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European Federation of Statisticians in the Pharmaceutical Industry

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EFSPI/*PSI* invites you to attend our webinar

Structured Benefit–Risk Assessment

Presentations:

Benefit-Risk Assessment via Case Studies: Key Considerations and Best Practices
by George Quartey

The emerging and merging fields of benefit-risk and health technology assessments
by Jason (Jixian Wang), Shahrul Mt-Isa and Susan Talbot, on behalf of the EFSPI BRA/HTA joint working group

The webinar occurs twice:
1st webinar: 2017 February 9, 5pm CET (4pm GMT)
2nd webinar: 2017 February 14, 5pm CET (4pm GMT)

Please register at

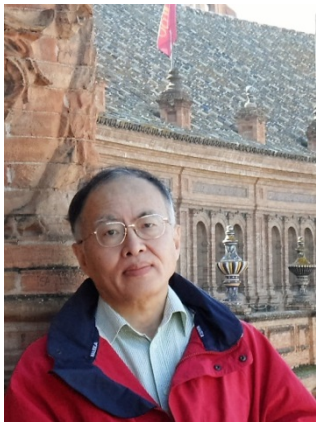
www.benefit-risk-assessment.com/webinar2017

Open to EFSPI/PSI members and non-members
Organized by the EFSPI/PSI special interest group on benefit-risk

Benefit-Risk Assessment via Case Studies: Key Considerations and Best Practices

Abstract: The development and implementation of benefit-risk assessment is multi-faceted and should be done throughout the clinical development life cycle. Use of structured benefit-risk framework could enhance regulatory decisions, both in terms of scientific validity and in terms of consistency and transparency to stakeholders. In this talk, we describe two real examples that regulatory agencies considered in benefit-risk evaluations, resulting in different outcomes in their approval and marketing status. These case studies illustrate a few key considerations (i.e subgroup identifications, endpoint selection with important clinical impacts, uncertainty quantification, risk mitigation etc.) for a full benefit-risk evaluation.

About the presenter: Dr George Quartey is a Strategic Innovation Leader for Safety Risk Management at Roche-Genentech with over 25 years of diverse experience in statistical research, risk-benefit modeling, comparative effectiveness research, evidence synthesis and data Mining. He is currently responsible for leading major innovation and enablement in areas relating to Benefit-Risk Assessment of Medicines, Machine Learning and Predictive Safety Monitoring as well as Safety Strategies for Handling HTA. Dr Quartey published and spoke widely on both theoretical and pragmatic aspects of benefit-risk assessment of medicines and served on several internal and external committees that inform policy on benefit-risk and quantitative safety methods including IMI PROTECT, QSPI Benefit-Risk Working Group and CIOMS X working group on "Evidence Synthesis and Meta-Analysis for Drug Safety". Dr Quartey is currently the co-director of the IMI EU2P program on benefit-risk assessment of medicines.



The emerging and merging fields of benefit-risk and health technology assessments

Abstract: Benefit-risk assessments (BRA) focus on clinical aspects of health care products and are often seen as purely regulatory activities, while health technology assessments (HTA) consider a wider range of aspects, but mainly concentrate on economic evaluations. Despite different objectives, the perspectives and requirements of the two domains are becoming more in sync than a decade ago. This is evidenced by the formations of various initiatives to address novel challenges, raising the bar for those directly involved in providing justifiable evidence for decision-making on health technologies for the good of public health. With increasing methodological demands and considerations that are no longer unique to HTA or BRA in regulatory submissions, more issues have surfaced and more questions have been raised. Despite the numerous efforts, the recommendations remain diverse and the efforts remain distinct. The EFSPI/PSI joint working group for BRA and HTA has conducted an extensive review of the initiatives and investigated methodologies to recommend practical approaches to improve HTA with an integrated BRA. We will present an up-to-date review of the outputs from key initiatives focusing on methodologies, and will compare approaches taken by HTA authorities with those taken by the regulatory agencies.

About the presenter: Jason (Jixian) Wang is a principle statistician at Celgene, with over 25 years of experiences as statistician in a number of areas in pharmaceutical statistics, has published more than 50 peer reviewed papers and a book on exposure-response modeling. He worked on health economics and outcome researches and epidemiology in academic institutes for several years before moving to industry positions supporting clinical pharmacology in Phase I-III trials and regulatory submissions, with a number of successful NDA submissions to the FDA/EMEA . Since 2014, he has been working on health economics and outcomes researches to support global market access. His current interests are on health economics modeling, real world evidence generation and causal inference, and structured benefit-risk and health technology assessments. He is a member of PSI special interest groups for real world data (formally epidemiology), modeling and simulation and health technology assessment (HTA). He is leading a working group on clinical trial extrapolation for HTA, and is a coordinator for the EFSPI joint working group for benefit-risk assessment and HTA.