

**Request for Approval under the “Generic Clearance for the Collection of
Qualitative Feedback on Agency Service Delivery (NICHD)”
(OMB#: 0925-0648 ExpDate: 6/30/2024)**

2022-23 Principles of Pediatric Clinical Pharmacology – Learning Objectives

10/12/2022: Developing your Elevator Speeches and Negotiation Tips and Insights

Lecture Speaker: Lauren Celano

Learning Objectives:

- Understand the purpose of an elevator pitch.
- Learn how to develop an elevator pitch.
- Learn how to tailor an elevator pitch.
- Understand what is negotiable in a job offer.
- Understand how to determine what is most important for each individual to negotiate.
- Learn different strategies to negotiate an offer.

10/19/2022: Inside NIH Study Sections – Navigating Grant Submission & Review

Lecture Speaker: Dianne Hardy

Learning Objectives:

- Understand review criteria
- Understand what happens when you submit your grant application

10/26/2022: Ontogeny of Transporters

Lecture Speaker: Saskia deWildt

Learning Objectives:

- Explain the clinical relevance of membrane transporters in pediatric drug therapy and discuss several examples
- Describe transporter specific developmental patterns
- List research approaches for studying pediatric drug transporters
- Identify major challenges in elucidating the human ontogeny of drug transporters

11/2/2022: Drug Exposure and Response in Pregnancy

Lecture Speaker: Raman Venkataramanan

Learning Objectives:

- Describe important physiologic factors that impact drug exposure in pregnancy
- Design studies to evaluate pregnancy mediated changes in drug exposure
- Predict potential dosing changes for drugs with specific PK properties
- Interpret literature on PK in pregnancy

11/9/2022: Physiologically-Based Pharmacokinetic Modeling

Lecture Speaker: Sara Quinney

Learning Objectives:

- Recognize PBPK modeling structure and components, including drug- and system-specific parameters, and the difference between PBPK and empirical PK models.
- Understand how PBPK can support pediatric drug development and precision therapy.
- Discuss best practices for developing a pediatric PBPK model

11/16/2022: Pharmacokinetic and Pharmacodynamic Studies for Inhaled Asthma Drugs**Lecture Speaker:** Leslie Hendeles**Learning Objectives:**

- Explain how fluticasone propionate blood levels can be used to determine the relative amount of inhaled corticosteroid delivered to the airways.
- Describe how the static charge on a valved holding chamber affects the relative amount of albuterol delivered to the airways.
- Understand how a methacholine challenge can be used to determine the bioequivalence of a generic albuterol metered dose inhaler.

11/30/2022: Pharmacogenomics and Bioinformatics in Drug Discovery**Lecture Speaker:** Anil Jegga**Learning Objectives:**

- Introduce and give an overview of some of the state-of-art databases and servers that can be used for pharmacogenomics research and drug discovery
- Explain how existing data can be harnessed to “guide” or “inform” translational medicine
- Provide examples of the application of data repurposing for drug discovery

12/7/2022: Quantitative Pharmacologic Systems Models**Lecture Speaker:** Jeff Barrett**Learning Objectives:**

- Understand the mechanics of QSP modeling as applied to pediatric drug development and extrapolation strategies
- Examine the potential for QSP to examine adult and pediatric disease similarity
- Understand uses cases and how these examples have been incorporated into recent ICH guidance on pediatric extrapolation

12/14/2022: Path Towards Authorization of a COVID-19 Vaccine for Children**Lecture Speaker:** Emmanuel Walter**Learning Objectives:**

- Describe the rationale and benefits for vaccinating children to prevent COVID-19 disease
- Outline the steps to development of a COVID-19 vaccine for children
- Describe effectiveness of the COVID-19 vaccine in children
- Describe the safety considerations regarding the use of mRNA COVID-19 vaccines in children

1/11/2023: Stages and Phases - the Importance of Mentorship Throughout Your Career**Lecture Speaker:** Susan Abdel-Rahman and Stephani Stancil**Learning Objectives:**

- Build and strengthen constructive, productive relationships between mentors and mentees
- Define and distinguish various levels of engagement
- Expand your toolbox for fostering professional growth

1/18/2023: Application of Metabolomics in Pediatric Type 2 Diabetes**Lecture Speaker:** Jennifer Meijer**Learning Objectives:**

- Receive an overview of metabolomics sample collection, instrumental analysis, and data analysis.
- Understand the application of metabolomics in acute macronutrient challenges, including a high-fat challenge for prediction of type 2 diabetes risk.
- Receive an overview of metabolic changes in response to glucagon-like peptide-1 receptor agonist treatments.

1/25/2023: In Vivo Bioimaging in Pediatric Infections

Lecture Speaker: Sanjay Kumar Jain

Learning Objectives:

- Identify the differences between conventional and molecular imaging approaches to measure antimicrobial drug distribution.
- Recognize the spatiotemporal kinetics of antimicrobial drug distribution.