



# Workshop: Genomics in Cancer Risk Assessment

August 27-28, 2009 Venice, Italy



Parallel Satellite Workshop:  
10th International Conference on Environmental Mutagens (ICEM) Aug 20-25 2009 Firenze  
VII World Congress on Alternatives & Animal Use in the Life Sciences Aug 30 –Sept 3, 2009 Rome

## “Genomics in Cancer Risk Assessment”

Toxicological assessments of chemical compounds and drugs currently rely heavily on extrapolation from animal studies to human health risks. A wide range of *in vitro* assays has been devised to complement animal experiments to better understand potential risks from exposures, with the ultimate goal of replacing *in vivo* experimentation altogether. While a few *in vitro* cell-based or tissue-based assays have been developed that provide significant insight into organ-specific toxicities, the integration of toxicogenomic information into these assays has recently provided substantial improvements in hazard identification and predictive organ toxicity. One area that holds particular promise in utilizing toxicogenomics information is that of evaluating cancer risk associated with exposures to drugs and chemicals in our environment. The current testing paradigm consists of a short term genetic toxicity testing that detects damage to the genetic material of the cell, followed by carcinogenicity testing that relies on a chronic exposure of mice and rats via 2-year bioassays. Because of technical limitations of 2-year rodent bioassays, the data from the genetic toxicology testing battery is used for evaluating carcinogenic potential of drugs in early clinical development and of most industrial chemicals. Although the role of genetic damage in cancer development is well understood, the relationship between genetic toxicity testing and cancer development is imprecise due to limitations of these assays such as their over-sensitivity or their inability to detect non-genotoxic mechanisms of carcinogenesis. Furthermore, technical and ethical concerns associated with carcinogenicity testing in animals including the significant difficulty of the translation of results from *in vivo* rodent carcinogenicity results to the actual cancer risk to human populations provide challenge to industry and regulatory agencies. Therefore, a better understanding of carcinogenic mechanisms including their relevance to humans would significantly facilitate human cancer risk assessment. In this symposium we will discuss emerging genomic-based approaches applicable to toxicity and cancer hazard identification and risk assessment. A special emphasis will be given to development and evaluation of alternative *in vitro* models that have the potential to significantly reduce the use of laboratory animals. The participants will interact with leading experts from academia, industry, and governmental research and regulatory agencies. The outcome of the symposium is to identify promising approaches and identify gaps that need to be addressed in order to implement genomic approaches into a new safety evaluation strategy for drugs and chemicals that will satisfy current and future demands.





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## Organizing committee:

Jiri Aubrecht, Pfizer/HESI Genomics Committee  
Raffaella Corvi, European Centre for the Validation of Alternative Methods (EC ECVAM)  
Bernward Garthoff, Bayer CropScience  
Jos Kleinjans, Maastricht University/carcinoGENOMICS  
Anneloes Melman, Maastricht University/carcinoGENOMICS  
Raegan O'Lone, Health and Environmental Sciences Institute (HESI)  
Richard S. Paules, NIEHS/HESI Genomics Committee  
Rene Reijnders, Maastricht University/carcinoGENOMICS

## Draft Program

Thursday, August 27<sup>th</sup> 2009

- 9:00 am **Welcome and Introduction – Richard S. Paules, NIEHS**
- 9:15 - 9:45 am **Keynote Address I: Genomics at the FDA - Elizabeth Mansfield, Senior Genomics Advisor to the Commissioner, US FDA**
- 9:45 - 10:00 am **Break**
- 10:00 - 12:00 am **Session I. Current Approaches in Cancer Risk Assessment for Drugs and Chemicals**  
**Jan-Willem van der Laan, EMEA/RIVM, National Institute of Public Health & Environment, The Netherlands**  
**Wim de Coen, European Chemicals Agency, Helsinki**
- 12:00 - 1:00 pm **Lunch**
- 1:00 - 3:00 pm **Session II. In Vivo Approaches in Carcinogen Risk Assessment**  
**Hans-Juergen Ahr, Bayer Healthcare AG**  
**Mark Fielden, Amgen**  
**Rick Irwin, NTP, NIEHS**  
**Laura Suter, Hoffmann-LaRoche, Basel**
- 3:00 - 3:15 pm **Break**
- 3:15 - 5:15 pm **Session III. In Vitro Approaches in Carcinogen Risk Assessment**  
**Jiri Aubrecht, Pfizer**  
**Joost H. M. van Delft, Maastricht University**  
**Raffaella Corvi, EC ECVAM, JRC, Ispra**  
**Robert J. Kavlock, US EPA (ToxCast)**
- 6:30 - 7:30 pm **Poster Session**
- 7:30 pm **Welcome Reception**



Netherlands Genomics Initiative



National Institute of Environmental Health Sciences

carcinogenOMICS  
a Project of the European Union





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Friday, August 28<sup>th</sup> 2009

- 8:30 - 10:30 am      **Session IV. Human Carcinogen Risk Assessment**  
**Soterios Kyrtopoulos**, National Hellenic Research Foundation, Athens (the new EU FP7project EnviroGenoMarkers)  
**Kenneth Ramos**, U. of Louisville  
**Leona Samson**, MIT  
**Martyn Smith**, U. California, Berkeley
- 10:30 - 10:45      **Break**
- 10:45 - 12:20 pm    **Session V. 'Omics' and Risk Assessment in the 21<sup>st</sup> Century**  
**Vera Rogiers**, Free University Brussels  
**Christopher J. Portier**, NIEHS
- 12:20 - 1:30 pm     **Lunch**
- 1:30 - 3:10 pm      **Session VI. Challenges for the Future in Carcinogen Risk Assessment**  
**Paul Carmichael**, Unilever, UK  
**Jim MacDonald**, Chrysalis Pharma Consulting  
**Jonathan Moggs**, Novartis, Basel
- 3:10 - 3:30 pm      **Break**
- 3:30 - 4:15 pm      **Keynote Address II: Omics in the Present and Future of Human Medicine**  
**Hans Lehrach**, Max Planck Institute for Molecular Genetics, Berlin
- 4:15 - 5:30 pm      **Session VII. Panel Discussion - The Way Forward and the Role of Genomics**  
**David Rouquie**, BayerCropScience, Sophia Antipolis  
**James (Jim) S. Bus**, Dow Chemical  
**Nina Hallmark**, ExxonMobil  
**Beatriz Silva Lima**, Natl. Auth. of Med. & Health Products, and U. of Lisbon, Portugal  
**Vittorio Silano**, European Food Safety Agency

Workshop Concluding Remarks - Jos Kleinjans /Jiri Aubrecht

6:30 pm              **Gala Dinner, San Servolo**

