



**8<sup>th</sup> – 9<sup>th</sup> March 2016**  
Hilton Garden Inn  
Heathrow, UK

**A PSI Training Course on**  
**Structured Benefit-Risk**  
**Assessment –**  
**Methodology and Practice**

**Presented by**  
**Benefit-Risk SIG**

Lecturers taken from academia and industry with an involvement in the IMI PROTECT Initiative on Benefit-Risk. The aim of this workshop is to provide participants an understanding of structured benefit-risk assessments, and the regulatory requirements on benefit-risk assessment within the EU. The 2 day course includes a practical workshop whereby participants will critically evaluate the benefit-risk balance of medicinal and healthcare product(s) in a robust and transparent manner. The course will provide participants the opportunity to gain insight and develop modelling skills in benefit-risk assessment, with an emphasis on multi-criteria decision analysis.

**The following topics will be covered:**

- Regulatory issues surrounding benefit-risk (BR) assessment
- Planning a structured BR assessment
- BR assessment methodologies
- Making the right methodology choices
- The involvement of multiple stakeholders in a BR assessment
- BR assessment in regulatory submissions
- Quantitative modelling in BR assessment
- Modelling benefit-risk balance and uncertainty involving multiple stakeholders
- Application and issues of BR assessment in health technology assessments

Risk Assessment and industry group's own initiatives. Keynote speakers include Prof Deborah Ashby (Imperial College) and Prof Larry Phillips (London School of Economics).

**Course runs from:**            **12:00 – 18.30 (registration from 10:00) on Day 1 and**  
   **09:00 – 16:30 on Day 2.**

**Registration**

Please register online at [www.psiweb.org](http://www.psiweb.org) and click on Events; payment now available online.  
Registration costs (includes lunch and refreshments)

**Registration for this 2 day course is now closed.**

**Registration**

PSI Members:            £495 plus VAT  
Non-members:         £570 plus VAT (includes PSI membership for 1 year)  
Academic:                £295 plus VAT

PSI aims to be fully inclusive and endeavours to accommodate delegates with disabilities wherever possible. Please help us to help you by letting us know if you require additional facilities or have any special requirements. Please contact us on +44 (0)1730 715 235 or at [PSI@mci-group.com](mailto:PSI@mci-group.com) for further information.

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