

NIH Principles of Clinical Pharmacology Syllabus 2022-2023

Module 1: Introduction to Clinical Pharmacology	
Lectures	Post-Lecture Activities
Introduction to Module 1 - Dr. Craig Thomas	
Introduction to Clinical Pharmacology and Therapeutics - Dr. Juan J.L. Lertora	Case Study: Steady-State Calculation
Introduction to Pharmacology, Drug Development and Clinical Pharmacology - Dr. William D. Figg	Understanding the Basics of Pharmacology
Practical Pharmacology - Dr. Anne Zajicek	Case Study: Practice with Prescriptions
Biochemical Mechanisms for Drug Toxicity - Dr. A. Beasley Green	Case Study: Statins & Hepatotoxicity
Ethics in Pediatric Clinical Pharmacology - Dr. Donna L. Snyder	Case Study: Pediatric Extrapolation
Ethics in Adult Clinical Pharmacology - Dr. Ezekiel J. Emanuel	Principles of Ethics
Module 2: Pharmacokinetics	
Lectures	Post-Lecture Activities
Introduction to Module 2 - Dr. Anne Zajicek	
Drug Absorption and Bio-availability - Dr. Jan Beumer	Case Study: The Impact of Food on Bioavailability
Compartmental Analysis of Drug Distribution - Dr. Arthur Atkinson	Case Study: Effect of Protein Binding on V_d
Noncompartmental vs. Compartmental Approaches to Pharmacokinetic Analysis - Dr. Paolo Vicini	Case Study: Nonlinear PK Calculation
Population Pharmacokinetics - Dr. Robert R. Bies	Population PK Terminology
Chemical Analysis of Drugs and Metabolites - Dr. Andrew Goey	Case Study by Dr. Robert Parise: Introduction to Mass Spectrometry
Pharmacokinetics/Pharmacodynamics of Protein Drugs - Dr. Jürgen Venitz	Case Study by Dr. Jürgen Venitz: PK/PD of TNF Blockers
Module 3: Drug Metabolism and Transport	
Lectures	Post-Lecture Activities
Introduction to Module 3 - Dr. Lisa M. Cordes	
Pathways of Drug Metabolism Part 1: Phase I Drug Metabolism - Dr. Kenneth Thummel Part 2: Phase II Drug Metabolism - Dr. Deanna Kroetz	Case Study by Dr. Lionel D. Lewis: "Victims & Perpetrators" in Therapeutics
Drug Transporters in ADME and Drug Action - Dr. Joseph Ware	Case Study by Dr. Jomy M. George: Transporter Mediated Drug-Drug Interactions
P-Glycoprotein and Drug Transport Part 1: ABC Transporters in Health and Disease - Dr. Michael Gottesman Part 2: ABC Transporters in the Blood-Brain Barrier - Dr. Matthew Hall	Case Study: The Mystery of Loperamide
Membrane Transport - Dr. Kathy Giacomini	Membrane Transporters in Drug Development
Drug Transport Across the Blood Brain Barrier - Dr. Sadhana Jackson	Permeability of the Blood Brain Barrier
Module 4: Pharmacokinetics and Drug Therapy in Special Populations	
Lectures	Post-Lecture Activities
Introduction to Module 4 - Dr. Bruce Waldrop	
Pharmacokinetic Considerations in Patients with Renal Impairment - Dr. Darren Roberts Part 1: Introduction to Pharmacokinetics in Kidney Disease Part 2: Pharmacokinetics in Chronic Kidney Disease Part 3: Pharmacokinetics in Acute Kidney Injury	Case Study: Drug Dosing in Patients with Chronic Kidney Disease
Pharmacokinetics in Patients Requiring Renal Replacement Therapy Part 1: PK in Patients Requiring Hemodialysis - Dr. Arthur Atkinson Part 2: Continuous Renal Replacement Therapy - Dr. Gregory Susla	Continuous Renal Replacement Therapy: Who, When, Why, How

The Liver and Drugs - Dr. Jürgen Venitz	Case Study: Dose Adjustments Based on Child-Pugh Score
Drug Therapy in Pregnant and Nursing Women - Dr. Anne Zajicek	Case Study: Risks of Phenobarbital During Lactation
Developmental and Pediatric Pharmacology - Dr. John N. van den Anker	Developmental Changes That Influence Drug Disposition
Drug Therapy in the Geriatric Population - Dr. Darrell R. Abernethy	Case Study: DOACs in the Elderly
Pharmacokinetics and Obesity - Dr. Manjunath Pai	Case Study: Drug Dosing in Obesity

Module 5: Assessment of Drug Effects

Lectures	Post-Lecture Activities
Introduction to Module 5 - Dr. Terry Seaton	
Biomarkers of Drug Effects - Dr. Robert Schuck	Pharmacodynamic/Response Biomarkers
Pharmacodynamic and Pharmacokinetic Modeling of Data - Dr. Joga Gobburu	PK/PD Modeling Exercise by Dr. Cody J. Peer
Disease Progression Models - Dr. Diane Mould	Key Concepts of Disease Progression Modeling
Role of Pharmacodynamics in Drug Development - Dr. James Doroshov	Pharmacodynamic & Proof of Mechanism Biomarkers

Module 6: Drug Discovery and Development

Lectures	Post-Lecture Activities
Introduction to Module 6 - Dr. William Zamboni	
Drug Discovery - Dr. Edward Sausville	Drug Discovery Basics
Quantitative Systems Pharmacology - Dr. D. Lansing Taylor	Integrating Diverse Data Sources into Computation Models
Computational Methods of Drug Discovery and Design - Dr. Glen Kellogg	Computational Methods Key Definitions
Combinatorial Drug Screening - Dr. Craig Thomas	Case Study: BRAF & MEK Inhibitors in Melanoma
Natural Products - Dr. Barry O'Keefe	Decisions on Screening Natural Products
Drug Formulation & Delivery - Dr. Robert Ternik	Biopharmaceutics Classification System
Considerations in the Development of Biologics - Dr. Mansoor Khan	Biosimilars
Drug Development in the Pediatric Population - Dr. Anne Zajicek	Clinical Research Involving Children
Animal Scale Up and First-in-Human Studies - Dr. Jerry Collins	Estimating the Starting Dose in FiH Studies
Dose Selection and Optimization in the Adult Population - Dr. Yaning Wang	Case Study: Secukinumab Dosing Optimization
Design of Clinical Drug Development Programs - Dr. Christopher D. Breder	Clinical Drug Development Path
FDA Approval Considerations - Dr. Paul Kluetz	Discussion on Clinical Trial Endpoints by Dr. Barry Goldspiel

Module 7: Pharmacogenomics and Pharmacotherapy

Lectures	Post-Lecture Activities
Introduction to Module 7 - Dr. Elvin Price	
Pharmacometabolomics: Implications for Clinical Pharmacology - Dr. Richard Weinshilboum	Case Study: SSRIs & Pharmacometabolomics
Pharmacogenomics - Dr. Michael Pacanowski	Case Study: Ivacaftor & CFTR
Dose Modifications Based on Pharmacogenomics Research - Dr. Howard McLeod	Case Study: Dosing Guidelines for Azathioprine & TPMT
Clinical Pharmacogenomics Testing - Dr. Mary Relling	Drugs & Genes
Clinical Drug Interactions - Dr. Sarah Robertson	Case Study: Clinical Implications of Grapefruit Juice
Clinical Assessment of Adverse Drug Reactions - Dr. Christopher D. Breder	Case Study: Describing Adverse Events Using CTCAE
Post-Marketing Drug Safety Surveillance - Dr. Peter Waldron	Case Study: MedWatch Voluntary Reporting
Quality Assurance for Drug Therapy - Dr. Charles Daniels	Medication Use Evaluation

Topics of Special Interest

Lectures	Post-Lecture Activities
Use of Positron Emission Tomography (PET) in Pharmacokinetics - Dr. Robert Innis	Basics of PET in PK
Enabling Technologies in Drug Formulation - Dr. Ping Gao	Understanding Drug Formulations
Immunotherapeutics - Dr. James Gulley	Case Study by Dr. Lisa M. Cordes: Immunotherapy- Related Adverse Events
T-Cell Therapies: Principles and Practice - Dr. James Yang	Structures of Adoptive Cell Therapies