



International Society
of Pharmacovigilance

November 2, 2018

North American Chapter (NASOP) Annual Meeting

Roundtable: Structured Benefit-Risk Assessment Across the Therapeutic Product Lifecycle

Moderators:

Veronique Kugener, SVP, Head, Global Patient Safety Evaluation
(Takeda) and **Abimbola Cole**, Post-PharmD Fellow (Takeda)

Presenters:

Laura Peppers, Senior Director, Aggregate Safety Assessment
Global Pharmacovigilance (Astellas)

Sara Eggers, Decision Support and Analysis Team (FDA)

Rania Mouchantaf, Manager (Health Canada)

Carmit Strauss, Benefit Risk Management Scientist (AMGEN)

Yola Moride, Professor (Université de Montréal & Rutgers
University)

Register by October 19

To register and for other inquiries please email:

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AGENDA

8:00am Registration

8:30am Welcome Remarks

9-11:30am Roundtable

- Introduction to Structured Benefit-Risk Assessments
- Structured Benefit-Risk Assessment for Human Drug Review
- Benefit Risk Evaluation Throughout the Product Life Cycle – a Health Canada Perspective
- Industry Implementation of the Structured Benefit Risk Assessment
- Data Sources for Structured Benefit-Risk Assessment and Impact on Evaluations

11-11:30am Panel / Q & A

12:30pm NASoP Meeting

1:30pm Closing remarks

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