

NIH Principles of Clinical Pharmacology Syllabus 2023-2024

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 Pharmacokinetic Modeling Vignette by Dr. Robert R. Bies plus a Population Pharmacokinetic Terminology Activity
Chemical Analysis of Drugs and Metabolites - Dr. Andrew Goey	Case Study by Dr. Robert Parise: Introduction to Mass Spectrometry
Pharmacokinetics & Pharmacodynamics of Therapeutic Proteins – Dr. Bernd Meibohm	Pharmacologic Characteristics of Therapeutic Proteins
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
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 by Dr. Jomy M. George: Transporter Mediated Drug-Drug Interactions
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	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
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
Overview of Pharmacogenomics - Dr. Howard McLeod	Case Study: Dosing Guidelines for Azathioprine & TPMT
Implementing Pharmacogenomics into Practice - Dr. Mary Relling	Drugs & Genes
Pharmacogenomics: FDA Perspective - Dr. Michael Pacanowski	Case Study: Ivacaftor & CFTR
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 (Supplementary Materials)

About This Module:

This Module contains supplementary materials for participants who are interested in learning more. Although these lectures are not classified as core lectures and are not part of the final exam, they will add to the participant's knowledge base on pharmacology.

Supplementary Lectures	Post-Lecture Activities
Use of Positron Emission Tomography (PET) in Pharmacokinetics - Dr. Robert Innis	Basics of PET in PK
Drug Transporters in ADME and Drug Action - Dr. Joseph Ware	Case Study: The Mystery of Loperamide
Enabling Technologies in Drug Formulation - Dr. Ping Gao	Understanding Drug Formulations
Computational Methods of Drug Discovery and Design - Dr. Glen Kellogg	Computational Methods Key Definitions
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
NCI Drug Development Workshop: How to Advance a Therapeutic Candidate from Bench to Bedside	Case Studies: Development of Small Molecule Products Development of Biological Products