European Statistical Meeting (EFSPI/PSI): Structured Benefit-Risk Assessment

Tuesday 17th September, London

Structured Benefit-Risk assessments on both novel and marketed medicines are now being carried out with greater frequency by the pharmaceutical industry, academia, regulatory agencies and payers in order to help with greater transparency but also to help enable better decisions to be made. This one day, face to face, meeting is being organised jointly between EFSPI and PSI to give the latest information around structured Benefit-Risk assessments from academic, industry and regulatory perspectives. The day will start with the thinking behind structured benefit risk assessments and then move onto the reality of carrying one out using examples from both industry and the IMI PROTECT Benefit Risk-Work Package. So whether you are new to Benefit-Risk, or trying to find better ways of carrying out a Benefit-Risk assessment, this will be for you.

9:00 **Registration & Coffee**

9:25 **Welcome & Introduction**

AN INTRODUCTION

9:30 **Why and how do we do benefit-risk assessment in drug regulation: lessons from IMI PROTECT**
Prof Deborah Ashby (Imperial College London)

10:15 **A regulatory perspective of Structured Benefit-Risk**
Dr Andrew Thomson (MHRA)

11:00 **Tea & Coffee**

11:15 **Implementing a structured Benefit Risk Approach - A Company perspective**
Rebecca Sudlow-(Associate Director, Roche Products Limited)

12:00 **Lunch**

THE REALITY

13:00 **IMI PROTECT case study: Structured Benefit-Risk applied to natalizumab**
Dr Richard Nixon (Novartis)

13:45 **An industry case study: Using impactful presentations to support structured Benefit-Risk assessments in practice**
Dr Ian Hirsch (AstraZeneca)

14:30 **Tea & Coffee**

14:45 **An IMI PROTECT case study:- Telithromycin**
Dr Christine Hallgreen

15:30 **Benefit-Risk Analysis in practice: What have teams and decision makers found most useful?**
Alfons Lieftucht (Director, Benefit-Risk Evaluation, GSK)

16:15 **Discussion**

17:00 **Close**

Venue
Royal Statistical Society
Errol Street
London
United Kingdom

Registration fees

Early Bird Rates
(on or before Wednesday 31st July)

Industry = £135 (excluding VAT)
£162 (including VAT)

Academic = £85 (excluding VAT)
£102 (including VAT)

Standard Rates
(after Wednesday 31st July)

Industry = £160 (excluding VAT)
£192 (including VAT)

Academic = £100 (excluding VAT)
£120 (including VAT)