FDA'S 2013 Clinical Investigator Training Course
Agenda

Tuesday November 12		
7:30 – 8:20	Registration, Distribution of course material, and Breakfast	
Session 1: The Clinical Trial Protocol		
8:20 – 8:30	Welcome	Rosemary Tiernan, MD, MPH (CDER)
8:30 – 9:00	FDA Structure and Mandate	Rosemary Tiernan, MD, MPH (CDER)
9:00 – 10:00	The Design of Clinical Trials (Part 1)	Robert Temple, MD (CDER)
10:00 – 10:15	**Break**	
10:15 – 10:45	The Design of Clinical Trials (Part II)	Robert Temple, MD (CDER)
10:45 – 11:00	Discussion/Questions	Robert Temple, MD (CDER)
11:00 – 11:30	Clinical Trial Endpoints	Eugene Sullivan, MD (EJS Consulting, LLC)
11:30 – 12:00	Issues in Clinical Trial Designs for Devices	Owen Faris, Ph.D (CDRH)
12:00 – 1:00	**Lunch**	
1:00 – 1:30	Issues in Clinical Trial Design for Companion Diagnostic Devices	Sally Hojvat, Ph.D. (CDRH)
1:30 – 2:15	Informed consent and ethical considerations in clinical trials	Dale Hammerschmidt, MD (University of Minnesota)
2:15 – 2:30	Discussion/Questions	
2:30 – 2:45	**Break**	
2:45 – 3:15	Safety Considerations in Phase 1 Trials	Sumathi Nambiar, MD (CDER)

3:15 – 3:45	Safety Assessment in Clinical Trials and Beyond	Yuliya Yasinskaya, MD (CDER)
3:45 – 4:15	Clinical Discussion of Special Populations	Ryan Owen, Ph.D. (CDER)
4:15 – 4:30	Discussion/Questions	
Wednesday November 13		
8:30 – 9:00	FDA Perspective on International Studies	Kassa Ayalew, M.D., M.P.H. (CDER)
Session 2: FDA and the Regulation of Clinical Trials		
9:00 – 9:45	Good Clinical Practice (GCP) Key Topics	Bridget Foltz (OC)
9:45 – 10:15	Investigator Responsibilities – Regulation and Clinical Trials (Part I)	Cynthia Kleppinger, MD (CDER)
10:15 – 10:30	**Break**	
10:30 – 11:00	Investigator Responsibilities – Regulation and Clinical Trials (Part 2)	Cynthia Kleppinger, MD (CDER)
11:00 – 11:45	The Analysis of Investigator Data, Sources of Bias and Error	Susan Ellenberg, Ph.D. (University of Pennsylvania)
11:45 – 12:00	Discussion and Questions	Session 2 Presenters Panel
12:00 – 1:00	**Lunch**	
Session 3: Understanding the investigator brochure – Non-Clinical and Phase 1 Studies		
1:00 – 1:30	CMC and the investigator Brochure (Drugs): Ensuring the Quality of a Drug used in a Clinical Trial	Dorota Matecka (CDER)
1:30 – 2:00	Biosimilar Biological Products	Sue Lim (CDER) slides will be late
2:00 – 2:45	Pharmacology/Toxicology in the Investigator Brochure	Brenda Gehrke, Ph.D (CDER)

2:45 – 3:00	Discussion/Questions	
3:00 – 3:15	**Break**	
Session 4: Early Clinical Studies Session		
3:15 – 3:45	Clinical pharmacology 1: Phase 1 studies and Early Drug development	Gerlie Gieser, Ph. D. (CDER)
3:45 – 4:15	Clinical pharmacology 2: Clinical Considerations During Phase 2 and Phase 3 of Drug Development	Kellie Reynolds, Pharm.D. (CDER) no slides
4:15 – 4:45	Discussion/Questions	

Thursday November 14		
Session 5: Putting It All Together – Application and Compliance Issues **Concurrent Breakout Sessions for Drug/Device/Biologics – same topics offered simultaneously specific to each product type**		
Session 1 8:30 – 10:00	**Center for Drug Evaluation and Research** How to put together an IND submission Clinical Investigator Site Inspections-What to Expect	Judit Milstein (CDER) Constance Cullity, M.D. (CDER)
Session 1 8:30 – 10:00	**Center for Biologics Evaluation and Research** How to put together an Application	Donald Fink, Ph.D. (CBER) Patrick Au, Ph.D. (CBER) Rachel Witten, M.D. (CBER)
Session 1 8:30 – 10:00	**Center for Devices and Radiological Health** How to put together an Application	Lynn Henley (CDRH) Nichole Chamberlain (CDRH) bringing with her
10:00-10:15	**Break**	
Session 2 10:15 -11:15	**Center for Drug Evaluation and Research** Ensuring the Safety of Clinical Trials: AE Reporting, DSMBs, IRBs	Mathew Thomas (CDER) bringing with him
Session 2 10:15 -11:15	**Center for Biologics Evaluation and Research** Ensuring the Safety of Clinical Trials: AE Reporting, DSMBs, IRBs	Patricia Holobaugh (CBER)
Session 2	**Center for Devices and Radiological Health**	Nilsa Loyo-Berrios (CDRH) bringing with

10:15 -11:15	Device Post Approval and Registry Studies	her Daniel Canos (CDRH) bringing with him
11:15 – 11:45	CDER Discussion/Questions	
11:15 – 11:45	CBER Discussion/Questions	
11:15 – 11:45	CDRH Discussion/Questions	
11:45 – 12:45	**Lunch**	
Session 6: Safety of Clinical Trials and Special Populations		
12:45 – 1:15	Special Cardiac Safety Concerns	Shari Targum, MD (CDER)
1:15 – 1:45	Drug-Induced Liver Injury (DILI)	Lana Pauls, MPH (CDER)
1:45-2:15	A Patient Advocate's Perspective on Clinical Trials	Jane Reese-Coulbourne Reagan-Udall Foundation
2:15-3:15	Roundtable : The Clinical Investigator's Role in Drug Development: a multi stakeholder perspective	Douglas Peddicord, PhD, ACRO Neil J. Weissman, MD, MedStar Health Research Institute Christine Pierre, SCRS Sabrina Savic-Comic, MD, The Medicine Company
3:15 – 3:30	**Explain Evaluation Process, Wrap up and Adjourn**	Leonard Sacks, MD (CDER)