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 Dereee-School of Graduate & Professional Education | Areti Krepapa, 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
### 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 Baroutou, 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
 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 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