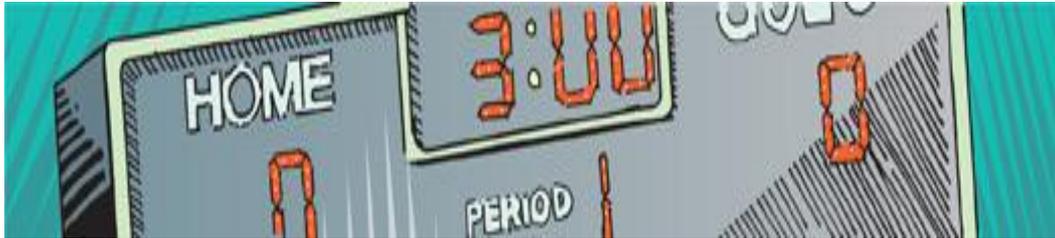


**CENTRE FOR INNOVATION IN REGULATORY SCIENCE**



**Scorecard Programme  
Discussion Forum on  
Balancing the Quality Scorecards:  
Regulatory Review and Submitted Dossier**

**Burnham Beeches Hotel, Grove Road, Burnham SL1 8DP**

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**Agenda**

5 & 6 March 2012

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**CONFIDENTIAL**

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## INTRODUCTION

This Forum is being arranged to take the next step in the development of the quality scorecards for measuring the quality of the submitted dossier and its regulatory review.

The objective of this programme is to achieve an internationally accepted **balanced electronic scorecard** for monitoring the quality of regulatory submissions and their review. Whilst the speed of review has a major influence on patient's access to medicines, it is also important to recognise the sponsor's role in the submission of a high-quality dossier and the regulatory agency's responsibility to conduct a quality review. With this goal in mind, over the last five years the Centre has developed and tested a scorecard for measuring the quality of the regulatory submission and the review process.

### Programme accomplishments to date

- Developed two scorecards – one to measure the quality of the sponsor's submission and the second to measure the quality of the regulatory review
- Conducted a retrospective pilot study involving three agencies (Health Canada, Australian TGA and Swissmedic) and seven companies, with reported analysis on 42 scorecards
- Created a database that enables a profile to be constructed for each agency and company, which when analysed, identifies the areas in which organisations exceed standards and where improvements can be made

Although the two scorecards have been utilised and found to be of value by both companies and agencies, over the time period from the scorecards inception in 2004 both agencies and companies have evolved the quality of their process and dossiers such that the time is right to reevaluate the original scorecard. In this evaluation agencies and companies will be asked to make decisions on how each parameter is weighted relative to each other so as to enable the scorecards to provide focused feedback with regard to the key areas agencies and companies excel or require improvement.

It is envisaged that this interactive working meeting will enable the development of two balanced scorecards which will be piloted within Europe prior to its utilisation in other countries.

### OBJECTIVES OF THE MEETING ARE TO:

- Review the two scorecards and to weight each of the parameters measured;
- Discuss the weights collectively amongst companies and agencies so that the balanced scorecards meets the needs of the stakeholders
- To produce two balanced scorecards, one to measure the quality of the dossier and one the quality of the review process.

### TIMING AND LOCATION

The meeting will take place at the **Burnham Beeches Hotel**, Grove Road, Burnham SL1 8DP, commencing at 7.00pm on Monday 5<sup>th</sup> March, with a background to the exercise and dinner, and ending at 3.30pm on Tuesday 6<sup>th</sup> March.

### FORMAT AND STYLE

The meeting will be designed to allow maximum general feedback and interactions, along with specific recommendations for the next stage in the development of the Scorecards.

## DISCUSSION FORUM ON BALANCING THE QUALITY SCORECARDS

### DAY 1: MONDAY 5<sup>TH</sup> MARCH 2012

18:30: Registration and drinks reception

#### **Session 1: Introduction to the Exercise**

19:00 hrs	<b>Chairman's introduction</b>	<b>Lawrence Liberti</b> , Executive Director, CIRS
	<b>Overview to the exercise</b> <i>A summary of the development of the scorecards and the objectives of work to be undertaken – orientation for agencies and companies</i>	<b>Dr Neil McAuslane</b> , Director, CIRS
19:30 hrs	<b>Dinner</b>	

### DAY 2: TUESDAY 6<sup>TH</sup> MARCH 2012

#### **Session 2: Balancing the Scorecards**

08.30 hrs	<b>Chairman's welcome and introduction</b>	<b>Prof Stuart Walker</b> , Founder, CIRS
08.45 hrs	<b>Balancing the Scorecard on the Review process: Pre-meeting exercise feedback</b> <i>(Prior to the meeting all participants will be sent both scorecards and asked to review the scorecard and from their perspective weight the parameters. These will then be used to identify how the scorecard could be balanced and also provide a basis for discussion)</i>	<b>All participants</b>
	<b>Round Table discussions: Agreeing the weighting and content of the Scorecard on the Review Process</b>	
10:30 hrs	<b>Break</b>	
11.00 hrs	<b>Balancing the Scorecard on the Quality of the Dossier: Pre-meeting exercise feedback</b>	<b>All participants</b>
	<b>Round Table discussions: Agreeing the weighting and content of the Scorecard on the quality of the dossier</b>	
12.45 hrs	<b>Lunch</b>	
<b>Session 3: Revising the Scorecards and Next Steps</b>		
13.45 hrs	<b>Review of both Scorecards – ensuring balance</b> <b>Development of the next phase of Scorecard project</b> <b>Next Steps</b>	
15:30 hrs	<b>End</b>	