



ACCP

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

Symposia

MONDAY, SEPTEMBER 21, 2020 | Symposium 2 | 10:00 – 11:30 AM

What is the Right Dose in Cancer Patients With Hepatic Dysfunction? Considerations in the Translation of Pharmacokinetic Studies from Clinical Trial to Clinic

THERAPEUTIC AREAS OF APPLIED CLINICAL PHARMACOLOGY TRACK

Offers both CME & CPE Credit

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ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:

Nithya Srinivas, PhD, Research Investigator, Incyte Corp

Islam R. Younis, PhD, Director, Astellas Pharma US Inc

TARGET AUDIENCE:

This Symposium will be useful for clinical oncology providers treating patients with hepatic impairment in the setting of clinical trials and in general practice, and for clinical pharmacologists in academia, industry or regulatory fields.

GOALS & OBJECTIVES:

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

1. Describe the different approaches for grading hepatic impairment and the sensitivities of these approaches for detecting changes in drug exposure;
2. Discuss the interplay between Child-Pugh criteria and National Cancer Inst criteria in informing dosing recommendations in cancer patients;
3. Evaluate the current paradigm and recent trends for deriving dosing recommendations in cancer patients with hepatic impairment;
4. Describe how dosing recommendation for drugs indicated to treat cancer patients with hepatic impairment are utilized in the clinic.

Introduction: What is the Right Dose in Cancer Patients With Hepatic Dysfunction?

Nithya Srinivas, PhD, Research Investigator, Incyte Corp

Methods to Assess Hepatic Impairment & Implications for Pharmacokinetics in Oncology

Islam R. Younis, PhD, Director, Astellas Pharma US Inc

An Industry Perspective on Recent Trends in Supporting Dosing Recommendations for Oncology Drugs for Patients With Hepatic Impairment

Mohamed Elmeliegy, PhD, Director, Pfizer Inc

Regulatory Expectations on Data Collection & Analysis Approaches to Inform Dosing Recommendations for Oncology Drugs in Cancer Patients With Hepatic Impairment

Hisham Qosa, PhD, Clinical Pharmacologist, US Food & Drug Administration

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