

“PRINCIPLES OF CLINICAL PHARMACOLOGY” COURSE**2008-2009 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://www.cc.nih.gov/training/training/principles.html>

September 4th Introduction to course Lertora (NIH CC)

MODULE 1: PHARMACOKINETICS:

September 11th	Clinical pharmacokinetics	J. Lertora (NIH CC)
September 18th	Chemical assay of drugs and drug metabolites	S. Markey (NIH NIMH)
September 25th	Compartmental analysis of drug distribution	J. Lertora (NIH CC)
October 2nd	Drug absorption and bioavailability	J. Lertora (NIH CC)
October 9th	Use of positron emission tomography (PET) in pharmacokinetics	R. Innis (NIH NIMH)
October 16th	Effects of renal disease on pharmacokinetics	J. Lertora (NIH CC)
October 23rd	SPECIAL LECTURE: Pharmacokinetics in patients requiring renal replacement therapy	A. Atkinson (Northwestern Un.) and G. Susla (MedImmune, Inc.)
October 30th	Noncompartmental vs. compartmental approaches to PK analysis	P. Vicini (Pfizer, Inc.)
November 6th	Effects of liver disease on pharmacokinetics	J. Lertora (NIH CC)
November 13th	Population pharmacokinetics	R. Miller (Pfizer, Inc.)

MODULE 2: DRUG METABOLISM AND TRANSPORT:

November 20 th	Pathways of drug metabolism	S. Markey (NIH NIMH)
December 4th	Pharmacogenetics	D. Flockhart (IUPUI)
December 11 th	Drug Interactions	S. Penzak (NIH CC)
December 18th	Biochemical mechanisms of drug toxicity	L. Pohl (NIH NHLBI)
January 8th	Equilibrative and concentrative transport	J. Ware (Genentech, Inc.)
January 15th	SPECIAL LECTURE: P-glycoprotein and drug transport	M. Gottesman (NIH OIR) and R. Innis (NIH NIMH)

MODULE 3: ASSESSMENT OF DRUG EFFECTS:

January 22nd	Dose response and concentration response analysis	F. Balis (NIH NCI)
January 29th	Disease progression models and clinical trial simulation	D. Mould (Projections Research, Inc.)
February 5th	Physiological and laboratory markers of drug effect	J. Woodcock (FDA)

MODULE 4: OPTIMIZING AND EVALUATING PATIENT THERAPY:

February 12th	Drug therapy in pregnant and nursing women	M. Fredericksen (Northwestern Un.)
February 19th	Developmental and pediatric pharmacology	F. Balis (NIH NCI)
February 26th	Drug therapy in the elderly	D. Abernethy (U.S. Pharmacopeia)
March 5th	Quality assessment of drug therapy	C. Daniels (UCSD)
March 12th	Clinical analysis of adverse drug reactions	K. Calis (NIH CC)

MODULE 5: DRUG DISCOVERY AND DEVELOPMENT:

March 19th	Drug discovery	E. Sausville (Un. of Maryland Medical System)
March 26th	Pre-clinical drug development	C. Takimoto (Centocor R&D, Inc./Johnson & Johnson)
April 2nd	Animal scale up and Phase I studies	J. Collins (NIH NCI) and R. Dedrick (NIH NIBIB)
April 9th	Pharmacokinetics of biotechnology products and large molecules	P. Garzone (PD3G Consulting)
April 16th	Design of clinical drug development programs	C. Grudzinskas (NDA Partners, LLC and CDDS, UCSF)
April 23rd	Role of the FDA in guiding drug development	C. Peck (CDDS, UCSF)