Attendees Obtain Free CE Credits from ACCP Virtual Journal Club Webinars!

Accelerating Drug Development in Pediatric Oncology With the Clinical Pharmacology Storehouse

2019 ACCP Virtual Journal Club Webinars

Live Session: Wednesday, April 24, 2019 from 2:00pm to 3:00pm ET

On Demand: April 24, 2019 to April 24, 2022

Why is this webinar important to you?
Pediatric drug development is a challenging process due to the rarity of the population, the need to meet regulatory requirements across the globe, the associated uncertainty in extrapolating data from adults, the paucity of validated biomarkers and the lack of systematic testing of drugs in pediatric patients. In oncology, pediatric drug development has additional challenges that have historically delayed availability of safe and effective medicines for children. In particular, the traditional approach to pediatric oncology drug development involves conducting Phase 1 studies in children once the drug has been characterized and, in some cases, approved for use in adults. The objective of this article is to describe clinical pharmacology factors that influence pediatric oncology trial design and execution and to highlight efficient approaches for designing and expediting oncology drug development in children. The topics highlighted in this article include (1) study design considerations, (2) updated dosing approaches, (3) ways to overcome the significant biopharmaceutical challenges unique to the oncology pediatric population and (4) use of data analysis strategies for extrapolating data from adults, with case studies. Finally, suggestions for ways to use clinical pharmacology approaches to accelerate pediatric oncology drug development are provided.

ACPE Accreditation Statement
The American College of Clinical Pharmacology is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education.
UAN: 0238-0000-19-031-L/H01-P – ACPE 1 Contact Hours
Activity Type: Knowledge-based **Format:** Live & Home-study **Target Audience**: 'P'

ACCME Accreditation Statement
The American College of Clinical Pharmacology is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

ACCME Designation Statement
The Accreditation Council for Continuing Medical Education designates this live and enduring CE activity for 1 *AMA PRA Category 1™* credit. Physicians should only claim credit commensurate with the extent of their participation in the activity.

Target Audience
Interprofessional team of Physicians, Pharmacists, PhDs, Nurse Practitioners and Physician Assistants.

Learning Objectives
After completing this activity, the learner will be able to:

1) Articulate various study designs for including younger children in First-in-Human Phase 1 oncology trials;

2) List various nontraditional microvolume PK sampling techniques (e.g. dried blood spots) to increase frequency, quantity and thus quality of PK/PD sampling data obtained in pediatric oncology studies;
3) Describe opportunities for applying modeling and simulation strategies for the purposes of selecting a starting pediatric oncology dose;
4) Explain model-informed drug development approaches to extrapolation of drug-drug interactions from adults to children.

Requirements to Receive Credit
In order to receive continuing medical education (CME) or continuing pharmacy education (CPE) credit, the learner must register for the educational activity, study the provided journal article, attend the Live webinar or view the On Demand webinar, complete the online learning Self-assessment Post-test as well as the online course Evaluation and CME/CPE Certificate. Credits and CME/CPE Certificates must be claimed within thirty (30) days of completing the webinar, Post-test and Evaluation. Contact CE@ACCP1.org with any questions.

Disclosures:

Author/Faculty: Mohamad Shebley, PhD, Director & Volwiler Research Fellow, AbbVie Inc, Clinical Pharmacology & Pharmacometrics, has nothing to disclose related to this educational content.

Moderator/Planner: Parag Kumar, PharmD, Associate Director, Otsuka Pharmaceutical Development & Commercialization Inc, Clinical Pharmacology, has nothing to disclose related to this educational content.

CE Reviewer: Amar Raza, MBBS, DDiab, MBA, FCP, Country Medical Director, Allergan India, Medical & Scientific Affairs, has nothing to disclose related to this educational content.

Schedule & Fees
ACCP webinar programs occur several times per year. Registration for the webinars are required but are free of charge to all learners.

Acknowledgement of Financial Support
No financial support was received for this educational activity.

Home Study Initial Release and Expiration Dates
Date of Issuance: April 24, 2019
Expiration Date: April 24, 2022

Helpful Tips
For best audio and visual quality, we recommend viewing the webinar in the Chrome browser. If you do not have Chrome, you may download it here.

Test your browser compatibility before the webinar by clicking here.

Download the article and slide handouts and access the webinar here.

For help during the webinar, please call (571) 291-3493 ext 4.

Learn how to print your CME/CPE Certificate here.
