Analysis & Reporting of QTc Prolongation Potential of New Drugs Using R Tools, Expectations & General Guidance for Regulatory Submissions

DRUG DEVELOPMENT TRACK
Offers both CME & CPE Credit
UAN #JA4008220-0000-20-008-L03-P
ACPE – 3 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:
Ana Ruiz-Garcia, PharmD, PhD, Senior Principal Scientist I, Metrum Research Group LLC
Dhananjay D. Marathe, PhD, Principal Scientist, Quantitative Pharmacology & Pharmacometrics, Merck & Co Inc

TARGET AUDIENCE:
This Workshop will be useful for clinical pharmacologists and drug developers.

GOALS & OBJECTIVES:
Following the completion of this activity, the learner will be able to:
1. Become familiar with the ECG-pharmacokinetic analysis using R;
2. Create a report using R Markdown;
3. Gain understanding about the sample size and exposure margin requirements for TQT substitution request based on studies without a positive control;
4. Have a deeper understanding of some of the common challenges and potential solutions for design/analysis issues.

ECG-Pharmacokinetic Analysis Using R: Theory & Hands On
Steve Riley, PharmD, PhD, Senior Director, Clinical Pharmacology, Pfizer Inc

Break

Goodness-of-Fit Diagnostics Using R & R Markdown Reporting Tool
Ana Ruiz-Garcia, PharmD, PhD, Senior Principal Scientist I, Metrum Research Group LLC

Experience Regarding Expectations & General Guidance for Regulatory Submissions Under ICH E14 Q&A (R3) for TQT Study Substitution Requests Based on Concentration-QTc Analysis
Dhananjay D. Marathe, PhD, Principal Scientist, Quantitative Pharmacology & Pharmacometrics, Merck & Co Inc

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