SUNDAY, SEPTEMBER 15, 2019 | Symposium 2 | 10:00 – 11:30 AM

The Evolution of Pharmacokinetic Studies in Patients With Impaired Renal Function: Emerging Designs & Trends

DEVELOPMENT TRACK

Offers both CME & CPE Credit

UAN #0238-0000-19-002-L01-P

ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

CHAIR:

Lorraine M. Rusch, PhD, President, High Point Clinical Trials Ctr

TARGET AUDIENCE:

This Symposium will be useful for pharmacologists, drug development professionals, ADME scientists, regulatory specialists, physicians, nephrologists and gerontologists.

GOALS & OBJECTIVES:

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

1. Explain the physiological and medical aspects of chronic kidney disease as it relates to drug development;
2. Differentiate between the US and EU guidelines for conducting renal impairment studies;
3. Describe the various strategies which can be employed to address the requirements of conducting a renal impairment study based on the actual ADME characteristics of the drug in development;
4. Demonstrate renal impairment studies to meet the regulatory guidelines which are executable and medically manageable.

10:00 – 10:10 AM

Introduction: The Evolution of Pharmacokinetic Studies in Patients With Impaired Renal Function – Emerging Designs & Trends

Lorraine M. Rusch, PhD, President, High Point Clinical Trials Ctr

10:10 – 10:30 AM

Medical Management of Renally-impaired Patients

Robert J. Noveck, MD, PhD, Principal, Noveck Consultancy

10:30 – 10:55 AM

The Drug Developer's Approach to Evaluating Renally-impaired Patients as Part of an NDA Submission

Bruce Morimoto, PhD, Vice President, Alkahest Inc, Drug Development Operations

10:55 – 11:15 AM

The Challenge of Patient Identification, Enrollment & Medical Management of Renally-impaired Patients

Clayton A. Dehn, MS, Vice President, High Point Clinical Trials Ctr, Clinical Pharmacology Svcs

11:15 – 11:30 AM

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