# Agenda for 2019 Tufts Annual Postgraduate Course in Clinical Pharmacology, Drug Development and Regulation

## MONDAY, FEBRUARY 4, 2019

**Moderator:** Richard I. Shader, MD  
**8:00-8:30 AM**  
*Open Registration, Continental Breakfast*

**8:30-8:45**  
*Welcome, Orientation, Course Objectives & Introduction* | Kenneth Kaitin

**8:45-9:45**  

**9:45-10:00**  
*Refreshment Break*

**10:00-11:00**  
Translational Medicine – Discovery to Development | Chandrasekhar Natarajan

**11:00-12:00 PM**  
Principles of Clinical Pharmacology | Jerry Collins

**12:00-1:00**  
*Lunch*

**Moderator:** Kenneth I Kaitin, PhD  
**1:00-2:00**  
Pharmacogenomics | Michael Court

**2:00-3:00**  
Clinical Pharmacologic Evaluation of Intrinsic and Extrinsic Factor Effects in Global Drug Development | Karthik Venkatakrishnan

**3:00-3:45**  
Drug Development Regulation Part 1: USA | Alberto Grignolo

**3:45-4:00**  
*Refreshment Break*

**4:00-4:45**  
Drug Development Regulation Pt. 2: Brief Overview of EU, Japan, China and Emerging Markets | Alberto Grignolo

**4:45-5:45**  
The Current Environment For Drug Development: Strategies for Boosting R&D Efficiency and Productivity | Kenneth Kaitin

**5:45-8:00**  
*Networking Reception*

## TUESDAY, FEBRUARY 5, 2019

**Moderator:** Richard I. Shader, MD  
**8:00-8:30 AM**  
*Continental Breakfast*

**8:30-9:15**  
The Basics of Clinical Trial Design | Richard Shader

**9:15-10:00**  
Institutional Review Boards: An Ethical and Regulatory Overview | Susan Kornetsky

**10:00-10:15**  
*Refreshment Break*

**10:15-11:15**  
The Role of Chance in Randomized Controlled Trials: Lecture | Janet Forrester

**11:15-12:00 PM**  
Evaluating the Role of Chance in Clinical Trials: Workshop | Janet Forrester

**12:00-1:00**  
*Lunch with Mock Drug Groups*

**Moderator:** Richard I. Shader, MD  
**1:00-2:00**  
The Next Wave of Adaptive Trials: Broad Implementation & Efficient Clinical Development | Jerald Schindler

**2:00-2:15**  
Instant Experience in Clinical Trials | Richard Shader

**2:15-3:00**  
Pre-Mock Drug Group Case Study Lecture | Helen Boucher

**3:00-5:30**  
Mock Drug Groups: Session I | Richard Shader & Helen Boucher

## WEDNESDAY, FEBRUARY 6, 2019

**Moderator:** Richard I. Shader, MD  
**7:30-8:00 AM**  
*Continental Breakfast*

**8:00-10:00**  
Mock Drug Groups: Session II | Richard Shader & Helen Boucher

**10:00-10:15**  
*Refreshment Break*

**10:15-11:15**  
Pharmaceutical Marketing & the New World Order of Advertising, Social Media & Regulation | Laura Housman

**11:15-12:15 PM**  
Basics of CMC/Quality in Drug Development | Robert Morgan

**12:15-1:15**  
*Lunch*

**Moderator:** Kenneth I Kaitin, PhD  
**1:15-3:00**  
Understanding the FDA: An Open Conversation and Q&A | Ellis Unger

**3:00-4:00**  
Optimizing Protocol Design to Improve Study Conduct Performance | Kenneth Getz

**4:00-5:45**  
Mock Drug Groups: Presentations | Richard Shader & Helen Boucher

**5:45-7:30**  
*Mid-Week Networking Reception: Take an Opportunity to Meet Someone New!*

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THURSDAY, FEBRUARY 7, 2019

Moderator: Kenneth I Kaitin, PhD
8:30-9:00 AM Continental Breakfast
9:00-10:00 BioSimilars: Challenges and Opportunities | Alison Taunton-Rigby
10:00-11:00 Vaccines and Immunotherapies | Niranjan Sardesai
11:00-11:15 Refreshment Break
11:15-12:15 PM Regulatory Science: An Integrated Approach of Evidence Generation for Regulatory Approval & Optimal Label | Iman Barilero
12:15-1:15 Lunch

Moderator: Richard I. Shader, MD
2:15-2:45 Discussion of Postmarketing/Drug Safety Breakout Groups | Paul Beninger
2:45-4:45 Breakout Session: An Interactive Discussion on Postmarketing Surprises & Drug Safety | Paul Beninger, Kenneth Kaitin & Richard Shader
4:45-5:45 Postmarketing Presentations | Paul Beninger, Kenneth Kaitin & Richard Shader

FRIDAY, FEBRUARY 8, 2019

Moderator: Kenneth I Kaitin, PhD
8:15-8:45 AM Continental Breakfast
8:45-9:45 Measuring the Value of Prescription Drugs | Peter Neumann
9:45-10:45 How to Select and Work with CRO’s | Laurie Halloran
10:45-11:45 Patient Centricity: The Nuts and Bolts | Stella Stergiopoulos
11:45-12:00 PM Course Wrap Up | Kenneth Kaitin