

## 7<sup>TH</sup> LATIN AMERICAN CONGRESS OF CLINICAL RESEARCH



### Harmonization and the Future of Drug Development in Latin America

November 10 - 12, 2010

Maksoud Plaza Hotel - São Paulo - Brazil

## TUTORIAL 2

### 7<sup>th</sup> Latin American Congress of Clinical Research

**Date: November 10th, 2010**

***Clinical Project Management: Essential Tools to Optimize Clinical Trial Operations***

**Cris Howard, MBA, MEd, PMP**

**7:30 – 8:00 Registration and Continental Breakfast**

**8:00 – 8:30 Welcome and Introductions**

Introductions

Results of Pre-Course Interest Survey

Course Objectives

**8:30 – 9:15 MODULE 1: What is Clinical Project Management?**

Successes in biopharmaceutical product development

Challenges facing biopharmaceutical product development

Opportunities within biopharmaceutical product development

Key definitions

Characteristics of a successful project manager

SELF ASSESSMENT: Characteristics of a successful project manager.

**9:15 – 9:45 MODULE 2: Defining the Clinical Project Scope**

Strategic vision & objectives

Scope statements

**9:45 – 10:00 Refreshment Break**

**10:00 – 12:30 MODULE 3: Planning the Work**

SMALL GROUP EXERCISE: Breaking down the work:  
sub-projects  
work packages  
deliverables

SMALL GROUP EXERCISE: Work package durations

SMALL GROUP EXERCISE: Creating a network map

SMALL GROUP EXERCISE: Producing the schedule

SMALL GROUP EXERCISE: Critical path compression & managing float

**12:30 – 13:30 Luncheon**

**13:30 – 13:45 Review**

**13:45 – 14:30 MODULE 4: Clinical Project Risk Management**

Risk assessment

Risk control

SMALL GROUP EXERCISE: Clinical project risk identification and planning

**14:30 – 15:30 MODULE 5: Preparing a Clinical Trial Budget**

Tips & tricks in budget forecasting

Laying the budget groundwork

Fixed fees

Variable fees

Pass-through costs

Clinical trial line items

Stating your assumptions

**3:30 – 3:45 pm Refreshment Break**

**3:45 – 4:15 pm MODULE 6: Clinical Trial Execution, Monitoring and Control**

The project management triangle

Investigator score card

Clinical trial score card

**16:15 – 16:45 MODULE 7: Closing the Project**

Project Termination

Team closure

Lessons learned

**16:45 – 17:00 Wrap-up**

**REVIEW**

Re-visit: Course objectives / Results of pre-course interest survey

Summary of lessons learned

Course evaluation

