Tufts UNIVERSITY | Tufts Center for the Study of Drug Development

# Tufts CSDD 2022 Postgraduate Course in Clinical Pharmacology, Drug Development, and Regulation

## *WEEK ONE*

### Day 1: Wednesday, April 6, 2022

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| **Moderator:** | **Kenneth I Kaitin, PhD** |
| 12:00-12:30pm EST | Welcome, Introduction, Course Objectives \| **Kenneth Kaitin, PhD** |
| 12:30-1:30pm | Introduction to the Drug Development Process **\| Richard I. Shader, MD** |
| 1:30-1:45pm | *Break* |
| 1:45-3:00pm | Clinical Pharmacology and Translational Medicine – Discovery to Development **\| Chandrasekhar Natarajan, BPharm, MSc** |
| 3:00-4:00pm | The Changing Landscape for Drug Development: Trends and Challenges in Pharmaceutical R&D **\| Kenneth Kaitin, PhD** |

### Day 2: Thursday, April 7, 2022

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| **Moderator:** | **Kenneth I Kaitin, PhD** |
| 12:00-1:00pm EST | Drug Development Regulation-Part 1: USA **\| Alberto Grignolo, PhD** |
| 1:00-1:45pm | Drug Development Regulation-Part 2: Rest of World **\| Alberto Grignolo, PhD** |
| 1:45-2:00pm | *Break* |
| 2:00-3:00pm | Understanding the Medical Affairs Function **\| Pol Vandenbroucke, MD, MSc, MBA, FFPM** |
| 3:00-4:00pm | Biosimilars: Your Questions Answered **\| Ron Lanton III, Esq.** |

## *WEEK TWO*

### Day 3: Wednesday, April 13, 2022

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| **Moderator:** | **Kenneth I Kaitin, PhD** |
| 12:00-1:00pm EST | Basics of Clinical Trial Design and Execution **\| Orest Hurko, MD** |
| 1:00-1:45pm | Human Research Protection: An Ethical and Regulatory Overview **\| Susan Kornetsky, MPH** |
| 1:45-2:00pm | *Break* |
| 2:00-3:00pm | Adaptive Trials: Broad Implementation & Efficient Clinical Development **\| Jerald Schindler, DrPH** |
| 2:45-4:00pm | Understanding the FDA: An Open Conversation and Q&A **\| Ellis F. Unger, MD** |

### Day 4: Thursday, April 14, 2022

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| **Moderator:** | **Kenneth I Kaitin, PhD** |
| 12:00-12:45pm EST | Optimizing Protocol Design to Improve Study Conduct Performance **\| Kenneth A. Getz, MBA** |
| 12:45-1:45pm | Real World Data (RWD) Across the Life Cycle, from Trial Design to Post Approval Safety and Efficacy Detection: A Case Study **\| Jeffrey Brown, PhD, and Mats Sundgren, PhD** |
| 1:45-2:00pm | *Break* |
| 2:00-3:00pm | Artificial Intelligence and its Use in Drug Development Process: A Case Study **\| Prasanna Rao** |
| 3:00-4:00pm | The Role of Epidemiology in Drug Development: A Global Perspective**\| Paul Beninger, MD, MBA** |

## ***WEEK THREE***

### Day 5: Wednesday, April 20, 2022

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| **Moderator:** | **Kenneth I Kaitin, PhD** |
| 12:00-1:00pm EST | Pharmacovigilance, Post-Market Surveillance, and Risk Management **\| Paul Beninger, MD, MBA** |
| 1:00-1:45pm | CMC, Quality, and Clinical Materials Supply **\| Rob Franco, PhD** |
| 1:45-2:00pm | *Break* |
| 2:00-3:00pm | Creating a Commercial Strategy: Balancing Public Health and Free Speech **\| Peter J. Pitts** |
| 3:00-4:00pm | Vaccine Development: Lessons Learned from the COVID Vaccine Experience **\| Anita Patel, PharmD** |

### Day 6: Thursday, April 21, 2022

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| **Moderator:** | **Kenneth I Kaitin, PhD** |
| 12:00-1:00pm EST | Measuring the Value of Prescription Drugs **\| Peter J. Neumann, ScD** |
| 1:00-2:00pm | Alliance Management **\| Christine Carberry, PhD** |
| 2:00-2:15pm | Break |
| 2:15-3:15pm | Bio/Pharm Investing 101 **\| Les Funtleyder, MPH** |
| 3:15-4:00pm | Course Wrap-Up **\| Kenneth Kaitin, PhD** |

## Course Faculty

- **Kenneth I Kaitin, PhD (Course Moderator):** Professor and Senior Fellow, Tufts Center for the Study of Drug Development, Tufts University School of Medicine; Advisory Professor, Shanghai Medical College, Fudan University; Consultant
- **Paul Beninger, MD, MBA:** Associate Professor and Director MD/MBA Program, Tufts University School of Medicine; Former Vice President of Pharmacovigilance, Genzyme, Inc.; Former Division Director, Medical Devices, US Food and Drug Administration
- **Jeffrey Brown, PhD:** Chief Scientific Officer, TriNetX
- **Christine Carberry, PhD:** Consultant, Carberry Consulting
- **Rob Franco, PhD:** President, Coe Point Management Consultants; Senior Fellow, Tufts Center for the Study of Drug Development; Former Partner, PwC Consulting-Pharmaceutical R&D
- **Les Funtleyder, MPH:** Portfolio Manager-Healthcare, E Squared Capital Management, LLC
- **Kenneth A. Getz, MBA:** Executive Director and Professor, Tufts Center for the Study of Drug Development, Tufts University School of Medicine; Founder and Board Chair, CISCRP
- **Alberto Grignolo, PhD:** Corporate Vice President, Corporation Strategy & Thought Leadership, Parexel
- **Orest Hurko, MD:** Senior Clinical Consultant, Sun Pharma, ApicBio; Adjunct Associate Professor, Tufts University School of Medicine
- **Susan Kornetsky, MPH:** Senior Director, Clinical Research Compliance, Boston Children's Hospital
- **Ron Lanton III, Esq:** Principal, Lanton Law
- **Chandrasekhar Natarajan, BPharm, MSc, MS:** Chief Scientific Officer, ViNa Pharma Consulting; Adjunct Faculty, Tufts University School of Medicine
- **Peter J. Neumann, ScD:** Director, Center for the Evaluation of Value and Risk, Tufts Medical Center; Professor, Tufts University School of Medicine
- **Anita Patel, PharmD:** Deputy, Chief Operating Officer, US Department of Health and Human Services; Former CDC COVID-19 Response Leadership, US Center for Disease Control and Prevention
- **Peter J. Pitts:** President, Center for Medicine in the Public Interest; Former Associate Commissioner, US Food and Drug Administration
- **Prasanna Rao:** Head, Artificial Intelligence and Data Science, Pfizer, Inc.
- **Richard I. Shader, MD:** Professor Emeritus of Immunology and Psychiatry, Tufts University School of Medicine
- **Jerald Schindler, DrPH:** Vice President, Enterprise Statistics, Medtronics, Inc.
- **Mats Sundgren, PhD:** Global Health Informatics Director, Data Science and AI, BioPharmaceuticals R&D, AstraZeneca
- **Ellis F. Unger, MD:** Former Director, Office of Drug Evaluation-I, and Director, Office of Cardiology, Hematology, Endocrinology, and Nephrology, US Food and Drug Administration
- **Pol Vandenbrouke, MD, MSc, MBA, FFPM:** Chief Medical Officer, Hospital Business Unit, Pfizer, Inc.