**TUESDAY, SEPTEMBER 17, 2019 | Symposium 11 | 8:00 – 11:30 AM**

# *Considerations for Expanding Oncology Trial Eligibility Criteria to Include Patients With Organ Impairment*

**DEVELOPMENT TRACK**

***Offers both CME & CPE Credit***

**UAN #0238-0000-19-011-L01-P**

**ACPE – 3 CONTACT HOURS/KNOWLEDGE-BASED**

**CO-CHAIRS:**

**Joanna C. Masters, PharmD**, Associate Director, Pfizer Inc, Clinical Pharmacology & Pharmacometrics, Global Product Development

**April M. Barbour, PhD**, Director, Incyte Research Inst, Clinical Pharmacokinetics, Drug Metabolism & Biopharmaceutics

**TARGET AUDIENCE:**

This Symposium will be useful for clinical oncology providers treating patients with renal or hepatic impairment within or outside of clinical trials and for clinical pharmacologists in academia, industry or regulatory designing or reviewing oncology clinical trials and/or informing dose regimen selection for special populations within or outside of a clinical trial.

**GOALS & OBJECTIVES:**

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

1. Highlight the role of clinical pharmacologists in determining trial inclusion/exclusion criteria, including generation and interpretation of nonclinical and early clinical data, physiologically-based pharmacokinetic, population pharmacokinetic or pharmacokinetic/pharmacodynamic models and human ADME data;
2. Evaluate the risks and benefits of expanding trial eligibility criteria to include organ-impaired patients in oncology trials based on the amount of total data available at that time in development;
3. Formulate a robust clinical pharmacology strategy for a drug in development, including incorporation of data generated from trials with expanded eligibility criteria to include organ-impaired patients;
4. Explain how to treat special population patients within a larger clinical trial using expanded eligibility criteria.

8:00 – 8:10 AM

### Introduction & Overview of Oncology Trial Eligibility Criteria Initiatives & the Role of Clinical Pharmacology

*Joanna C. Masters, PharmD, Associate Director, Pfizer Inc, Clinical Pharmacology & Pharmacometrics, Global Product Development*

8:10 – 8:40 AM

### Clinical Pharmacology Data Supporting Inclusion of Organ-impaired Patients in Oncology Trials: A Regulatory Perspective

*Atiqur Rahman, PhD, Director, US Food & Drug Administration, Clinical Pharmacology V, Office of Clinical Pharmacology, OTS/CDER*

8:40 – 9:05 AM

### Considerations for Study Design & Primary Analysis When Including Populations of Organ-impaired Patients in Oncology Clinical Trials

*Thomas Gwise, PhD, Deputy Division Director, US Food & Drug Administration, DBV/CDER/OTS/OB*

9:05 – 9:30 AM

### How to Expand Oncology Clinical Development Plans to Promote Inclusion of Organ-impaired Patients: Cross-functional Considerations in Industry

*Kourosh Parivar, MPharm, Vice President & Head, Pfizer Inc, Oncology Clinical Pharmacology*

9:30 – 10:00 AM / **Break**

10:00 – 10:30 AM

### Challenges & Opportunities When Treating Organ-impaired Patients in Early- & Late-phase Oncology Trials

*Anthony W. Tolcher, MD, Director of Clinical Research & Co-Founder, Next Oncology*

10:30 – 10:55 AM

### Quantitative Clinical Pharmacology to Support Dosing in Special Populations

*April M. Barbour, PhD, Director, Incyte Research Inst, Clinical Pharmacokinetics, Drug Metabolism & Biopharmaceutics*

10:55 – 11:30 AM

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