The Assessment of Benefits and Harms and Their Relative Importance for Patients, Industry and Agencies: How should they be captured?

2 - 3 April 2014

PROGRAMME

Woodlands Park Hotel, Cobham, Surrey, UK

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

Background

The Assessment of Benefits and Harms and their Relative Importance for Patients, Industry and Agencies – How should they be captured?

Patients' perspective on benefits and harms is critical to the development and review of medicines. The challenge for agencies and companies and patients is not whether this should occur, but how?

In addition, beside the data generated directly from clinical trials, patients and patient groups are only occasionally engaged in discussion of benefits and harms and how these can be considered in regard to the relative importance in their lives.

The challenge for patient participation from a company's perspective is usually around methodology and uncertainty as to the input will be accepted by regulatory agencies. Challenge for regulatory agencies is related to how to extrapolate patients' viewpoints on benefits and risks to the general patient population.

The key questions for discussion are; Do patients', agencies' and companies' perspectives on benefits, harms and relative importance differ; Should patient's perspective apart from clinical trials be collected and what influence will such information make to both company and agency decision making processes and; How should this information be elicited and can there be development of simple methodologies which meet both the agencies and companies requirements?

This workshop will focus on the potential differences between stakeholders and whether there can be a way of simply collecting patients' views on benefits, harms and relative importance that can enable the patient's perspective to inform company and agency decision making.

Workshop Objectives

- **Review methodologies** for capturing benefits and harms and their relative importance
- **Identify whether there are** differences in the relative importance of benefits and harms between stakeholders
- **Make recommendations** for different approaches that patients can take to inform companies and agencies of their needs

Venue

The Workshop will take place at the Woodlands Park Hotel, Cobham, Surrey, UK commencing at 09:00 on 2 April and finishing at 13:00 with lunch on 3 April 2014.

Style and Participation

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

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Day 1: 2 April 2014

08:30 Registration

SESSION 1: COLLECTION OF PATIENTS' PERSPECTIVES ON BENEFITS, HARMS AND RELATIVE IMPORTANCE		
09:00	**Chairman's welcome and introduction**	**Prof Robert Peterson,** Executive Director, Drug Safety Effectiveness Network, Canadian Institute of Health Research
09:10	**Keynote Presentation – Why understanding patient perspectives on benefits and harms of therapeutic products is critical to the future of regulatory agency decision making**	**Prof John Skerritt,** National Manager, Therapeutic Goods Administration, Australia
09:35	**Patient organisation viewpoint**	**Jean Mossman,** Policy Lead, European Brain Council
09:55	**Regulatory viewpoint**	**Dr Isabelle Moulon,** Head of Patients and Healthcare Professionals, European Medicines Agency
10:15	**Industry viewpoint**	**Dr Marilyn Metcalf**, Senior Director, Benefit Risk Evaluation, GlaxoSmithKline, USA
10:35	**Discussion**	
10:45	**Break**	
11:15	**What has been the experience of IMI PROTECT in the collection of patient views and how can this be used directly in the assessment of benefit risk?**	**Kimberly Hockley,** Research Assistant, Imperial Clinical Trials Unit, Imperial College, London
11:35	**Providing patient preferences into the regulatory discussions: What are the pathways being explored?**	**Andrea Beyer,** Senior Researcher, University of Groningen, The Netherlands
11:55	**Discussion**	
12:05	**How do other decision makers collect information from patients and how does this influence decision-making?** **HTA Agency Viewpoint**	**Lizzie Amis**, Patient Involvement Programme, NICE
12:25	**Discussion**	
12:30	**Lunch**	

Day 1: 2nd April 2014

SESSION 2: SIMPLE METHODOLOGIES TO CAPTURE PATIENTS' VIEWS ON BENEFITS, HARMS AND RELATIVE IMPORTANCE - WHAT COULD THEY LOOK LIKE?	
	Introduction to Session 2
13:30	**What simple methods could be used to elicit patients' views on benefits, harms and relative importance?** **Academic viewpoint – Dr Larry Phillips,** Emeritus Professor of Decision Sciences, London School of Economics and Political Science, UK **Regulatory viewpoint – Dr Pierre Démolis,** Vice Chairman, CHMP, ANSM, France **Industry viewpoint – Dr Jamie Cross,** Regulatory Program Director, Genentech Inc, USA
14:30	**Discussion**
14:40	**Introduction to the syndicates**
14:50	**Delegates to go to the breakout rooms**
15:00	**Syndicate Discussions** **Syndicate A: Collection of benefits, harms and relative importance information from patients: current methodologies – can these be simplified?** **Chairman: Dr Thomas Lonngren,** Independent Strategy Advisor, Pharma Executive Consulting, Sweden **Rapporteur: Maggie Tabberer,** Director, Patient Focussed Outcomes, GlaxoSmithKline, UK **Syndicate B: New methods for the collection of benefits, harms and relative importance from patients: Can these be synergistic with the benefit-risk framework?** **Chairman: Prof John Skerritt,** National Manager, Therapeutic Goods Administration, Australia **Rapporteur: Dr Linda Scarazzini**, Vice President, Medical Safety Evaluation, AbbVie Inc, USA **Syndicate C: Communication of Benefit-Risk: what should be in the public domain?** **Chairperson: Dr Petra Doerr,** Head of Communication and Networking, Swissmedic **Rapporteur: Nancy Pire-Smerkanich,** Educational Liaison, Doctoral Candidate, International Center for Regulatory Science, School of Pharmacy, University of Southern California, USA
18:00	**Close of day one**
19:00	**Reception**
19:30	**Dinner**

Day 2: 3rd April 2014

SESSION 3: COLLECTION AND COMMUNICATION OF PATIENTS' VIEWS ON BENEFITS, HARMS AND THEIR RELATIVE IMPORTANCE: THE RECOMMENDATIONS		
09:00	**Chair's Introduction**	**Dr Mary Baker**, Immediate Past President, European Brain Council
09:10	**Feedback from Syndicate Sessions**	
	The communication of benefits and harms to patients: How well are we doing and what needs to be improved?	
09:40	**Industry viewpoint**	**Dr Yatin Shivkar,** Director, Safety and Benefit-Risk Management Biogen Idec, USA
10:00	**Agency viewpoint**	**Barbara Sabourin**, Director General, Therapeutic Products Directorate, Health Canada
10:20	**Patient viewpoint**	**Prof Marcus Longley,** Director, Welsh Institute for Health and Social Care, University of South Wales, UK
10:40	**Discussion**	
10:45	**Break**	
	Future Perspectives – Looking forward to 2020: What will be the role of the patient?	
11:30	**Academic viewpoint**	**Prof Sam Salek,** Director, Centre for Socioeconomic Research, Cardiff University
11:45	**Industry viewpoint**	**Moira Daniels**, Vice President, Head Global Patient Safety Services, PAREXEL International, UK
12:00	**EMA viewpoint**	**Dr Pierre Démolis,** Vice Chairman, CHMP, ANSM, France
12:15	**Patient viewpoint**	**Christopher Friend,** Trustee, Genetic Alliance UK
12:30	**Discussion**	
12:45	**Close of Workshop followed by lunch**	