

DETAILED TUFTS CSDD 2024 POSTGRADUATE COURSE AGENDA

Each speaker will talk for ~45 minutes, leaving 5 minutes for Q&A & a five minute break, if time allows.

FEB 7: The R&D Process

MODERATOR: Kenneth Kaitin, PhD	
Opening Remarks	12:00-12:10pm
Comprehensive Overview of the R&D Process	12:10-1:05pm
Lawrence Friedhoff, MD, PhD Pharmaceutical Special Projects Group, LLC	
The Value of Target Product Profiles	1:05-2:00pm
Chris Albani, MBA PwC Strategy - Japan Healthcare	
Clinical Pharmacology & Translational Medicine	2:00-2:55pm
Koene R.A. Van Dijk, PhD KVD Consulting	
Trends & Challenges Impacting Drug Development	2:55-3:50pm
Kenneth Kaitin, PhD Tufts CSDD, Tufts University School of Medicine	
Wrap Up	3:50-4:00pm

FEB 14: Regulation & Ethical Oversight

MODERATOR: Lindsay McNair, MD, MPH, MSB	
Opening Remarks	12:00-12:10pm
The Global Regulatory Landscape	12:10-1:05pm
Lawrence Liberti, PhD USC D.K. Kim International Center for Regulatory Science	
Regulatory Documentation	1:05-2:00pm
Nancy Pire-Smerkanich, DRSc, MS USC School of Pharmacy	
Collaborating & Engaging with the FDA	2:00-2:55pm
Ameeta Parekh, PhD Food & Drug Administration (FDA)	
Bioethical Principles & the Ethical Review Process	2:55-3:50pm
Lindsay McNair, MD, MPH, MSB Equipoise Consulting	
Wrap Up	3:50-4:00pm

FEB 21: Clinical Development

MODERATOR: Kenneth Getz, MBA	
Opening Remarks	12:00-12:10pm
Protocol Design Strategy & Planning	12:10-1:00pm
John Balser, PhD Veristat	
Breakout Group Activity: Go/No-Go Decision Making	1:00-2:00pm
Robert Franco, PhD Coe Point Associates, LLC; Tufts CSDD	
Collaborating with CROs & Investigative Sites	2:00-2:55pm
Samir Shah, BS Shah Pharma Consulting Services, LLC	
Optimizing Clinical Trial Performance	2:55-3:50pm
Kenneth Getz, MBA Tufts CSDD, Tufts University School of Medicine	
Wrap Up	3:50-4:00pm

FEB 28: Special Topics in Drug Development

MODERATOR: Kenneth Getz, MBA	
Opening Remarks	12:00-12:10pm
AI Use in Drug Development	12:10-1:05pm
Prasanna Rao, BMS Pfizer	
The Role of Integrated Evidence	1:05-2:00pm
Gorana Capkun, PhD Merck KGaA	
Diversity, Equity, & Inclusion	2:00-2:55pm
Jennifer Kim, PhD Tufts CSDD, Tufts University School of Medicine	
CMC/Manufacturing	2:55-3:50pm
Robert Franco, PhD Coe Point Associates, LLC; Tufts CSDD	
Wrap Up	3:50-4:00pm

MAR 1: COVID-Lessons Learned & Pandemic Preparedness

MODERATOR: Kenneth Kaitin, PhD	
Opening Remarks	12:00-12:10pm
Measuring & Demonstrating Prescription Drug Value	12:10-1:05pm
Peter Neumann, ScD Tufts University School of Medicine	
COVID Vaccine Development - Lessons Learned	1:05-2:00pm
Anita Patel, PharmD Walgreens, fmr: CDC	
The New White House Pandemic Preparedness Commission	2:00-3:00pm
Chandresh Harjivan, MBA, MPH, PharmD The White House	
Wrap Up & Networking	3:00-4:00pm

