



# ACCP

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

## Pre-meeting Workshops

**WEDNESDAY, SEPTEMBER 9, 2020 | Pre-meeting Workshop 1 | 1:00 – 4:30 PM**

### *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.

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#### **ECG-Pharmacokinetic Analysis Using R: Theory & Hands On**

*Steve Riley, PharmD, PhD, Senior Director, Clinical Pharmacology, Pfizer Inc*

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#### **Break**

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#### **Goodness-of-Fit Diagnostics Using R & R Markdown Reporting Tool**

*Ana Ruiz-Garcia, PharmD, PhD, Senior Principal Scientist I, Metrum Research Group LLC*

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#### **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*

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