

Implementing Global Trial Management and Operations
October 10, 2012- October 11, 2012
PERI Training Facility ~ Arlington, VA
Agenda

Wednesday, October 10, 2012

Tab No.

7:30 – 8:00 AM	<i>Registration and Continental Breakfast</i>	
8:00 – 8:15 AM	<u>PERI Welcome Address</u> Marian Selby Course Manager/Meetings Manager	
8:15 – 8:45 AM	<u>Course Overview</u> Lionel D. Edwards, MD BS FFPM – Course Director President Pharma Pro Plus Inc.	
8:45 – 10:45 AM	<u>Strategic Clinical Planning Exercise and Discussion</u> Lionel D. Edwards, MD BS FFPM	4
	<ul style="list-style-type: none"> • Practical aspects of clinical protocol development • Working with investigators and study sites • Data management challenges • Summary and group discussion 	
10:45 - 11:00 AM	<i>Morning Break</i>	
11:00 AM - 12:00 PM	<u>Culture and Ethnic Effects on Clinical Trials</u> Lionel D. Edwards, MD BS FFPM	5
	<ul style="list-style-type: none"> • Intrinsic factors • Extrinsic factors 	
12:00 - 1:00 PM	<i>Lunch on your own</i>	
1:00 - 2:00 PM	<u>Session TBD</u>	6
2:00 - 3:00 PM	<u>Session TBD</u>	7
3:00 – 3:15 PM	<i>Afternoon Break</i>	
3:15 – 4:00 PM	<u>Exercises in Managing the Project</u> Lionel D. Edwards, MD BS FFPM	8
	<ul style="list-style-type: none"> • Exercise in risk assessment/contingency planning • Managing expectations • CRO selection/management 	

4:00 – 5:30 PM	<p><u>Budget Management</u> Nancy Daczowski Project Manager Clinical Operations Emergent BioSolutions</p> <ul style="list-style-type: none"> • Creating the project budget • Projected costs vs. actual spend 	9
Thursday, October 11, 2012		
7:30 – 8:00 AM	<p><i>Continental Breakfast</i></p>	
8:00 – 9:30 AM	<p><u>EU Clinical Directives</u> Lionel Edwards, MD BS FFPM</p> <ul style="list-style-type: none"> • Requirements for submission for clinical trial approvals in the European Union • Implications of the EU Clinical Trial directive on Trial Management 	10
9:30 – 10:45 AM	<p><u>Implementing Effective Clinical Trial Management in Today’s Competitive Environment</u> Lionel Edwards, MD BS FFPM</p> <ul style="list-style-type: none"> • Current status of the research industry • Clinical trial project performance • Current realities 	11
10:45 – 11:00 AM	<p><i>Morning Break</i></p>	
11:00 AM – 12:00 PM	<p><u>Manpower Assessment</u> Rick O’Hara, MBA Sr. Sourcing Manager Johnson and Johnson PRD, LLC.</p> <ul style="list-style-type: none"> • Introduction to manpower assessment • Three models for determining manpower 	12
12:00 – 1:00 PM	<p><i>Luncheon on your own</i></p>	
1:00 – 2:15 PM	<p><u>International Clinical Trials – Asian and Latin American Perspective</u> Lionel Edwards, MD BS FFPM</p> <ul style="list-style-type: none"> • India Market and Regulations • China and Japan Market and Regulations • Brazil, Argentina, Mexico Market and Regulations 	13

Thursday, October 11, 2012**Tab**

2:15 – 3:15 PM

Global Team Management**14**

Rick O'Hara, MBA

- Considerations for effective international teams
- Managing skill deficits
- Evaluating/monitoring the team's performance

3:15 – 3:30 PM

Afternoon Break

3:30 – 4:30 PM

Outsourcing**15**

Rick O'Hara, MBA

- Choosing a vendor
- Partnering: myth or reality?
- Practical situations, challenges, and issues

4:30 PM

Course Wrap-Up and Adjournment

Faculty

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