

**Tufts CSDD 2023 Postgraduate Course in Clinical Pharmacology, Drug Development,
and Regulation****WEEK ONE****Day 1: Wednesday, February 1, 2023**

Moderator:	Kenneth I Kaitin, PhD
12:00-12:30pm ET	Welcome, Introduction, Course Objectives Kenneth Kaitin, PhD
12:30-1:30pm	Overview of the Drug Development Process Richard I. Shader, MD
1:30-1:45pm	<i>Break</i>
1:45-3:00pm	Clinical Pharmacology and Translational Medicine – Discovery to Development Chandrasekhar Natarajan, BPharm, MSc
3:00-4:00pm	Target Product Profile (TPP): It's Value in Discovery and Development Christopher Albani, MBA

Day 2: Thursday, February 2, 2023

Moderator:	Kenneth I Kaitin, PhD
12:00-1:00pm ET	Human Research Protection: An Ethical and Regulatory Overview Susan Kornetsky, MPH
1:00-2:00pm	Adaptive Trials: Broad Implementation & Efficient Clinical Development Jerald Schindler, DrPH
2:00-2:15pm	<i>Break</i>
2:15-4:00pm	Regulation of Drug Development in the U.S. and Abroad Mwango Kashoki, MD, MPH

WEEK TWO**Day 3: Wednesday, February 8, 2023**

Moderator:	Kenneth I Kaitin, PhD
12:00-1:00pm ET	Regulatory Science: An Integrated Approach to Evidence Generation for Regulatory Approval and Optimal Label Iman Barilero, PharmD, PhD
1:00-2:00pm	<i>Breakout Group Activity: Go/No-Go Decision Making: Program Valuation and Portfolio Prioritization</i> Rob Franco, PhD
2:00-2:15pm	<i>Break</i>
2:15-3:00pm	Biosimilars: Your Questions Answered Ron Lanton III, Esq
3:00-4:00pm	Vaccine Development: Lessons Learned from the COVID Vaccine Experience Anita Patel, PharmD

Day 4: Thursday, February 9, 2023

Moderator:	Kenneth I Kaitin, PhD
12:00-12:45pm ET	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 sponsor - TBA)
1:45-2:00pm	<i>Break</i>
2:00-3:00pm	Pharmacovigilance, Post-Market Surveillance, and Risk Management Paul Beninger, MD, MBA
3:00-4:00pm	The Changing Landscape for Drug Development: Trends and Challenges in Pharmaceutical R&D Kenneth Kaitin, PhD

WEEK THREE**Day 5: Wednesday, February 15, 2023**

Moderator:	Kenneth I Kaitin, PhD
12:00-12:45pm ET	CMC, Quality, and Clinical Materials Supply Rob Franco, PhD
12:45-1:45pm	Artificial Intelligence and its Use in the Drug Development Process: A Case Study Prasanna Rao
1:45-2:00pm	<i>Break</i>
2:00-3:00pm	Understanding the Medical Affairs Function Pol Vandembroucke, MD, MSc, MBA, FFPM
3:00-4:00pm	Creating a Commercial Strategy: Balancing Public Health and Free Speech Peter J. Pitts

Day 6: Thursday, February 16, 2023

Moderator:	Kenneth I Kaitin, PhD
12:00-1:00pm ET	Measuring the Value of Prescription Drugs Peter J. Neumann, ScD
1:00-2:00pm	Alliance Management Christine Carberry, PhD
2:00-2:15pm	<i>Break</i>
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, China; Consultant
- **Christopher Albani, MBA:** Senior Executive Advisor, PwC Strategy – Japan Healthcare
- **Iman Barilero, PharmD, PhD:** Executive Advisor, Drug Development and Regulatory Sciences; Former Chief Regulatory Science Officer, Solid Biosciences
- **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
- **Susan Kornetsky, MPH:** Senior Director, Clinical Research Compliance, Boston Children’s Hospital
- **Mwango Kashoki, MD, MPH:** Vice President, Regulatory Affairs, Parexel International; Former Associate Director for Safety, and Clinical Team Leader, Center for Drug Evaluation and Research (CDER), US Food and Drug Administration
- **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 of Medicine, Tufts University School of Medicine
- **Anita Patel, PharmD:** Vice President, Pharmacy Services Development, Walgreens; Former 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:** Senior Director, Global Heal of AI/ML Data Monitoring and Management, Pfizer, Inc.
- **Jerald Schindler, DrPH:** Vice President, Enterprise Statistics, Medtronic, Inc.
- **Richard I. Shader, MD:** Professor Emeritus of Immunology and Psychiatry, Tufts University School of Medicine
- **Pol Vandenbrouke, MD, MSc, MBA, FFPM:** Chief Medical Officer, Hospital Business Unit, Pfizer, Inc. (ret)