

In short the ICPM 2008 offers you:

- A high level conference accredited with CME/CPD points by the British Faculty (18,5 points); the -Belgian College (15 points); the Swiss Society of Pharmaceutical Medicine 17 points and the SFG (15 points)
- Three high level short courses for FREE
- Excellent networking opportunity

Send in your application for ICPM 2008 now and indicate which course you want to go to. The number of participants will be limited to 20-30 to increase the interaction. Below you will find more information on the courses. Information can also be found on our website: www.icpm2008.org

Statistics for non interventional studies

RK Statistics

This short course will cover topics within the general area of statistics for non-intervention studies. The focus of the course will be on principles rather than technicalities. A range of topics will be covered including:

- General Statistical Issues
- Meta analysis
- Survival Data
- Odds Ratios, Relative Risks and Hazard Ratios
- Case-Control and Cohort Studies

Update in Risk Benefit Analysis

www.pharsafer.com

There is an increasing need to minimise the risks patients experience with medicines. By minimising risk Pharmaceutical Companies can maintain a positive Benefit-Risk profile for their products. This requires Companies to be vigilant

about the types of individual safety reports they receive and analyse the possible causality of the reported event to the product.

Once determined that a new report is a safety signal the Company must not only amend labeling to reflect the new finding but also to provide information concerning how it can effectively minimise such a risk occurring by developing strategies to ensure such a situation can not arise.

This talk looks at the new legislation in this area and discusses the requirements of Companies to engage in such Risk Management/Minimisation activities both before and after the product is licensed.

‘Handling media during crises’ by Top Executive of Hill & Knowlton

www.hillandknowlton.com

Knowing how to communicate during crises has become a major point of attention for executives around the world in the past decade. The dramatic change in media landscapes has been instrumental in this development. Each incident can turn into a media hype, with responsible managers being scrutinized by public opinion over their ability to be transparent and swift in their communications. This course will provide you with insights into how media behave during crises, what their drivers are, what their needs are - and how you address these needs AND keep control over the situation.

Based on real live examples, course leader Ingo Heijnen, director at the global PR-firm Hill & Knowlton, will guide you through do’s and don’ts in crisis communications. He will also put you to the test, by introducing a fake but realistic incident, that you will have to respond to. Camera’s will be rolling, a journalist will ask all the nasty questions - and it is up to you to make sure that the right message will be aired.

Developing Pharmaceutical Care Medicines after Blockbuster Era

Sunday, September 7

19.00

Opening Ceremony ICPM 2008
Welcome Reception
Rijksmuseum Amsterdam

Monday, September 8

Developing Pharmaceutical Care

09.00 - 10.30 & 10.30 - 12.00

Morning
plenary program

State of the Art in Translational Medicine

Chairs: Gustavo Kesselring, Joop van Gerven

- Physiology based modelling - Meindert Danhof - *LACDR*
- From bedside to bench - Andreas Wallnöfer - *F. Hoffmann-La Roche Ltd.*
- New translational models - Philip Scheltens - *VU University Medical Center*

State of the Art in Trial Design Technology

Chairs: Gerfried Nell, Paul de Koning

- Predictive utility of biomarkers, surrogate endpoints, role in decision making during development - Paul Rolan - *University of Adelaide*
- Pharmacogenomics in trial design - Kevin Cheeseman - *AstraZeneca*
- Adaptive clinical trial design: pro's and con's - Kit Roes - *Organon*

09.00 - 12.30

Morning
short course

- Statistics for non-interventional studies - Richard Kay - *RK Statistics*
- Update in Risk-Benefit Analyses - Graeme Ladds - *PharSafer Associates*
- Media Training - *Hill & Knowlton*

12.45 - 13.45

Lunch Symposia

Patient Centred Drug Development - *Nefarma*

14.00 - 15.30 & 16.00 - 17.30

Afternoon
parallel

Medical Research after Marketing Authorisation

Chairs: Bertrand Baumelou, Martijn Torremans

- Non-interventional studies - Giovanni Fiori - *MediData*
- Anticipating reimbursement issues - Hubertus Rosery - *AiM GmbH*
- US-EU Regulations & safety registries - Hugo Stephenson - *iGuard*

Off-Label Pharmacotherapy

Chairs: Jane Barrett, Eric Hoedemaker

- Off-label pharmacotherapy: when evidence without label - Ton de Boer - *Dept of Pharmaco-epidemiology and pharmacotherapy, University of Utrecht*
- Off-label Rx: cheap evidence, payers perspective - Albert Wertheimer - *Temple University / School of Pharmacy*
- Off-label-comparator through the eyes of EMEA - Noel Wathion - *EMA*

Modern Clinical Development 1 Outsourcing Strategies

Chairs: Domenico Criscuolo, Philippa Smit-Marshall

- Models for Outsourcing in Clinical research - Jeffrey McMullen - *PharmaNet Development Group*
- Partnering with CROs, trends and opportunities - Rene Sluijter - *Solvay Pharmaceuticals*
- Outsourcing needs of Biotech vs those of Pharma - Gillian Langford - *Alizyme*

Risk Assessment in Clinical Trials and Quality Issues

Chairs: Philip Salden, Tanja Hoffman

- Risk Assessment in Clinical Trials - Holger Liebig - *Parexel*
- Striving for Quality - Jeffrey Nagelstad - *sanofi-aventis*
- Quality at any Cost - Rita Hattemer-Apostel - *Verdandi AG*

17.30 - 18.30

Networking Event

19.30

IFAPP Presidents' Meeting

Okura Hotel



Tuesday, September 9

Medicines after Blockbuster Era

<p style="writing-mode: vertical-rl; transform: rotate(180deg);">Morning plenary program 09.00 - 10.30</p>	<p>Highly Specialized Indications in Research Paediatric research</p> <p>Chairs: Martin Offringa, Gerard van Leijenhorst</p> <ul style="list-style-type: none"> • Essentials of pediatric drug development - John van den Anker - <i>Children's National Medical Center</i> • Regulatory aspects of paediatric drug development - Agnès Saint-Raymond - <i>EMA</i> • The role of paediatric networks - Rosalind Smyth - <i>UK MCRN</i> 	
<p style="writing-mode: vertical-rl; transform: rotate(180deg);">Morning parallel program 10.30 - 12.00</p>	<p>Orphan World</p> <p>Chairs: Norbert Clemens, Ad Sitsen</p> <ul style="list-style-type: none"> • Ethical issues in funding orphan research - tbd • 25 yrs orphan drug development in US - Marlene Haffner - <i>Amgen</i> • Hurdles in orphan drug development - Bruno Giannetti - <i>Pharming Group NV</i> 	<p>MCRN Official Launch</p> <p>Chair: Martin Offringa</p> <ul style="list-style-type: none"> • VIP to be confirmed • Funders' address • Director's address • Press Conference
<p style="writing-mode: vertical-rl; transform: rotate(180deg);">Morning short course 09.00 - 12.30</p>	<ul style="list-style-type: none"> • Statistics for non-interventional studies - Richard Kay - <i>RK Statistics</i> • Update in Risk-Benefit Analyses - Graeme Ladds - <i>PharSafer Associates</i> • Media Training- Ingo Heijnen - <i>Hill & Knowlton</i> 	
<p style="writing-mode: vertical-rl; transform: rotate(180deg);">Lunch Symposia 12.45 - 13.45</p>	<p>Meet the MCRN entities - <i>GlaxoSmithKline</i></p> <ul style="list-style-type: none"> • Coordinating Centre • Clinical Study Groups • Methodology Platforms • Regional Research Clusters • National Training Officer • Trial Support Unit • Industry Liaison <p>Risk Management: A Patient Centric Approach - <i>Quintiles</i> Saad Shakir - <i>Drug Safety Research Unit (DSRU)</i> Hugo Stephenson - <i>iGuard</i> Dipti Amin - <i>Quintiles</i></p>	
<p style="writing-mode: vertical-rl; transform: rotate(180deg);">Afternoon parallel 14.00 - 15.30 & 16.00 - 17.30</p>	<p>Pharmaceutical Crisis Management</p> <p>Chairs: Chris Allen, Rudolf van Olden</p> <ul style="list-style-type: none"> • Role of Drug Safety Monitoring Boards - Karin Hedenmalm - <i>CTU Medical Products Agency</i> • Case report: Pre-Approval - Probiotics - Geert Blijham - <i>University Medical Center Utrecht</i> • Case Report: Post Approval - Glitazones - Alastair Benbow - <i>GlaxoSmithKline</i> <p>Getting new therapeutic modalities to the market</p> <p>Chairs: Luis Collia, Ed Schook</p> <ul style="list-style-type: none"> • Regulatory hurdle, need for change? - Bert Leufkens - <i>CBG-MEB NL</i> • Reimbursement hurdle, need for change? - Sir Michael Rawlins - <i>NICE UK</i> • Breaking News - tbd 	<p>Modern Clinical Development 2 Trends in Clinical Development</p> <p>Chairs: Johanna Schenk, Tanja Hoffman</p> <ul style="list-style-type: none"> • Stimulating Innovation: conditional and accelerated approach - Richard Tiner - <i>Association of the British Pharmaceutical Industry</i> • Patient Recruitment Strategies: Differences between Ph II/III - IV - Tom Ruane - <i>Quintiles</i> • Post marketing surveillance: Registries and other techniques - Nancy Dreyer - <i>Outcome</i> <p>Managing Cost Aspects in Clinical Development</p> <p>Chairs: Jean-Paul Deslypère, Philippa Smit-Marshall</p> <ul style="list-style-type: none"> • Cost management and Performance Metrics - David Sexton - <i>Pfizer Global Research and Development</i> • e-Clinical processes in improving cost efficiencies - Kenneth Getz - <i>CISCRP</i> • Improved efficiencies: Globalisation of Clinical Trials - Brian O'Keefe - <i>Malaysian Biotechnology Corporation</i>
<p style="writing-mode: vertical-rl; transform: rotate(180deg);">17.30 - 18.30</p>	<p>Networking Event</p>	
<p style="writing-mode: vertical-rl; transform: rotate(180deg);">19.30</p>	<p>Gala Dinner and IFAPP lecture – Patrick Dixon - <i>Global Change Ltd</i></p> <p>Beurs van Berlage</p>	

Wednesday, September 10 Pharmaceutical Future

Any end of the Blockbuster Mindset

Chairs: Stewart Geary, Henk-Jan Out

- R&D philosophy: private-public partnerships - Daan Crommelin - *Dutch Top Institute Pharma*
- Targeted therapies: nichebusters - Erik Tambuyzer - *Genzyme*
- Drivers behind science: role of financial investor - Martin Eigenhuijzen - *APG Investments*

Scientific Drivers behind Pharmaceutical Medicine

Chairs: Sander Becker, Montse Barceló

- Stem cell Research; New Panacea? - Steven A. Williams - *Pfizer*
- Latest Developments in Pharmaceutical Nanotechnology - Alexander Florence - *International Journal of Pharmaceutics*
- Personalized medicine: driver behind the end of the blockbuster era? - Michael Liebman - *Strategic Medicine*

Closing Ceremony

- ICPM 2010 at a glance

FARE WELL LUNCH

09.00 - 14.00

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