Workshop

The value of Utilizing a Systematic Standardized Approach to the Review of Medicines

A proposal for a two day training workshop for Regulators within Asia-Pacific taking into account:

1- Benefit-Risk Assessment of medicines
2- Good Review/Registration Practices
3- Building Quality into agency decision-making

15 - 16 May 2017

PROGRAMME

In collaboration with

Centre of Regulatory Excellence, Duke-NUS Medical School

Venue: Level 5, Room 5C
Duke-NUS, Singapore

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3rd May 2017

The value of utilizing a systematic standardized approach to the benefit risk assessment of medicines

Introduction

Determining the benefit-risk balance of a medicine is one of the most important steps in its development, review and post-approval reassessment. There is a general agreement amongst agencies and companies that there is a need for both to be utilizing a structured, standardised, systematic approach to benefit-risk assessment of medicines using a framework that should ideally be feasible and practical within the regulatory review process.

The advantage of a systematic standardised approach to the benefit-risk assessment of medicines is that the review would be more transparent, predictable and consistent. This would be in line with the WHO Good Review Practices for regulatory authorities released in 2015. In addition, the systematic standardisation of the benefit-risk assessment of medicines could be of considerable value to agencies as a cornerstone with respect to building quality into their decision making process as well as in communicating their views and decisions. Such a system would be of further value to agencies conducting both abridged and verification reviews where there is reliance to some degree on the assessment by reference agencies. In addition, if regulatory authorities wish to work together and collaborate within a region for both joint and shared reviews, then it is essential that there is agreement with respect to the clinical template and a critical part of this is the benefit-risk assessment section

CIRS has been involved in this area for over a decade, including the development of the Universal Methodology for Benefit-Risk Assessment (UMBRA) framework and its documentation, both within drug development and during the regulatory review. Furthermore, CIRS and CoRE have undertaken a collaborative initiative for agencies in Southeast Asia to assess the UMBRA framework and the associate summary documentation together with the user manual. The objective of this study was to evaluate the benefits and value of the UMBRA approach within agencies in a practical setting.

This workshop will bring together agencies that have either actively participated in the CIRS/CoRE project as well as agencies that are interested to learn and uunderstand how the benefit-risk decision framework is being built into the broader decision-making process. This workshop will aim to provide training on how to utilise a systematic structured approach to benefit risk assessment as well as understand how this approach can build good review practices and quality decision making into their processes.

Workshop Objectives

1. Provide an understanding of the approaches for benefit-risk assessment of medicines both by major international agencies and locally within Asia Pacific.

2. Discuss benefit risk as one of the cornerstones of good review practices and how utilization of a benefit risk framework builds quality into the decision making process

3. Evaluate the UMBRA eight-step qualitative framework in order to review its applicability within the agencies in the maturing markets

4. Discuss quality of decision making practices as a component of good review practices

Venue

The Workshop will take place at Duke-NUS in Singapore on the 15 - 16 May 2017.

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Overall Outline:

Closed Session

Day 1: **Session 1** (09:00 -12:30). Benefit-Risk Assessment – Feedback from iSABRE - Utilisation of a systematic structured framework to build consistency and process predictability into the review title – **for iSABRE agencies only (Malaysia, Indonesia, Taiwan, Philippines, Thailand)**

Open Sessions

Day 1: Session 2 (13:30 - 18:00). Current and Future Approaches to Benefit-Risk Assessment: Its Fundamental Role in the Assessment of New Medicines

Day 2: Session 3 (09:00 -12:30) **-** Beyond Benefit-Risk - Utilising the Benefit-Risk Framework and Documentation System within the Regulatory Process

Day 2: Session 4 (13:30 – 17:00) **-** Building Quality into Agency Decision Making Practices

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Day 1: Monday 15th May, Morning – Closed Session for Feedback from iSABRE agencies, (Malaysia, Indonesia, Taiwan, Philippines, Thailand)

SESSION 1: BENEFIT RISK ASSESSMENT – FEEDBACK FROM iSABRE - UTILISATION OF A SYSTEMATIC STRUCTURED FRAMEWORK TO BUILD CONSISTENCY AND PROCESS PREDICTABILITY INTO THE REVIEW	
08:30	**Registration**
09:00	**Welcome and introductions** A/Prof John Lim, Executive Director, CoRE
09:15	**Introduction to the objectives of the session and the background to the project and its aims** Professor Stuart Walker, Founder, CIRS
09:45	**Review of questionnaire feedback from agencies on the use of the template and documentation system within agencies** Dr James Leong, Head of Education, CoRE
10:20	**Discussion**
10:30	**Break and Photo taking session**
11:00	**Individual presentations from the agencies to outline the learning's from their case study** Challenges and opportunities in using the UMBRA framework and documentation template in relation to their current clinical assessment templates
12:00	**Facilitated discussion on the utilisation of the UMBRA framework and documentation system** *All participants*
12:45	**Next steps with and utilisation of ISABRE within local jurisdictions and to enable ongoing initiatives (eg: WHO ASEAN Joint Assessment, OpERA, Good Regulatory Management)**
13:00	**Lunch**

Day 1: Monday 15th May, Afternoon - Open to All agencies

SESSION 2: CURRENT AND FUTURE APPROACH TO BENEFIT RISK ASSESSMENT: ITS FUNDAMENTAL ROLE OF BENEFIT RISK IN THE ASSESSMENT OF NEW MEDICINES	
14:00	**Introduction to afternoon session**
14:10	**Introductory talk on the role of benefit-risk assessment of medicines by international agencies and why it is of critical importance to agencies** Professor Stuart Walker, Founder, CIRS
14:35	**Benefit Risk assessment – What do mature agencies consider in their assessment and how is this undertaken practically?** Australian TGA Perspective – How does TGA conduct benefit-risk assessment? Dr Kaye Robertson, Assistant Director, Prescription Medicines Clinical Evaluation Unit 3, Prescription Medicines Authorisation Branch, Therapeutic Goods Administration (TGA), Australia
15:00	**Discussion**
15:30	**Break**
16:00	**Review of UMBRA, the framework and documentation system and its utilization by agencies** Dr Neil McAuslane, Scientific Director, CIRS
16:25	**Experiences of using a structured approach** • Experience of evaluating the Framework and incorporation within the clinical assessment template Dr James Leong, Head of Education, CoRE
17:05	**Discussion** *All Participants*
17:30	**End of Session**

DAY 2: Tuesday 16th May - Open to all Agencies

SESSION 3: BEYOND BENEFIT RISK - UTILISING THE BENEFIT RISK FRAMEWORK AND DOCUMENTATION SYSTEM WITHIN THE REGULATORY PROCESS	
09:00	**Introduction to Session, recap day one and objectives of day 2** Professor Stuart Walker, Founder, CIRS
09:10	**Principles of the WHO Good Review Practice Guideline and the importance of implementation to the review process** Dr Neil McAuslane, Scientific Director, CIRS
09:35	**How the utilisation of a Benefit-Risk Framework in the review process enables adherence to Good Review Practices** Dr James Leong, Head of Education, CoRE
10:00	**Utilization of the Benefit-Risk Framework to enable better communication of summary basis of the decision across agencies and to other stakeholders** Professor Stuart Walker, Founder, CIRS
10:30	**Discussion**
10:45	**Break**
SESSION 4: ROUNDTABLE SESSION	
11:15	**Introduction to Roundtable Discussion/Exercise** Dr James Leong, Head of Education, CoRE
11.25	**WHO Joint Assessment Project** Ms Lim Bee Yee, Principal Assistant Director, Centre for Product Registration, National Pharmaceutical Regulatory Agency (NPRA), Malaysia
11.45	**Discussions on reviewer's thoughts, Challenges, opportunities to utilization of standardized systematic approach to Benefit Risk within their agencies** *All Participants*
12:20	**Feedback - Conclusions and Way forward**
12:30	**Lunch**
SESSION 5: BUILDING QUALITY INTO DECISION MAKING PRACTICES	
13:30	**Introduction to session**
13:35	**Quality of decision making – Why is this important and current practices by regulatory agencies?** Dr Neil McAuslane, Scientific Director, CIRS
14:00	**Introducing the 10 key Quality of Decision Making Practices (QDMP) and an instrument to measure QDMP** Professor Stuart Walker, Founder, CIRS
14:30	**Discussion**
14:45	**Break**
15:15	**Introduction to QoDos and completion of the instrument, followed by Discussion and feedback around quality of decision making – what are the key considerations.** *All participants*
16:15	**Lessons learnt from the workshop – potential training needs to facilitate benefit-risk and quality decision-making** Dr James Leong, Head of Education, CoRE
16:45	**Way Forward 2017 and 2018**
17:00	**End of Workshop**