

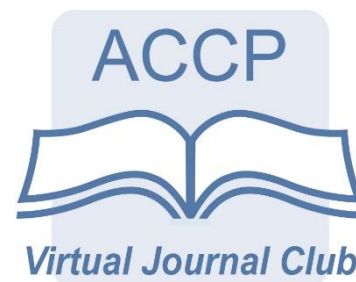
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Model-Informed Approach Supporting Drug Development and Regulatory Evaluation for Rare Diseases

2023 ACCP Virtual Journal Club Webinar

Live Session: Wednesday, May 17, 2023 from 2:00 to 3:00 PM ET

On Demand: May 17, 2023 to May 17, 2026



Why is this webinar important to you?

For rare diseases, it is challenging to enroll a large number of patients and obtain all critical information to support drug approval through traditional clinical trial approaches. In addition, over half of the population affected by rare diseases are children, which presents additional drug development challenges. In the context of rare diseases, maximizing the use of all available data is in the interest of drug developers and regulators. This provides opportunities for model-informed drug development (MIDD) to use and integrate all available sources and knowledge to quantitatively assess the benefit/risk of a new product under development and to inform dosing. Learners that complete this activity will be able to explain the application of MIDD in rare diseases.



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: 0665-0000-23-024-L99-P– ACPE 1 Contact Hours

Activity Type: Knowledge-based **Format:** Live **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 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

Physicians, Pharmacists, PhDs and other healthcare professionals interested in the application of model-informed drug development.

Learning Objectives

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

- 1) Explain why MIDD is important for rare diseases;
- 2) Discuss how MIDD can be applied to enhance drug development for rare diseases;
- 3) Learn about future direction for MIDD application to enhance drug development for rare diseases.

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

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webinar or view the On-Demand webinar, complete the online learning Self-assessment Post-test as well as the online course Evaluation. Credits and CME/CPE Certificates must be claimed within thirty (30) days of completing the live webinar, Post-test and Evaluation. Contact CE@ACCP1.org with any questions.

Disclosures:

Author/Faculty: Hao Zhu, PhD, Team Leader, US Food & Drug Administration, Faculty, has no relevant financial relationship(s) with ineligible companies to disclose.

Moderator/Planner: Mariam Ahmed, PhD, Associate Director, Takeda Pharmaceuticals Co Ltd, Planner, is an employee of Takeda Pharmaceuticals Co Ltd. All of the relevant financial relationships for this individual have been mitigated.

CE Reviewer: Amit Somani, PhD, Senior Clinical Pharmacology Reviewer, US Food & Drug Administration, Reviewer, has no relevant financial relationship(s) with ineligible companies to disclose.

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: May 17, 2023

Expiration Date: May 17, 2026

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](#).
