

**Professional Certificate in  
Clinical Pharmacology, Drug Development and Regulation**  
*Live-Interactive (via Zoom)*

**SCHEDULE**

**Thursday, March 11, 2021** | EST 10:00-14:00 / GR 17:00-21:00

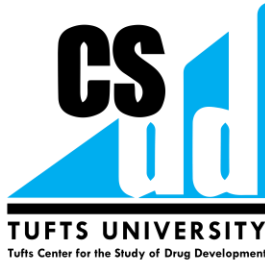
**Moderator:** **Theoharis C. Theoharides, PhD, MD**  
EST 10:00-10:15 Welcome, Dean of the Deree-School of Graduate & Professional Education | **Areti Kreppapa, PhD**  
EST 10:15-10:45 Welcome, Orientation, Course Objectives & Introduction | **Kenneth I Kaitin, PhD**  
EST 10:45-11:45 An Introduction to the Drug Development Process: A Global Perspective | **Dennis Vargo, MD**  
EST 11:45-12:00 *Break*  
EST 12:00-13:00 Translational Medicine – Discovery to Development | **Chandrasekhar Natarajan, BPharm, MSc**  
EST 13:00-14:00 Principles of Clinical Pharmacology | **Jerry M. Collins, PhD**

**Tuesday, March 16, 2021** | EST 10:00-14:15 / GR 16:00-20:15

**Moderator:** **Kenneth I Kaitin, PhD**  
EST 10:00-11:00 Drug Development Regulation Part 1: USA | **Alberto Grignolo, PhD**  
EST 11:00-12:00 Drug Development Regulation Part 2: World | **Alberto Grignolo, PhD**  
EST 12:00-12:15 *Break*  
EST 12:15-13:15 Reproducibility | **Theoharis C. Theoharides, PhD, MD**  
EST 13:15-14:15 Global Landscape for New Drug Development: Strategies for Boosting R&D Efficiency & Productivity | **Kenneth I Kaitin, PhD**

**Wednesday, March 17, 2021** | EST 10:00-14:15 / GR 16:00-20:15

**Moderator:** **Theoharis C. Theoharides, PhD, MD**  
EST 10:00-11:00 The Role of Epidemiology in Drug Development: A Global Perspective | **Paul Beninger, MD, MBA**



- EST 11:00-12:15 Human Research Protection: An Ethical and Regulatory Overview with Case Studies | **Susan Kornetsky, MPH**
- EST 12:15-12:30 *Break*
- EST 12:30-13:15 Power Determination and Statistical Analysis in Controlled Trials | **Janet E. A. Forrester, PhD**
- EST 13:15-14:15 Evaluating the Role of Chance in Clinical Trials: Workshop | **Janet E. A. Forrester, PhD**

**Thursday, March 18, 2021 | EST 10:00-14:00 / GR 16:00-20:00**

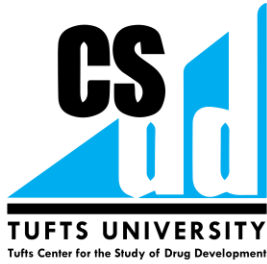
- Moderator: Kenneth I Kaitin, PhD**
- EST 10:00-11:00 Introduction to Clinical Trial Design | **Richard I. Shader, MD**
- EST 11:00-12:00 Adaptive Trials: Broad Implementation & Efficient Clinical Development | **Jerald Schindler, DrPH**
- EST 12:00-12:15 *Break*
- EST 12:15-13:00 Pre-Mock Drug Group Discussion | **Richard I. Shader, MD**
- EST 13:00-14:00 Mock Drug Group Activity: Session 1 | **Richard Shader, MD & Paul Beninger, PhD, MBA**

**Friday, March 19, 2021 | EST 10:00-14:00 / GR 16:00-20:00**

- Moderator: Kenneth I Kaitin, PhD**
- EST 10:00-11:00 Mock Drug Group Activity: Session 2 | **Richard Shader, MD & Paul Beninger, MD, MBA**
- EST 11:00-12:00 Mock Drug Groups: Presentations | **Richard Shader, MD & Paul Beninger, MD, MBA**
- EST 12:00-12:15 *Break*
- EST 12:15-13:00 Medical Affairs In Medicines Development | **Varbara Baroutsou, MD, PhD, GFMD**
- EST 13:00-14:00 Pharmaceutical Marketing: Advertising and Regulation | **George Vassilopoulos, DPharm, PhD**

**Monday, March 22, 2021 | EST 10:00-14:15 / GR 16:00-20:15**

- Moderator: Kenneth I Kaitin, PhD**
- EST 10:00-11:00 Vaccine Development | **Michael A. Egan, PhD**
- EST 11:00-12:00 Optimizing Protocol Design to Improve Study Conduct Performance | **Kenneth A. Getz, MBA**
- EST 12:00-12:15 *Break*
- EST 12:15-13:15 Basics of CMC/Quality in Drug Development | **Robert A. Morgan, MS, JD**
- EST 13:15-14:15 Pharmacovigilance, Post-Market Surveillance, and Risk Management | **Paul Beninger, MD, MBA**



**Tuesday, March 23, 2021 | EST 10:00-14:00 / GR 16:00-20:00**

- Moderator: Kenneth I Kaitin, PhD**
- EST 10:00-11:00 Drug Safety Breakout Group Discussion | **Paul Beninger, MD, MBA**
- EST 11:00-12:00 Breakout Group Activity: Drug Safety – Stakeholder Perspectives | **Paul Beninger, MD, MBA  
Kenneth Kaitin, PhD & Richard Shader, MD**
- EST 12:00-12:15 *Break*
- EST 12:15-13:15 *“MEET THE PRESS”*: Should This Life-Saving Medicine with Safety Issues Remain on the Market?  
| **Paul Beninger, MD, MBA & Kenneth Kaitin, PhD**
- EST 13:15-14:00 Breakout Group Activity Wrap-Up | **Paul Beninger, MD, MBA**

**Wednesday, March 24, 2021 | EST 10:00-14:00 / GR 16:00-20:00**

- Moderator: Kenneth I Kaitin, PhD**
- EST 10:00-11:00 “Patient Centricity” and its Impact on Drug Development | **Kenneth A. Getz, MBA**
- EST 11:00-12:00 AI and Next Generation Machine Learning: New Tools for Rational Drug Development and Repurposing | **Joseph Gormley**
- EST 12:00-12:15 *Break*
- EST 12:15-13:15 Measuring the Value of Prescription Drugs | **George Vassilopoulos, DPharm, PhD**
- EST 13:15-14:00 Course Wrap-Up | **Kenneth I Kaitin, PhD**