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

WEEK ONE
Day 1: Wednesday, April 6, 2022
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 Current Drug Development Landscape: Challenges in Pharma R&D | Kenneth Kaitin, PhD

Day 2: Thursday, April 7, 2022
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
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
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**

**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**

**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, Medtronic, 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.