Contemporary Insights Workshop

Exploring Approaches to Decision Making

11 - 12 June 2015

PROGRAMME

Venue: The Sofitel Hotel Washington, DC, USA

CENTRE FOR INNOVATION IN REGULATORY SCIENCE
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Centre for Innovation in Regulatory Science Workshop

Background

Exploring Approaches to Decision Making

The overarching elements of a framework for Benefit-Risk assessment have been well articulated over the last five years resulting in there being commonality in the steps taken by both agencies and companies to assess a medicine's benefit-risk profile. As companies and agencies embedded this framework into their decision-making process as a key tool to inform the discussion around the benefit risk assessment, a number of key questions arise:

- ***How can we ensure that the Framework is actively used as part of the decision process?***
- ***What is the process for its incorporation within current decision-making procedures?***
- ***How can the Framework help improve the quality of the decision to progress or submit a new medicine?***

These questions go beyond the implementation of just a benefit-risk framework, but represent a formal approach to quality decision making within an organisation. The science of decision making is well established, although in reality it's a mixture of science and art. A number of common features identify characteristics of a good quality decision: having creative implementable options; having meaningful, reliable information upon which to base a decision; identifying clear values and tradeoffs for each supportive element; using logically correct reasoning; and making a commitment to action. Indeed, these map well to the steps articulated in the UMBRA Benefit Risk Framework. However, decision-making within companies and agencies are in large part influenced by their organisational processes and procedures.

One way to determine whether quality decisions are being made is to assess the outcome and consequences of the decision. However, this is not often practical and can be extremely difficult to measure. Indeed, a good, well-made decision may have poor consequences and a bad decision may have good outcomes. Therefore, there is a need to ensure that processes within companies are structured so as to enable consistency around making good quality decisions.

Currently what is lacking is research & insight into the decision-making approaches for individuals and organisations involved in medicines research and development. An enhanced understanding of how to identify and apply quality decision-making practices may facilitate decision-making approaches and subsequently may enable improved practices for both the individual and the organisation.

Over the last 3 years, in addition to the work to develop a systematic structured approach to benefit risk, CIRS has undertaken a project to identify the important issues that influence quality decision-making from the perspective of the individual and organisations. As a result of this background research, a draft framework for good decision making in the development and review of medicines has been developed.

As the benefit-risk framework is now becoming the cornerstone of building quality into the critical decisions being made within companies and agencies, CIRS is interested in understanding and identifying how the benefit-risk decision framework is being built into the broader decision-making process. This workshop will focus on what the other factors and influences that companies and agencies need to consider to ensure they are building quality into their decision-making processes.

Workshop Objectives

- **Discuss the potential influences** on good decision making, within companies and agencies and whether a framework can improve the process
- **Identify considerations for both companies and agencies** when applying decision frameworks to their decision making processes
- **Make recommendations** how stakeholders can ensure they are building quality into their decision making processes

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Venue

The Workshop will take place at The Sofitel Hotel in Washington DC, commencing at 09:00 on 11th June and finishing at 15:30 on the 12th June 2015.

Style and Participation

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

An Important Note to Attendees

Welcome to this CIRS Workshop. Over the past 14 years, CIRS Workshops have established themselves as a safe harbour forum for a diverse mix of stakeholders to openly share their experiences, develop and challenge policies and practices and suggest novel approaches to addressing often vexing aspects of medicine, regulation and access.

Our constant goal is for all Workshop participants to share in this opportunity for open and constructive interaction.

As has been CIRS' longstanding practice, speaker slides will be shared with participants and CIRS will prepare a comprehensive Workshop report with summaries reviewed by the speakers. These can be shared freely within your organisations.

To maintain this atmosphere of collaborative, international multi-stakeholder interactions, as a Workshop attendee you agree NOT TO USE any form of audio or visual recording nor to broadcast or share any aspect of this Workshop by any medium, including but not limited to blogs or services such as Twitter, Facebook and LinkedIn, during or following this Workshop.

Thank you for respecting these practices. If you have any questions about this policy please do not hesitate to contact a member of the CIRS staff.

We look forward to your active participation and contributions.

Day 1: 11th June 2015

08.30 Registration

SESSION 1: UTILISING DECISION FRAMEWORKS: HOW ARE COMPANIES AND AGENCIES USING THE BENEFIT-RISK FRAMEWORK TO BUILD QUALITY INTO THEIR DECISION MAKING PROCESS?	
09:00	**Chair's Welcome and Introduction** **Dr Sandra Kweder**, Deputy Director, Office of New Drugs, Food and Drug Administration, USA
09:10	**From Benefit-Risk Frameworks to Quality Decision Making** **Prof Stuart Walker,** Founder, CIRS
	Improving the Quality of Regulatory Decision Making **"**Would a structured approach to benefit-risk assessment in the approval process improve transparency and predictability of decision making?"
09:30	**FDA viewpoint - Dr Richard Moscicki**, Deputy Center Director for Science Operation, US Food and Drug Administration, DIA
09:50	**EMA Viewpoint - Prof Hans-Georg Eichler,** Senior Medical Officer, EMA
10:10	**Health Canada viewpoint - Barbara Sabourin,** Director General, Therapeutics Products Directorate, Health Canada
10:30	**Discussion**
10:40	**Break**
	Improving the Quality of Company Decision Making **"**Does introducing a structured approach to benefit-risk assessment improve the quality of the decision making process?"
11:10	**Project Team Decisions – Dr Richard Hermann,** Safety Scientist, AstraZeneca, USA
11:30	**Submission Decision for New Drug Applications – Sharon Olmstead,** Global Head, Development and Regulatory Policy Novartis, USA
11:50	**Discussion**
	Beyond Benefit-Risk - Building Quality into Decision Making "Decision-frameworks as a critical decision tool within companies and agencies– What factors need to be considered by companies and agencies"
12:00	**Company Viewpoint – Dr Bennett Levitan,** Director, Janssen, USA
12:20	**Agency Viewpoint – Prof John Skerritt,** National Manager**,** Therapeutic Goods Administration, Australia
12:40	**Discussion**
13:00	**Lunch**

SESSION 2: CURRENT DECISION MAKING PROCESSES IN COMPANIES AND AGENCIES	
14:00	**Chair's Introduction** **Professor Sir Alasdair Breckenridge**
14:05	**Building Quality into the Decision Making Process: What Frameworks are Companies and Agencies Using?** "CIRS Survey on current processes and practices within companies, regulatory and HTA" **Dr Neil McAuslane,** Scientific Director, CIRS
	Challenges and Opportunities within current practices and processes
14:30	**Company Viewpoint – Dr Joseph Scheeren,** Head, Global Regulatory Affairs Pharma and Consumer Care, Bayer Consumer Care, Switzerland
14:50	**Regulatory Viewpoint – Prof Dr Hans Hillege**, Alternate CHMP Member, Medicines Evaluation Board, The Netherlands
15:10	**HTA Viewpoint – Dr Chander Sehgal,** Director, Common Drug Review (CDR) and Optimal Use, Canadian Agency for Drugs and Technologies in Health
15:30	**Discussion**
15:35	**Which Models have been Used Based on Decision Theory and ow Can These be Applied to Health Issues?** **Dr Lawrence Phillips,** Emeritus Professor of Decision Sciences, London School of Economics and Political Science, UK
15:55	**Discussion**
SESSION 3: SYNDICATE SESSIONS	
16:00	**Syndicate sessions** *Each syndicate will undertake the following using a structured format to address the syndicate topic. Based on a proposal and a set of questions or outline, the syndicate is asked to review debate and make recommendations to answer the question.* **Topic A: Good decision practices for submission/review/recommendation by companies and agencies (Regulatory and HTA): What should be the characteristics/attributes of a good decision framework?** **Chair:** Prof Sir Alasdair Breckenridge **Rapporteur**: Mary Jo Pritza, Senior Director, Regulatory Affairs, Astellas Pharma Global Development, USA **Topic B: Good decision practices for submission/review/recommendation by companies and agencies (Regulatory and HTA): How should good quality decision-making practices be measured?** **Chair:** Pam Smith, Vice President, Europe & Emerging Market Regulatory Affairs,AstraZeneca, UK **Rapporteur**: Adrian Griffin, Vice President, Global HTA and Reimbursement Strategies, Johnson & Johnson, UK **Topic C: Good decision practices for submission/review/recommendation by companies and agencies (Regulatory and HTA): What are the main challenges to good decision practices and what are the possible solutions?** **Chair**: Prof John Skerritt, Therapeutic Goods Administration, Australia **Rapporteur:** Dr James Leong, Centre of Regulatory Excellence, Duke-NUS Graduate Medical School Singapore
18:00	**End of Session**
19:00	**Reception**
19:30	**Dinner**

DAY 2: 12th June 2015

SESSION 3: SYNDICATE SESSIONS	
08:30	**Syndicate sessions resume**
10:00	**Break**
SESSION 4: SYNDICATE FEEDBACK AND PERSPECTIVES	
10:40	**Chair Introduction** **Prof Robert Peterson,** Executive Director, Drug Safety Effectiveness Network, Canadian Institute of Health Research
10:45	**Feedback of syndicate discussion and participants viewpoint following each syndicate discussion**
	Stakeholder Perspectives - Improving the quality of decision making processes and practices
11:45	**Patient perspectives** - **Patricia Furlong**, Founding President and CEO, Parent Project Muscular Dystrophy, USA
12.05	**Payer Perspective** – **Dr C Bernie Good**, Professor of Medicine, and Pharmacy, Chief, Section of General Internal Medicine at the VA Pittsburgh Healthcare System (VAPHS)
12.25	**PCORI Perspective** – **Jean Slutsky,** Chief Engagement and Dissemination Officer and Program Director for Communication and Dissemination Research, Patient-Centered Outcomes Research Institute (PCORI)**,** USA
12:45	**Discussion**
12:50	**Lunch**
13:50	**Chairman's Introduction**
	Future Perspectives: How should the quality of decision making processes be measured?
14:00	**Company Perspective – Karen Hauda,** Senior. Director, Regulatory Policy, Novo Nordisk Inc, USA
14:20	**Policy and academic Perspective- Singapore - Professor John Lim,** Deputy Director of Medical Services, Ministry of Health, Singapore and Executive Director, Centre of Regulatory Excellence, Duke-NUS Graduate Medical School, Singapore
14.40	**HTA Agency Perspective – Dr Alan MacDonald,** Vice-Chair of SMC and Chair of the SMC New Drugs Committee, Scottish Medicines Consortium
15:00	**Discussion**
15:10	**Way Forward – CIRS three year plan** **Lawrence Liberti,** Executive Director, CIRS
15:30	**Close of Workshop**