Building Quality into Companies Benefit-Risk Decision Making

How does the framework enable the decision-making process and what else needs to be considered

Technical Forum

Programme

5 December 2014

Ritz-Carlton Hotel, Philadelphia USA

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

Organiser
Larry Liberti: lliberti@cirsci.org
Neil McAuslane: nmcausalne@cirsci.org
Professor Stuart Walker: swalker@cirsci.org

3 September 2014

Centre for Innovation in Regulatory Science Technical Forum

Background

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. Indeed, many companies are now internally using the CIRS-BRAT framework in order to better articulate the benefit-risk profile of a new medicine. Some companies have embedded this framework into their decision-making process as they evaluate medicines during the key development and submission go/no go decision stage gates.

As the BR framework becomes embedded as a key tool within companies 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 the company's current decision-making procedures?***
- ***How is the information communicated to those who actually make the final decision and***
- ***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 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 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. However, although the steps for the benefit-risk Framework are well understood, what are 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 how the structured approaches to evaluating the evidence in balancing benefit-risk is undertaken and how this is incorporated into the broader key decision-making processes within companies**
- **Discuss what are the potential influences on good decision-making, both at the project team level and at a senior management level**
- **Develop considerations that companies need to be aware of when applying or imbedding the Benefit Risk framework within their decision-making processes.**

Venue

The Workshop will take place in at the Ritz-Carlton Hotel, Philadelphia, USA, commencing at 09:00 and finishing at 18:00 on Friday 5 December 2014

Organiser
Larry Liberti: lliberti@cirsci.org
Neil McAuslane: nmcausalne@cirsci.org
Professor Stuart Walker: swalker@cirsci.org

08:30 Registration and coffee

SESSION 1: HOW IS THE BENEFIT RISK FRAMEWORK BEING USED PRACTICALLY WITHIN COMPANIES AS PART OF THE DECISION-MAKING PROCESS:		
09:00	**Chairman's Introduction**	Lawrence Liberti, Executive Director, CIRS
09:10	**Moving to wider-scale utilisation of a benefit-risk framework as a critical decision tool within companies – What needs to be considered?**	**Dr Bennett Levitan,** Director, Janssen, USA
	Focus on process as to how the benefit-risk framework is used in companies as part of the decision- making process?	
09:40	**Company Experience - Use in the decision to submit an application**	**Dr Carmen Bozic,** Senior Vice President, Clinical and Safety Sciences, Biogen Idec, USA
10:10	**Benefit-Risk Assessment: Where We're At and Where We're Headed**	**Dr Becky Noel,** Director, Eli Lilly and Company, USA
10:40	**Discussion**	
11:00	**Break**	
11:30	**Roundtable Discussion and Feedback – Incorporating the Benefit-Risk Framework into the decision process – how can this best be achieved within companies?**	**All participants**
13:00	**Lunch**	
SESSION 2: IMPROVING THE QUALITY OF DECISION-MAKING BY INDIVIDUALS AND COMPANIES – WHAT SHOULD BE THE KEY CONSIDERATIONS?		
14:00	**Building quality into the decision-making process: What are the main factors that need to be considered by companies and why are these important?**	**Dr Neil McAuslane,** Director, CIRS
14:30	**Discussion**	
14:40	**How might companies better understand what influences their decision-making process?**	**Professor Stuart Walker,** Founder, CIRS
15:05	**What are the practical challenges for companies to improve the quality of their decision-making processes and procedures?**	**Dr Linda Scarazzini,** VP, Medical Safety Evaluation, Pharmacovigilance and Patient Safety, AbbVie, USA
15:30	**Break**	
16:00	**Roundtable Discussion and Feedback – Improving the quality of decision-making – how can this best be achieved within companies?**	**All participants**
17:30	**Chairman's Summary**	
18:00	**Close of meeting**	