Drug Development for Pharmaceutical Physicians and Scientists – Part II
Tuesday, November 13, 2012 – Wednesday, November 14, 2012
PERI Training Facility– Arlington, VA

Tuesday, November 13, 2012		**Tab No.**
7:30 – 8:00 AM	***Registration and Continental Breakfast***	
8:00 – 8:15 AM	**PERI Welcome and Course Introduction** Marian Selby Course Manager Pharmaceutical Education and Research Institute, Inc. (PERI)	
8:15 – 8:45 AM	**Course Overview** Lionel D. Edwards, MD, FFPM *Course Co-Director* Adjunct Professor, Temple University School of Pharmacy, Quality Affairs and Regulatory Affairs ▪ Faculty Introductions ▪ Participant Introductions ▪ Learning Goals and Burning Issues	
8:45 – 10:00 AM	**Phase 3 and Post-Marketing Studies 4 and 5** Lionel D. Edwards, MD, FFPM ▪ Phase 3 studies ▪ Clinical optimization ▪ Phase 4 and 5 studies ▪ The Role of Medical Affairs	***4***
10:00– 10:15 AM	***Refreshment Break***	
10:15– 11:15 AM	**Phase III Protocol Development** Robert J. Padley, MD Global Medical Director Abbott Laboratories • Forces that shape a Phase III development program • Key elements in a Phase III protocol • Additional factors to consider for a Phase III protocol and a late stage development program	***5***
11:15 AM – 12:45 PM **CONFIRMED**	**Structure and Content of Clinical Study Reports** Nita U. Patel, PhD Pharmaceutical Consultant ▪ Common Technical Document ▪ Clinical Study Report ▪ GCPs	***6***
12:45 – 1:45 PM	***Lunch on Your Own***	

Wednesday, November 14, 2012 (continued…) **Tab No.**

1:45 – 2:45 PM
Confirmed

Clinical Biostatistics with Focus on Phases 3 and 4 ***7***
Jay Horrow, MD
Executive Director, Clinical Development
AstraZeneca LP

- Review of statistical principles
- Statistical issues for phase 3 trials
- Large Outcomes Trials
- Regression, Forest Plots, and Non-inferiority
- Non-inferiority

2:45 – 3:45 PM

Clinical Safety Monitoring ***8***
Robert Padley, MD

- Safety issues throughout stages of clinical drug development
- Adverse events and requirements for safety reporting
- Key safety elements in individual and integrated clinical trail safety reports

3:45 – 4:00 PM ***Refreshment Break***

4:00 – 5:15 PM

Workshop – Designing the Phase III Clinical Program ***9***
Faculty

Wednesday, November 14, 2012

7:30 – 8:00 AM ***Continental Breakfast***

8:00 – 8:15 AM

Overview of Days 1 and 2
Faculty

8:15 – 9:30 AM

Preparing for Market Launch: The Role of Marketing in Product Development and Product Lifecycle ***10***
Lionel D. Edwards, MD, FFPM

- Productivity of drug development
- Strategic Plan

9:30 – 10:30 AM

Promotion and Marketing of Prescription Drugs ***11***

CDER/OMP/DDMAC
US Food and Drug Administration

- Principle regulatory standards for advertising and promotion of prescription drugs
- Examples of enforcement actions

10:30 – 10:45 AM **Refreshment Break**

Wednesday, November 14, 2012 continued…) **Tab No.**

10:45 – 11 :45 AM **Selecting and Working with CROs/SMOs** ***12***
Robert J. Chaponis, PharmD, FASCP
Head, US Medical Affairs
Novartis Consumer Health, Inc.

- Define external providers or outsourcing partners
- List the services offered by external providers
- Understand the issues when partnering with external providers
- Outline the contracting process and setting up the partnership
- Understand the roles and responsibilities when managing an outsourcing partner

11:45 – 12:30 PM **Workshop – Identifying and Intrepreting Adverse Events** ***13***
Faculty

12:30 – 1:30 PM ***Lunch on Your Own***

1:30 – 2:30 PM **Site Management and Monitoring** ***14***
Robert J. Chaponis, PharmD, FASCP

- Role of the Medical Monitor and Study Coordinator
- Guidelines for site management
- Investigator's responsibilities

2:30 – 3:30 PM **Pharmacovigilance and Risk Management** ***15***
Can not present

- Post-marketing risk assessment
- Regulatory environment
- US Regulations and Guidance
- Global and FDA risk management initiatives

3:30 – 3:45 PM **Refreshment Break**

3:45– 4:30 PM **Introduction to Health Economics and Outcomes Research** ***16***
Invited
Margarita Udall, MPH
Associate Director, US Health Economics & Outcomes Research
Global Market Access, Primary Care Business Unit
Pfizer Inc.

- Terminology: Some basic definitions
- Why are we doing this: Communicating value
- Advertising regulations pertaining to P/E & PROs
- P/E and PROs in drug development
- Advice & precautions

4:30 – 4:45 PM **Questions & Answers**

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Pharmacy

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Medical

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