

NIH Principles of Clinical Pharmacology Syllabus 2026-2027

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
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 Bioavailability - Dr. Jan Beumer	Case Study: The Impact of Food on Bioavailability
Multicompartmental PK Modeling – Dr. Scott R. Penzak	Case Study: Effect of Protein Binding on V_d
Noncompartmental vs. Compartmental Approaches to PK Analysis - Dr. Paolo Vicini	Case Study: Nonlinear PK Calculation
Population PK - Dr. Robert R. Bies	Population PK Modeling Vignette by Dr. Robert R. Bies
Machine Learning Algorithm for Population PK (pyDarwin) *NEW* – Dr. Robert R. Bies	Population PK Terminology Activity
Chemical Analysis of Drugs and Metabolites - Dr. Andrew Goey	Case Study by Dr. Robert Parise: Introduction to Mass Spectrometry
PK and PD of Therapeutic Proteins – Dr. Bernd Meibohm	Pharmacologic Characteristics of Therapeutic Proteins
Factors Affecting PK and PD of Complex Drugs *NEW* – Dr. William Zamboni	Clinical Pharmacology Considerations for Antibody-Drug Conjugates
Module 3: Drug Metabolism and Transport	
Lectures	Post-Lecture Activities
Introduction to Module 3 - Dr. Lisa M. Cordes	
Pathways of Drug Metabolism – Dr. Deanna Kroetz	Case Study by Dr. Lionel D. Lewis: “Victims & Perpetrators” in Therapeutics
Membrane Transport - Dr. Kathy Giacomini	Case Study: Transporter Mediated Interactions by Dr. Jomy M. George plus a Transporters in Drug Development Activity
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	
PK Considerations in Patients with Renal Impairment - Dr. Darren Roberts	Case Study: Drug Dosing in Patients with Chronic Kidney Disease
PK 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
PK in Patients with Liver Disease - Dr. Lionel Lewis	Case Study: Dose Adjustments Based on Child-Pugh Score
Drug Therapy in Pregnant and Nursing Women – Dr. Uma Reddy	Case Study: Risks of Levetiracetam During Lactation

Developmental and Pediatric Pharmacology - Dr. John N. van den Anker	Developmental Changes That Influence Drug Disposition
PK Considerations in Older Adults - Dr. Elvin T. Price	Case Study: DOACs in the Elderly
PK 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. Keith T. Schmidt	
Biochemical Mechanisms for Drug Toxicity - Dr. A. Beasley Green	Case Study: Statins & Hepatotoxicity
Biomarkers of Drug Effects - Dr. Robert Schuck	PD/Response Biomarkers
PD and PK Modeling of Data - Dr. Joga Gobburu	PK/PD Modeling Exercise by Dr. Cody Peer
Disease Progression Models - Dr. Diane Mould	Role of Disease Progression Models in Drug Development
Role of PD in Drug Development - Dr. James Doroshov	PD & 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
First-in-Human Studies *NEW* Part 1: Nonclinical IND-Enabling Studies – Dr. Elizabeth Glaze Part 2: First-in-Human Trials in Healthy Volunteers – Dr. Robert Noveck Part 3: Oncology Phase 1 Trials and Dose Optimization – Dr. Mark Ratain	Case Studies: Dose Selection and Optimization by Dr. Yaning Wang
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
Post-Marketing Drug Safety Surveillance - Dr. Peter Waldron	Case Study: MedWatch Voluntary Reporting

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

Use of Positron Emission Tomography (PET) in Pharmacokinetics - Dr. Robert Innis

Enabling Technologies in Drug Formulation - Dr. Ping Gao

Computational Methods of Drug Discovery and Design - Dr. Glen Kellogg

NCI Drug Development Workshop: How to Advance a Therapeutic Candidate from Bench to Bedside

Emeritus Lectures

Drug Transporters in ADME and Drug Action - Dr. Joseph Ware

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

Compartmental Analysis of Drug Distribution – Dr. Arthur Atkinson

Animal Scale Up and First-in-Human Studies - Dr. Jerry Collins

Clinical Assessment of Adverse Drug Reactions – Dr. Christopher D. Breder

Quality Assurance for Drug Therapy - Dr. Charles Daniels