Annual Workshop on

Visualising Benefit-Risk: The key to developing a framework that informs stakeholder perspective and clarity of decision making

16 - 17 June 2011

PROGRAMME AND WORKSHOP DOCUMENTS

Venue: The Madison Hotel, Washington DC, USA

CENTRE FOR INNOVATION IN REGULATORY SCIENCE
(FORMERLY CMR INTERNATIONAL INSTITUTE FOR REGUATORY SCIENCE)
The Johnson Building, 77 Hatton Garden, London EC1N 8JS, UK, Telephone: +44 (0) 207 433 4000 Email: ghepton@cirsci.org

Organiser
Professor Stuart Walker: swalker@cirsci.org
Neil McAuslane: nmcauslane@cirsci.org

Centre for Innovation in Regulatory Science Workshop

Background

Visualising Benefit-Risk: The key to developing a framework that informs stakeholder perspective and clarity of decision making

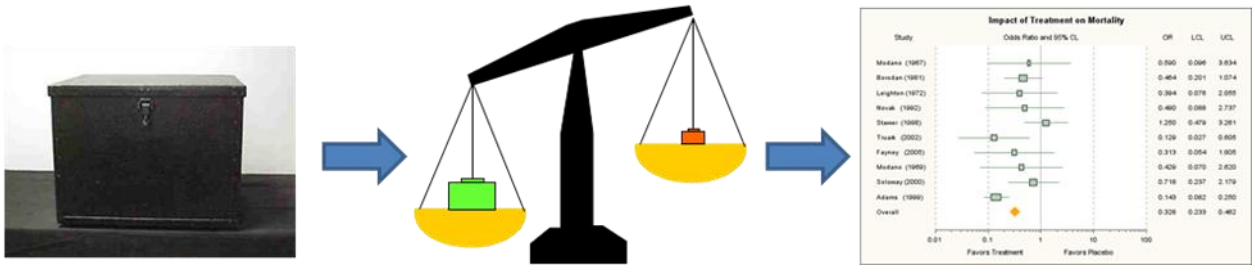
In 2010 the Centre held its annual meeting on benefit-risk in Washington, DC to discuss weightings and values within frameworks. It was agreed that one way of ensuring the development of the most effective framework is through undertaking scenarios with different stakeholders and products.

This method will allow identification of ways in which agencies and companies will use the framework and establish practical methodologies to be used in the review of new medicines. That Workshop also identified a number of barriers to acceptance of a benefit-risk framework and possible solutions which include continuing dialogue between agencies and companies and working through examples as a way of both evolving the thinking and gaining acceptance to the value of a process for articulating benefit-risk in a transparent manner.

In 2011, as the development of a benefit-risk framework moves forward through FDA, EMA, BRAT and the consortium of four agencies being facilitated by the Centre, this Workshop will again bring the groups together with industry, many of whom are developing their own methodology with common objectives.

Workshop Objectives

- **Discussing the progress** made since 2010 by the different groups on defining and implementing a benefit-risk framework within their organizations.
- **Furthering the thinking** of how to undertake weightings and valuing within the framework using worked examples/ scenarios and testing the difference between industry and agencies using practical examples.
- **Identifying how and what** visualisation techniques can aid both the inputs and outputs of the process of describing benefits and risks and how this enables stakeholders to a better articulation, understanding and clarity of the benefit-risk decision



Venue

The Workshop will take place at The Madison Hotel, Washington DC, USA commencing at 08.30 on Thursday 16th June and finishing 13.00 on Friday 17th June 2011.

Style and Participation

Following the agreed practices for Institute Workshops, the meeting will be closed and the size will be limited to allow productive networking and discussions.

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Professor Stuart Walker: swalker@cirsci.org
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Day 1: Thursday 16 June 2011

08:30 Registration

SESSION 1: DEVELOPMENT OF A FRAMEWORK FOR BENEFIT-RISK: CHALLENGES AND ARE WE THERE YET?		
09.00	**Chairman's welcome and introduction**	**Prof Bruno Flamion,** Chairman, Belgian Committee for Reimbursement of Medicines, Belgian National Institute for Health and Disability Insurance
	Is there a need for an internationally accepted approach for the systematic routine and standardised documentation of decision making in the Benefit-Risk assessment of medicines?	
09.10	**EMA Viewpoint**	**Prof Hans-Georg Eichler,** Senior Medical Officer, European Medicines Agency
09:35	**FDA Viewpoint**	**Dr Theresa Mullin,** Director, Office of Planning and Informatics, CDER, Food and Drug Administration
10:00	**Industry Viewpoint**	**Dr Ellen Strahlman,** Chief Medical Officer GlaxoSmithKline, USA
10.25	**Discussion**	
10.30	**Break**	
11:00	**Progressing the Benefit-Risk Framework – What is getting in the way – methodology, culture or some other factor?**	**Prof Stuart Walker and Dr Neil McAuslane,** Centre for Innovation in Regulatory Science
	Benefit-Risk Framework Development and Visualisation: Current status and forward plans	
11.20	***Status of EMA Framework Development***	**Dr Lawrence D. Phillips,** Professor, London School of Economics and Political Science, UK
11.40	***Status of Four agencies consortium***	**Dr Supriya Sharma,** Director General, Therapeutic Products Directorate, Health Canada
12.00	***Status of BRAT Framework Development***	**Dr Diana Hughes,** Vice President, Worldwide Safety Strategy, Primary Care Business Unit Lead, Pfizer Inc, USA
12:20	**Status of IMI PROTECT Consortium on benefit-risk communication**	**Dr Alain Micaleff,** Senior Medical Safety Advisor, MerckSerono SA, Switzerland
12:40	**Discussion**	
13:00	**Lunch**	

SESSION 2: SYNDICATE SESSIONS		
14:00	**Introduction to the Scenarios and Methodology**	**Dr Bennett Levitan**, Director, Epidemiology, Johnson & Johnson PRD, USA
14.45	**Syndicate sessions** **Each syndicate will use a structured format relating to the same scenario. Based on a real case scenario the same exercise and approach for weightings and valuing benefits and risks will be utilised, with one group using a qualitative approach and the other a quantitative approach.**	
	Syndicate 1 Qualitative approach **Chairman: Dr Jason Ferla,** Director of Prescription Medicines Clinical Unit 3, Therapeutic Goods Administration, Australia **Rapporteur: Dr John Ferguson,** VP & Global Head, Pharmacovigilance & Medical Safety, Novartis Vaccines & Diagnostics USA **Facilitator: Dr Becky Noel,** Research Scientist**,** Eli Lilly and Company, USA **Syndicate 2 Qualitative approach** **Chairman: Dr Filip Mussen,** Senior Director, Global Regulatory Affairs Neurosciences, Janssen R&D, Belgium **Rapporteur: Dr Richard Hermann,** Director, Clinical Research, Epidemiology, AstraZeneca R&D, USA **Facilitator: Dr Bennett Levitan,** Director, Epidemiology, Johnson & Johnson., USA **Syndicate 3: Quantitative approach** **Chairman: Prof Hans-Georg Eichler**, Senior Medical Officer**,** European Medicines Agency **Rapporteur: Dr Carmen Bozic,** Vice President and Global Head of Drug Safety and Risk Management, Biogen Idec, USA **Facilitator: Dr Lawrence D. Phillips**, Professor, London School of Economics and Political Science, UK	
18.30	**End of Syndicate Discussion and end of day one**	
19.00	**Reception**	
19.30	**Dinner**	

DAY 2: Friday 17 June 2011

SESSION 3: CHALLENGES AND DIFFICULTIES OF PRESENTING BENEFIT-RISK INFORMATION TO STAKEHOLDERS – IS VISUALISATION THE KEY TO INFORMED DECISION MAKING AND INFORMATION SYMMETRY?		
08.30	**Chairman's Introduction**	**Prof Sir Alasdair Breckenridge**, Chairman, Medicines and Healthcare products Regulatory Agency, UK,
08:35	**Feedback of day one syndicate discussion**	
09.35	**Visualisation options for presenting benefit-risk information on a new medicine to agencies: Does this need to be improved?** *Current approaches to presentation of data and submissions on benefits and risks are not always presented in a coherent and well structured manner. How do companies articulate the benefit risk and how is an agency best informed? What role does visualisation play in imparting or framing the companies view of the Benefit-Risk of a new medicine? Can the representation of the benefits and risks be improved?*	
	Industry Viewpoint	**Dr James Felli,** Research Fellow, Eli Lilly & Co, USA
	Agency Viewpoint	**Dr Mark Walderhaug,** Associate Office Director for Risk Assessment CBER, Food and Drug Administration, USA
10.20	**Discussion**	
10.30	**Break**	
	Presenting the regulatory decision on the benefit-risk of a new medicine to Physicians: What are the visualisation techniques Agencies think are best and do Physicians find them useful?	
11.00	Presenting the regulatory decision on the benefit-risk of a new medicine to healthcare professionals	**Dr Jane Ahlqvist-Rastad**, Senior Expert, Medical Products Agency, Sweden
11.20	Communication of benefit-risk information to patients by physicians, pharmacists and nurses for shared decision making	**Prof Sam Salek**, Professor of Pharmacoepidemiology, Cardiff University
11.40	**Discussion**	
11.50	**Presenting Benefit-Risk information on a new medicine to Patients: What are the challenges and can visualisation improve understanding?**	**Prof Ruth Day**, Director, Medical Cognition Laboratory, Duke University, USA
12.15	**Discussion**	
12.20	**What role has "perception" in communicating and understanding benefit-risk assessment of medicines?**	**Prof Sylvie Perreault,** Faculty of Pharmacy, University of Montreal, Canada
12.50	**Possible next Steps**	**Prof Stuart Walker,** Centre for Innovation in Regulatory Science
13.00	**Close of Workshop followed by lunch**	