

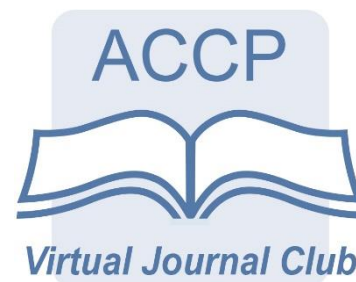
ACCP Virtual Journal Club Webinars!

Model-Informed Approaches to Support Drug Development for Patients With Obesity: A Regulatory Perspective

2024 ACCP Virtual Journal Club Webinar

Live Session: Wednesday, October 30th, 2024, from 1:00 to 2:00 PM ET

On Demand: October 30th, 2024 to October 30th, 2027



Why is this webinar important to you?

This presentation incorporates the use of Model-Informed Drug Development (MIDD) approaches to address the unique challenges in drug development and regulatory decision-making for patients with obesity. Given the high prevalence of obesity in the general population, it is essential to identify appropriate drug development strategies with optimal dosing for this patient group. However, the unique physiological and pathological characteristics of the obese population may present hurdles in clinical development programs. This presentation will provide an overview of the impact of obesity on pharmacokinetics, pharmacodynamics and the efficacy of drugs and, more importantly, demonstrate how MIDD approaches are applied at various stages of drug development and regulatory review for patients with obesity, with a focus on dosing regimen optimization, through case studies from recent submissions.



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: 0665-0000-24-034-L01-P & 0665-0000-24-034-H01-P

Contact Hours: 1.0

Activity Type: Knowledge-based

Format: Live and Home-study

Target Audience: 'P'



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ACCME Accreditation Statement

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ACCME Designation Statement

The Accreditation Council for Continuing Medical Education designates this journal 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 MDs, PhDs, PharmDs and other health care professionals, including students, trainees and professionals at all levels, who are involved or interested in drug development for patients with obesity.

Learning Objectives

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

- Describe the impact of obesity on drug pharmacokinetics, pharmacodynamics and efficacy;
- Identify the unique challenges and opportunities in drug development for patients with obesity;
- Recognize the utility of model-informed drug development in facilitating clinical trial design and regulatory decision-making in patients with obesity.

Faculty:

Author/Faculty: Xiaolei Pan, PhD, Senior Staff Fellow, US Food & Drug Administration
Moderator/Planner: Sihem Bihorel, PharmD, PhD, Senior Director, Merck & Co Inc
CE Reviewer: Tushar Garimella, MD, PhD, Senior Director, Daiichi Sankyo Co Ltd

All of the relevant financial relationships for these individuals have been mitigated.

Schedule & Fees

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

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](#).