

The 4th  
**Oncology Clinical Trials in Emerging Regions**

23-24 April 2012

Prague, CZ

## Conference Agenda

### Day 1 – 23<sup>rd</sup> April 2012

<b>8.00 – 9.00</b>	<b>Registration</b>
<b>9.00 – 9.10</b>	<b>Chairman's opening remarks</b>
<b>9.00 – 09.40</b> Presentation	<b>Challenges of clinical trials in Eastern Europe: an overview</b> <ul style="list-style-type: none"><li>• A comparison of cost, risk and market opportunities</li><li>• Future challenges and opportunities</li></ul> <p><b>Cecilia Simonelli, MD, Head of Oncology &amp; Immunology Therapeutic Area, Menarini –Ricerche</b></p>
<b>9.40 – 10.20</b> Presentation	<b>Conducting oncology clinical trials in emerging regions: a guide to regulations</b> <ul style="list-style-type: none"><li>• Regulatory compliance in different regions</li><li>• Minimising risk and ensuring patient safety</li></ul> <p><b>Anna Harrington Morozova, Executive Director, RAPIEM (Regulatory Affairs Professionals for Innovation in Emerging Markets) and former Director of Regulatory Affairs Emerging Markets, GlaxoSmithKline</b></p>
<b>10.20</b>	<b>Morning refreshments</b>
<b>10.30 – 11.30</b>	<b>Prearranged One-on-One meeting Sessions</b>
<b>11.30 – 12.10</b> Presentation	<b>Exploring How the Emerging Regions of Russia and Eastern Europe Outperform Other Countries in Global Clinical Trial Recruitment</b> <ul style="list-style-type: none"><li>• Evaluating Emerging Markets - Perceptions and Comparison of Key Countries</li><li>• Examining Top Performing Enrollment Regions of Russia, Ukraine, Belarus and The Baltics On a Global Phase III Breast Cancer Trial in 20+ Countries</li><li>• Optimizing Clinical Trials in Russia and Eastern Europe</li></ul> <p><b>David Passov, President and CEO, ClinStar</b></p>
<b>12.10 - 12.50</b> Presentation	<b>Challenges of adaptive clinical trial design</b> <ul style="list-style-type: none"><li>• The main differences between the traditional clinical development path and adaptive design</li><li>• Selection of molecules and therapeutic indications for adaptive design in clinical development</li><li>• Understanding the flexibility of an adaptive trial process to guarantee your oncology trial is conducted in a timely manner</li><li>• Assessing the newest adaptive designs being incorporated into oncology trials to understand the current requirements</li><li>• Exploring the general recommendations of adaptive design trial to ensure the highest standard is delivered throughout</li><li>• Understanding regulatory authority requirements</li><li>• A review of examples of adaptive design studies</li></ul> <p><b>Tomas Skacel, International Medical Director, Amgen, Switzerland</b></p>
<b>12.50 – 13.50</b>	<b>Lunch</b>
<b>13.50 – 14.30</b> Presentation	<b>Complex multiregional trials in oncology - finding the Lagrangian point for culture, standards of care, and innovative clinical methodology</b> <p><b>Gerald Messerschmidt, Vice President, Oncology Medical Affairs, Worldwide Clinical Trials</b></p>

**14.30 – 15.10**  
**Panel Discussion**

**Operating and delivering successful clinical trials in emerging regions**

- Current trends in outsourcing clinical trials in emerging regions
- Regulatory issues and legal requirements
- Logistical considerations
- Examining cross-cultural considerations that may affect your clinical trials

**15.10**

**Afternoon refreshments**

**15.20 – 16.20**

**Prearranged One-on-One meeting sessions**

**16.20 – 17.00**

**Cardio-oncology: a new clinical and drug development paradigm**

- What is drug induced cardiovascular toxicity and how is cardio-oncology defined?
- How does cardio-oncology impact drug development and cancer treatment outcomes?
- What have we (and the regulators) learned from high profile oncology drug induced CV toxicity?
- What mitigation strategies are available for reducing CV toxicity in oncology drug development

**Boaz Mendzelevski, MD, Consultant Cardiologist, Cardiac Safety Consultants Ltd**

**17.00 – 17.40**

**Case study: conducting oncology clinical trials in Latin America**

- Reviewing the key issues that make a clinical trials successful in Latin America
- Analysing the common pitfalls
- Differentiating between expectations and obligations

**Marlene Llopiz-Aviles, President of AMEIFAC - Association of Medical Specialists in the Pharmaceutical Industry - Asociacion de Medicos Especialistas en la Industria Farmaceutica, A.C**

**Secretary of the Executive Board for IFAPP - International Federation of Associations of Pharmaceutical Physicians**

**17.40 – 18.40**  
**Round table sessions**

**Round Table Discussions**

- |                          |                               |
|--------------------------|-------------------------------|
| 1) Regulatory Affairs    | 2) Logistics and Supply Chain |
| 3) Patient Recruitment   | 4) Data Management            |
| 5) Safety and Compliance |                               |

**18.40 – 19.40**

**Networking Drinks Reception**

**Day 2 on next page >>>**

**9.10 – 9.50**  
**Presentation**

**The clinical development of biosimilar drugs in oncology**

- Emerging Markets from a clinical perspective
- Clinical development for biosimilars in Oncology

**Irek Otulski, Director of Clinical Development, Polpharma, Poland**

**9.50 – 10.30**  
**Presentation**

**A Phase 2 Case Study: Incorporating a Blinded Independent Central Read for Oncology Trials Conducted in Emerging Regions**

- Criteria for Site Selection and Qualification
- Standardized Training and Testing for Radiologists and Investigators
- Qualification BICR –how does this affect screen failure rate?
- Progression BICR
- Evaluation Charters
- Data Quality and Data Collection

**Lu Anne Honors, Director, Clinical Operations, Human Genome Sciences**

**10.30**

**Morning refreshments**

**10.40 – 11.40**

**Prearranged One-on-One meeting sessions**

**11.40 – 12.20**  
**Presentation**

**Case study: conducting oncology trials in Central and Eastern Europe**

- Study start-up phase
- Enrolment phase
- Quality and other related matters

**Denis Mir, Senior Manager, Clinical Operations - Oncology, Eisai Global Clinical Development**

**12.20 – 13.00**  
**Presentation**

**Identifying and overcoming the challenges of patient recruitment in oncology clinical trials in emerging regions**

- Creating interest in your trial: which strategies will work for you?
- Ensuring and communicating the benefits to patients
- Ethical considerations

**Janet Flisak, Clinical Program Leader Oncology, Global Clinical Operations, Johnson & Johnson**

**13.00 – 14.00**

**Lunch**

**14.00 – 14.40**  
**Panel Discussion**

**Oncology clinical trial conduct in emerging countries: Best practice and lessons learnt**

- Cost savings: a realistic assessment
- Balancing quality against cost
- Will FDA/EMA accept the data?
- Patient access
- Reimbursement issues

**14.40 – 15.20**  
**Presentation**

**Personalized medicine in oncology**

- An example of integrated platform for diagnostics, therapy, clinical trials and drug registries from the Czech Republic
- Challenges unique to the Czech Republic

**Marian Hajduch, MD., PhD., Associate Professor of Oncology and Director, Institute of Molecular and Translational Medicine, Faculty of Medicine and Dentistry, Palacky University and University Hospital in Olomouc**

**15.20 – 15.30**

**Chairman's Closing Remarks**

**15.30 – 16.00**

**Afternoon refreshments**