Workshop on Advances and Roadblocks for Use of Genomics Data in Cancer Risk Assessment for Drugs and Chemicals

May 25-26th 2017

McGill University Faculty Club
Montreal, Canada

Program

Day 1

8:00am	Registration & breakfast
9:00am	Welcome & presentation of meeting goals

- Alison Harrill, Division of the National Toxicology Program, National Institute of Environmental Health Sciences, US NIH & Carole Yauk, Health Canada

<u>Session 1: Regulatory Applications and Perspectives</u>

Session Co-Chairs: Frank Sistare, Merck & Co., Inc. & Jan Willem van der Laan, Medicines Evaluation Board

9:10am	Session opening remarks
9:15am	Regulatory state of the art for human pharmaceuticals (international perspectives)

- Roland Frötschl, Federal Institute for Drugs and Medical Devices, Germany
- Akiyoshi Nishikawa, National Institute of Health Sciences, Japan

Regulatory state of the art for chemicals (international perspectives)

- Akiyoshi Nishikawa, National Institute of Health Sciences, Japan
- Vincent Cogliano, US Environmental Protection Agency
- Miriam Jacobs, Public Health England

- Tara Barton-Maclaren, Health Canada
- Richard Paules, Division of the National Toxicology Program, National Institute of Environmental Health Sciences, US NIH

10:30 am Panel discussion on regulatory state of the art and roadblocks

11:15 am Break

Session 2: Considerations for Applications of Genomics Data for Regulatory Decision Making

Session Co-Chairs: Roland Frötschl, Federal Institute for Drugs and Medical Devices, Germany & Jonathan Moggs, Novartis

11:30am Session opening remarks

11:35am Make Genomics Reproducible Again – MAQC and Beyond

- Weida Tong, US Food and Drug Administration

12:00pm The NTP experience with genomic dose response modeling following the Elk River Chemical Spill

- Scott Auerbach, US National Institute of Environmental Health Sciences

12:30pm Lunch

1:30pm Analyzing data: Towards developing a framework for transcriptomics and other "Big Data" analysis for regulatory application. A work in progress

- David Rouquie, Bayer SAS

2:00pm Network-based approaches and systems toxicology for risk assessment

- James Stevens, Lilly Research Laboratories

2:30pm Panel Discussion: Technical Aspects for Use in Regulatory Decision-Making

3:15pm Break

Session 3: Case Studies

Session Co-Chairs: Heidrun Ellinger, Bayer AG & Jos Kleinjans, Maastricht University

3:30pm Session opening remarks

3:35pm Case study 1: Preclinical tissue-based transcriptomic and epigenomic indicators of neoplastic risk

- Jonathan Moggs, Novartis

4:00pm Case study 2: Transcriptomic profiles of genotoxic vs. nongenotoxic carcinogens

- Heidrun Ellinger, Bayer AG

4:25pm Case study 3: Transcriptomics-based in vitro models for predicting genotoxicity/carcinogenicity

- Jos Kleinjans, Maastricht University

4:50pm Case study 4: Leveraging toxicogenomics data to build predictive biomarkers supporting AOP assessment

- Chris Corton, US Environmental Protection Agency

5:15pm Case Study 5: Genomic analysis of insulin analogue induced mouse mammary tumors

- Bas ter Braak, Leiden University

5:40pm Closing remarks Day 1

- Alison Harrill, Division of the National Toxicology Program, National Institute of Environmental Health Sciences, US NIH & Carole Yauk, Health Canada

5:50pm Poster session and reception

7:30pm Adjourn Day 1

Day 2

8:30am	Breakfast
9:00am	Opening remarks • Heidrun Ellinger, Bayer AG & Jos Kleinjans, Maastricht University
	Session 3: Case Studies (continued)
9:15am	Case Study 6: Analysis of transcriptomic dose response data in the context of chemical risk assessment: Lessons from short-term *in vivo* studies and extension to high-throughput *in vitro* screening • Russell Thomas, US Environmental Protection Agency
9:40am	Case Study 7: Integrating toxicogenomics into conventional human health risk assessment to inform mechanism of action and point of departure for chemical exposures • Carole Yauk, Health Canada
10:05am	Coffee break
	Session 4: International Activities and Recommendations Session Co-Chairs: Jan Willem van der Laan, Medicines Evaluation Board & Carole Yauk, Health Canada
10:20am	Session opening remarks
10:25am	OECD and EU perspectives for characterising and implementing new approach methods • Raffaella Corvi, European Union Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM), DG JRC of the European Commission • Nathalie Delrue, Organisation for Economic Co-operation and Development (OECD)

11:05am	Current status of ICH S1 pharmaceutical carcinogenicity testing guidance development - potential strategic impact of implementing genomics. • Frank Sistare, Merck & Co., Inc
11:35am	Discussion
11:45am	Lunch

Session 5: Break-out Session

- **How are genomics data integrated with the current cancer risk assessment paradigm?**

Session Co-Chairs: Kathryn Bailey, Syngenta & Richard Paules, Division of the National Toxicology Program, National Institute of Environmental Health Sciences, US NIH

12:45pm	Session opening remarks
12:50pm	Breakouts: Discussion regarding recommendations based on the plenary discussion
2:50pm	Break
3:05pm	Summaries from each breakout group on recommendations and discussion Co-Chairs: Niladri Basu, McGill University & Richard Paules, Division of the National Toxicology Program, National Institute of Environmental Health Sciences, US NIH
4:45pm	Conclusion and Wrap up • Jan Willem van der Laan, Medicines Evaluation Board
5:00pm	Adjourn