"PRINCIPLES OF CLINICAL PHARMACOLOGY" COURSE

2012-2013 SCHEDULE

All sessions will meet Thursday evenings from 6:30 p.m. to approximately 7:45 p.m. in the NIH Clinical Center, Building 10, in the Lipsett Amphitheater in Bethesda, Maryland. Course Web Site: http://pcp.nihtraining.com

MODULE 1: PHARMACOKINETICS:

Introduction to Clinical Pharmacology and Pharmacokinetics	
Clinical Applications of Pharmacokinetics	J. Lertora (NIH CC)
Compartmental analysis of drug distribution	J. Lertora (NIH CC)
Chemical assay of drugs and drug metabolites	S. Markey (NIH NIMH)
Use of positron emission tomography (PET) in pharmacokinetics	R. Innis (NIH NIMH)
Drug absorption and bioavailability	J. Lertora (NIH CC)
Effects of renal disease on pharmacokinetics	J. Lertora (NIH CC)
Noncompartmental vs. compartmental approaches to PK analysis	P. Vicini (Pfizer, Inc)
SPECIAL LECTURE: Pharmacokinetics in patients requiring	
renal replacement therapy	A. Atkinson (Northwestern U.) and
	G. Susla (MedImmune, Inc)
Effects of liver disease on pharmacokinetics	J. Lertora (NIH CC)
Population pharmacokinetics	R. Miller (Daiichi Sankyo, Inc.)
	Clinical Applications of Pharmacokinetics Compartmental analysis of drug distribution Chemical assay of drugs and drug metabolites Use of positron emission tomography (PET) in pharmacokinetics Drug absorption and bioavailability Effects of renal disease on pharmacokinetics Noncompartmental vs. compartmental approaches to PK analysis SPECIAL LECTURE: Pharmacokinetics in patients requiring renal replacement therapy

MODULE 2: DRUG METABOLISM AND TRANSPORT:

November 15th	Pathways of drug metabolism	S. Markey (NIH NIMH)
November 29th	Drug Interactions	S. Penzak (NIH CC)
December 6th	Pharmacogenomics	D. Flockhart (IUPUI)
December 13th	Molecular and cellular mechanisms of severe adverse drug reactions L. Pohl (NIH NHLBI)	
January 3rd	SPECIAL LECTURE: P-glycoprotein and drug transport	M. Gottesman (NIH OIR) and
		R. Innis (NIH NIMH)
January 10th	Equilibrative and concentrative drug transport	J. Ware (Genentech, Inc.)

MODULE 3: ASSESSMENT OF DRUG EFFECTS:

January 17th	Dose response and concentration response analysis	J. Lertora (NIH CC)
January 24th	Disease progression models and clinical trial simulation	D. Mould (Projections Research, Inc.)
January 31st	Physiological and laboratory markers of drug effect	J. Woodcock (FDA)

MODULE 4: OPTIMIZING AND EVALUATING PATIENT THERAPY:

February 7th	Clinical analysis of adverse drug reactions	C. Chamberlain (NIH CC)
February 14th	Drug therapy in the elderly	D. Abernethy (FDA)
February 21st	Drug therapy in pregnant and nursing women	M. Frederiksen (Northwestern Un.)
February 28th	Developmental and pediatric pharmacology	J. van den Anker (Children's National
		Medical Center)
March 7th	Quality assessment of drug therapy	C. Daniels (UCSD)

MODULE 5: DRUG DISCOVERY AND DEVELOPMENT:

March 14th	Drug discovery	E. Sausville (Un. of Maryland Medical
		System)
March 21th	Nonclinical drug development	C. Takimoto (Centocor R&D, Inc./Johnson &
		Johnson)
March 28th	Animal scale up and Phase I studies	J. Collins (NIH NCI)
April 4th	Development of biotechnology products and large molecules	P. Garzone ((Pfizer, Inc.)
April 11th	SPECIAL LECTURE: Dynamics of cell based therapies	D. Stroncek (NIH CC)
April 18th	Design of clinical drug development programs	C. Breder (FDA)
April 25th	Role of the FDA in guiding drug development	C. Peck (CDDS, UCSF)