Workshop

What are the key performance metrics that agencies and companies should use to measure the regulatory process and practices to facilitate the licensing of new medicines?

3 & 4 FEBRUARY 2016

PROGRAMME

Venue: InterContinental Hotel, Kuala Lumpur, Malaysia

CENTRE FOR INNOVATION IN REGULATORY SCIENCE

The Johnson Building, 77 Hatton Garden, London EC1N 8JS, UK, Telephone: +44 (0) 207 433 4247 Email: ghepton@cirsci.org

Organiser

Neil McAuslane: nmcauslane@cirsci.org

Prisha Patel: ppatel@cirsci.org

Lawrence Liberti: lliberti@cirsci.org

Draft: 21 January 2016

Centre for Innovation in Regulatory Science Workshop

What key performance metrics should agencies and companies use to measure the regulatory process and practices to facilitate the licensing of new medicines?

Background

Regulatory performance is inextricable linked to the availability of new medicines, but there can be many factors that can influence this within different jurisdictions. These factors include company strategy, regulatory policy, company time to answer agency questions, review time, resources available, route of review, pricing and reimbursement, quality of the submission, review and decision making. Indeed in assessing an agency performance this can include pre, during and post authorisation activities.

CIRS has developed markers for good review practices and also previously indentified key enablers and barriers to the review of new medicines. In addition CIRS has been measuring the review process and time to a product being licensed and reimbursed through a number of its benchmarking studies.

Mature agencies such as US FDA, EMA, Health Canada and TGA have set themselves key qualitative and quantitative performance indicators (KPI), against which they and their stakeholders can measure their performance. Companies have also set themselves internal KPIs to help improve and manage the regulatory process of getting medicines from development to patients globally.

Emerging regulatory agencies are now developing their own performance metrics are interested in what should be measured (quantitative and measures of quality), how this is best undertaken and what role metrics have in improving their processes and practices. These measurements could serve as a barometer of change providing active feedback on the effectiveness of changes being proposed or implemented in various jurisdiction.

In today's environment patients access to is not only influenced by the regulatory review can also involve another step which can range from a full health technology assessment (HTA) to evaluate both clinical and cost effectiveness for the healthcare system to just a budget impact.

The aim of this workshop is to discuss the what, why and how question of which regulatory measures do companies and agencies feel are relevant in today's environment to measure the journey that a medicine under goes following development to being available to patients across different jurisdictions and how these measures could enable the quality of the processes, practices and planning of both agencies and companies.

Workshop Objectives

- Identify and provide the rationale for selecting key regulatory performance areas that agencies and their stakeholders believe should be measured and to discuss how this can best be achieved.
- Discuss how agencies and companies actually measure their performance and how this can enable change by improving efficiency, effectiveness and quality of the processes and practices.
- Make recommendations of what key performance metrics should be measured that can help improve internal performance of both companies and agencies to ensure safe and effective medicines availability in a timely manner.

Style and Participation

Following the agreed practices for CIRS Workshops, the meeting participation is by invitation to maintain a size that encourages a neutral environment that promotes productive dialogue and networking. We aim to advance the debate and discussion around the subject of the Workshop and to produce constructive recommendations based on the Workshop activities.

Organiser
Neil McAuslane: nmcauslane@cirsci.org
Prisha Patel: ppatel@cirsci.org
Lawrence Liberti: lliberti@cirsci.org

Draft: 21 January 2016

Day 1: 3 February 2016

08:30 Registration

SESSION 1: MEASURING PERFORMANCE IS AN ESSENTIAL COMPONENT OF GOOD REGULATORY PRACTICES AND DECISION MAKING	
09:00	**Chair's welcome and introduction** **Dr Murray Lumpkin,** Deputy Director – Integrated Development and Lead for Global Regulatory Systems Initiatives, Bill and Melinda Gates Foundation, USA
09:05	**Country welcome and introduction** **Dato' Eisah Rahman,** Senior Director of Pharmaceutical Services, Ministry of Health, Malaysia
09:10	**Current reform of the medicines regulatory system. Perspective from China** **Director General YUAN Lin**, Director General, Department of International Cooperation, China Food and Drug Administration (CFDA)
09:30	**Measuring regulatory agencies performance: Why this is critical for strong governance and evolution of regulatory capacity?** **Dr Tomas Salmonson,** Chair, CHMP, European Medicines Agency
09:55	**What are the core qualitative and quantitative performance metrics agencies should consider and why? Health Canada perspective** **Barbara Sabourin,** Director General, Therapeutic Products Directorate, Health Canada
10:15	**Discussion**
10:30	**Break**
	Stakeholder perspectives: Why agencies need to establish performance indicators, both qualitatively and quantitatively and how this can help medicines providers/users?
11:00	**Pharmaceutical Company perspective – Dr Paul Huckle,** Chief Regulatory Officer and Senior Vice President ,GlaxoSmithKline, USA
11:20	**Patient perspective** – **Dr Durhane Wong-Rieger**, President and CEO, Canadian Organization for Rare Disorders
11:40	**Discussion**
	Planning, improving, reporting – What Qualitative and/or Quantitative Performance indicators are agencies incorporating into their practices and processes?
11:45	**Singapore – Dr Yee Hoo Looi**, Acting Deputy Director – Therapeutic Products Branch, Health Sciences Authority
12:00	**Indonesia – Dra. Nurma Hidayati**, Director of Drug and Biological Products Evaluation, National Agency of Drug and Food Control (NADFC)
12:15	**Philippines - Pia Angelique D. Priagola,** Food Drug Regulation Officer III, Food and Drug Administration
12:30	**Malaysia – Dato' Eisah Rahman,** Senior Director of Pharmaceutical Services, Ministry of Health
12:45	**Taiwan – Dr Churn-Shiouh Gau,** Chief Executive Director, Center for Drug Evaluation
13:00	**Lunch**

Day 1 cont: 3 February 2016

SESSION 2: MEASURING PERFORMANCE – HOW CAN THIS IMPROVE PERFORMANCE FOR AGENCIES AND COMPANIES	
14:00	**Chair's Introduction** **Barbara Sabourin,** Director General, Therapeutic Products Directorate, Health Canada
14:05	**Internal processes and practices to measure KPI - how have these evolved in a mature agency and what recommendations should be made to agencies considering implementation of KPI?** **Dr John Skerritt,** Deputy Secretary for Regulatory Services, Department of Health, Australia
14:25 *14:40* *15:00*	**Use of performance metrics and training to improve practices and process - what can be measured and what are the critical success factors** **Measuring companies and regulators: Benchmarking Through Key Performance Indicators** **Prisha Patel,** Manager, Global Development Programme, CIRS **WHO PQ performance indicators, what they are, how do they measure them, are they reported and how do they use them to improve performance?** **Dr Lembit Rägo**, Head, Regulation of Medicines and other Health Technologies, WHO, Switzerland **Improving practices and process through mapping and training – How can this best be achieved?** **Prof John Lim,** Deputy Director of Medical Services and Executive Director, Centre of Regulatory Excellence, Singapore
15:20	**Discussion**
15:30	**Break**
16:00	**Company factors that affect agency performance - how can these be best be measured and managed by agencies. Perspective from Brazil** **Ricardo Borges**, Manager of the General Office of Drugs, ANVISA
16:20	**Discussion**
16.25	**What internal regulatory metrics do companies measure themselves by /use that enable their planning, submission and understanding in getting a medicine to market globally? A Company Perspective** **Dr Alec Tiong**, Head, Regulatory Affairs, Japan &Asia-Pacific , AbbVie, Singapore
16.45	**Building quality into the decision-making process: What are the main factors that need to be considered?** **Dr Neil McAuslane,** Scientific Director, CIRS
17.05	**Discussion**
17:15	**Introduction to Day 2 Roundtable Discussions**
17:30	**End Day one**
19:00	**Reception**
19:30	**Dinner**

Day 2: 4 February 2016

SESSION 3: ROUNDTABLE DISCUSSIONS	
08.30	**Roundtable Discussions (Suggestions - 3-5 topics to be selected)** *Each roundtable is asked consider both qualitative and quantitative measurements. Please review, debate and make recommendations for the following:* **Roundtable A: What are the critical KPI's that inform an agency's effective and efficient performance?** **Chair: Prof Hans-Georg Eichler**, Senior Medical Officer, EMA **Rapporteur: Dr Felipe Dolz,** Vice President, Global Regulatory Policy and Intelligence, Sanofi, USA **Roundtable B: What are the key measures of quality decision making that an agency can adopt that can improve its planning and review?** **Chair: Dr Tomas Salmonson,** Chair, CHMP, European Medicines Agency **Rapporteur: Magda Bujar,** Research Analyst, CIRS **Roundtable C: Building a performance driven culture: How can this be defined achieved and where do agencies start?** **Chair: Barbara Sabourin,** Director General ,Therapeutic Products Directorate, Health Canada **Rapporteur: Fraser Stodart**, Senior Director, Global Emerging Markets (GEMS) – Regulatory Affairs, Biogen, UK **Roundtable D: Company agency interactions: What are the quantitative and qualitative measures that an agency and company can use to maximize outcomes?** **Chair: Prof Thomas Kühler,** Senior Director, Novo Nordisk A/S, Denmark **Rapporteur: Dr David King**, Director, Regulatory Policy and Intelligence, Shire, UK **Roundtable E: Regional alignment initiative- what should be measured and can metrics enable the process?** **Chair: Dr John Skerritt**, Deputy Secretary for Regulatory Services, Department of Health, Australia **Rapporteur: Sjaak Bot**, Vice-President, Head of EMEA Regulatory Affairs, Janssen, The Netherlands
12:00	**End of roundtable discussions and Lunch**
13:00	**Chair's Introduction** **Prof Sir Alastair Breckenridge**
13:05	**Feedback by roundtable rapporteurs and discussion.**

SESSION 4: ENSURING AVAILABILITY OF MEDICINES THAT ARE SAFE AND EFFECTIVE	
14:30	**Submission lag: What are the key factors that delay a medicine's submission and how can these be mitigated?** **Dr Sandra Lim**, Head of Regulatory Affairs-Asia Pacific, Bayer (South East Asia), Singapore
14:50	**Evolution of HTA agencies across Asia – Changing the access landscape – how could the impact be measured?** **Dr Sorapop Kiatpongsan**, Lecturer, Faculty of Medicine, Chulalongkorn University, Thailand
15:10	**Discussion**
	Improving availability and meeting unmet medical need: What are the facilitated regulatory pathways that can be considered and what measures should be put in place
15:15	**Mature Agency Perspective – Prof Hans-Georg Eichler,** Senior Medical Officer, European Medicines Agency
15:35	**Characteristics of emerging agency pathways: what are the key processes and substantive building blocks – Larry Liberti,** Executive Director, CIRS
15:55	**Bill and Melinda Gates Foundation perspective - Dr Murray Lumpkin,** Deputy Director – Integrated Development and Lead for Global Regulatory Systems Initiatives, Bill and Melinda Gates Foundation, USA
16:15	**Discussion**
16:20	**Chairman's summary and close of Workshop**