2018 Agenda for Tufts CSDD's Annual Postgraduate Course in Clinical Pharmacology, Drug Development and Regulation

MONDAY, FEBRUARY 5, 2018

MODERATOR:	**Richard I. Shader, MD**
8:00-8:30 AM	Open Registration, Continental Breakfast
8:30-8:45	Welcome, Orientation, Course Objectives & Introduction | **Kaitin**
8:45-9:45	The Basics of the Drug Development Process and its Phases | **Shader**
9:45-10:00	**Refreshment Break**
10:00-11:00	Translational Medicine - Discovery to Development | **Natarajan**
11:00-12:00 PM	Principles and Perspectives on Clinical Pharmacology | **Collins**
12:00-1:00	**Lunch Break**
MODERATOR:	**Kenneth I Kaitin, PhD**
1:00-2:00	Pharmacogenomics | **Court**
2:00-3:00	Drug-Drug Interactions: Principles and Evaluation in Drug Development | **Venkatakrishnan**
3:00-3:45	Drug Development Regulation Part 1: USA | **Grignolo**
3:45-4:00	**Refreshment Break**
4:00-4:45	Drug Development Regulation Pt. 2: Brief Overview of EU, Japan and Emerging Markets **Grignolo**
4:45-5:45	The Current Environment for Biomedical Innovation: Increasing R&D Efficiency and Productivity **Kaitin**
5:45-8:00	**Networking Reception**

TUESDAY, FEBRUARY 6, 2018

MODERATOR:	**Richard I. Shader, MD**
8:00-8:30 AM	Continental Breakfast
8:30-9:15	The Basics of Clinical Trial Design | **Shader**
9:15-10:00	Protection of Human Subjects/Institutional Review Boards | **Kornetsky**
10:00-10:15	**Refreshment Break**
10:15-11:15	The Role of Chance in Randomized Controlled Trials: Lecture | **Forrester**
11:15-12:00 PM	Evaluating the Role of Chance in Clinical Trials: Workshop | **Forrester**
12:00-1:00	**Lunch Break**
MODERATOR:	**Richard I. Shader, MD**
1:00-2:00	Adaptive Trials Designs: Broad Implementation & Efficient Clinical Development | **Schindler**
2:00-2:15	Instant Experience in Clinical Trials | **Shader**
2:15-3:00	Pre-Mock Drug Group Case Study Lecture | **Boucher**
3:00-5:30	Mock Drug Groups: Session I | **Shader & Boucher**

2018 Agenda for Tufts CSDD's Annual Postgraduate Course in Clinical Pharmacology, Drug Development and Regulation

WEDNESDAY FEBRUARY 7, 2018

MODERATOR:	**Richard I. Shader, MD**
7:30-8:00AM	Continental Breakfast
8:00-10:00	Mock Drug Groups: Session II | **Shader & Boucher**
10:00-10:15	**Refreshment Break**
10:15-11:15	Basics of CMC/Quality in Drug Development | **Morgan**
11:15-12:15PM	Diagnostic-Therapeutic Co-development Strategies and Best Practice | **Rasmussen**
12:15-1:15	**Lunch with Mock Drug Groups**
MODERATOR:	**Kenneth I Kaitin, PhD**
1:15-3:00	Understanding the FDA: An Open Conversation and Q&A | **Unger**
3:00-4:00	Optimizing Protocol Design to Improve Study Conduct Performance | **Getz**
4:00-5:45	Mock Drug Groups: Presentations | **Shader & Boucher**

THURSDAY, FEBRUARY 8, 2018

MODERATOR:	**Kenneth I Kaitin, PhD**
8:30-9:00 AM	Continental Breakfast
9:00-10:00	BioSimilars: Challenges and Opportunities | **Taunton-Rigby**
10:00-11:00	Vaccines and Immunotherapies | **Sardesai**
11:00-11:15	**Refreshment Break**
11:15-12:15 PM	Pharmaceutical Marketing & the New World Order of Advertising, Social Media & Regulation **Housman**
12:15-1:15	**Lunch Break**
MODERATOR:	**Richard I. Shader, MD**
1:15-2:15	Pharmacovigilance & the Scope of Safety | **Beninger**
2:15-2:45	Postmarketing Surveillance & Risk Management of Drugs | **Beninger**
2:45-3:00	Discussion of Postmarketing/Drug Safety Breakout Groups | **Beninger**
3:00-:4:45	Breakout Session: An Interactive Discussion on Postmarketing Surprises & Drug Safety **Beninger, Kaitin & Shader**
4:45-5:45	Postmarketing Presentations | **Beninger, Kaitin & Shader**

FRIDAY, FEBRUARY 9, 2018

MODERATOR:	**Kenneth I Kaitin, PhD**
8:15-8:45 AM	Continental Breakfast
8:45-9:45	Measuring the Value of Prescription Drugs | **Neumann**
9:45-10:45	How to Select and Work with CRO's | **Halloran**
10:45-11:45	Patient Centricity: The Nuts and Bolts | **Stergiopoulos**
11:45-12:00 PM	Course Wrap Up | **Kaitin**