



ACCP

AMERICAN COLLEGE OF CLINICAL PHARMACOLOGY®
Advancing Clinical Care through Pharmacology®

Symposia

TUESDAY, SEPTEMBER 17, 2019 | Symposium 16 | 3:30 – 5:00 PM

Complex Innovative Methodologies in Oncology Clinical Trials: Towards Accelerating Development of Anti-cancer Therapies

DEVELOPMENT TRACK

Offers both CME & CPE Credit

UAN #0238-0000-19-016-L01-P

ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:

Amal Ayyoub, PhD, Clinical Pharmacology Reviewer, US Food & Drug Administration, Office of Clinical Pharmacology, Office of Translational Sciences, CDER

Yingxue Chen, PhD, Director of Quantitative Clinical Pharmacology, AstraZeneca plc, Early Clinical Development

TARGET AUDIENCE:

This Symposium will be useful for clinical drug development professionals, including clinical pharmacologists, biostatisticians and medical professionals involved in the planning and design of clinical trials.

GOALS & OBJECTIVES:

Following the completion of this activity, the learner will be able to:

1. Explore innovative methodologies implemented in oncology clinical trials (master protocols [umbrella, basket, platform trials]), expansion cohorts and adaptive designs that span drug development from First-in-Human to Phase 3 trials;
2. Describe the benefits of complex innovative methodologies and the challenges associated with implementation;
3. Explain the regulatory perspective on best practices to inform oncology drug development and approval of therapies.

3:30 – 3:50 PM

Complex Innovative Designs in Oncology Drug Development: An Overview

Amal Ayyoub, PhD, Clinical Pharmacology Reviewer, US Food & Drug Administration, Office of Clinical Pharmacology, Office of Translational Sciences, CDER

3:50 – 4:10 PM

Advanced Trial Designs in Oncology Drug Development

Yingxue Chen, PhD, Director of Quantitative Clinical Pharmacology, AstraZeneca plc, Early Clinical Development

4:10 – 4:30 PM

A Generalized Design for Confirmatory Basket Trials

Robert A. Beckman, MD, Professor of Oncology & Biostatistics, Bioinformatics & Biomathematics, Georgetown Univ Medical Ctr, Lombardi Comprehensive Cancer Ctr & Innovation Ctr for Biomedical Informatics

4:30 – 4:50 PM

Use of Historical Data in the Design & Analysis of Oncology Clinical Trials

Nidal Al-Huniti, PhD, Executive Director & US Oncology Lead, AstraZeneca plc, Quantitative Clinical Pharmacology

4:50 – 5:00 PM

Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluations