

**TENTATIVE AGENDA FOR TUFTS 2012 POSTGRADUATE COURSE IN
CLINICAL PHARMACOLOGY, DRUG DEVELOPMENT AND REGULATION****Sunday, February 5th**

6:00 – 7:00PM Registration
[Grand Ballroom Foyer]

Monday, February 6th**MODERATOR: Richard I. Shader, M.D.**

8:00 – 8:45AM Open Registration, Continental Breakfast
[Grand Ballroom Foyer]

8:45 – 9:00 Welcome, Orientation, Course Objectives & Introduction Kaitin
[Grand Ballroom]

9:00 – 10:00 The Basics of the Drug Development Process, its Phases, Shader
and Typical Trial Designs
[Grand Ballroom]

10:00 – 10:15 REFRESHMENT BREAK
[Grand Ballroom Foyer]

10:15 – 11:15 Principles of Clinical Pharmacology Collins
[Grand Ballroom]

11:15 – 12:15PM Clinical Pharmacology: Focus on PK and Phase I Curry
[Grand Ballroom]

12:15 – 1:30 LUNCH
[Main Dining Room]

MODERATOR: Kenneth I. Kaitin, Ph.D.

1:30 – 2:30 The Current Environment for Pharmaceutical Development Kaitin
[Grand Ballroom]

2:30 – 3:30 Innovative Clinical Design Strategies Butz
[Grand Ballroom]

3:30 – 3:45 REFRESHMENT BREAK
[Grand Ballroom Foyer]

3:45 – 5:45 Drug Development Regulation: USA, EU and a Brief Overview of Grignolo
Japan, China, Latin America and India
[Grand Ballroom]

5:45 – 8:00 RECEPTION
[Main Dining Room]

Tuesday, February 7th**MODERATOR: Richard I. Shader, M.D.**

8:00 – 8:30AM	Continental Breakfast <i>[Grand Ballroom Foyer]</i>	
8:30 – 9:15	Protecting People in Research: Reviewing, Approving and Managing Research Involving Human Subjects <i>[Grand Ballroom]</i>	Russell-Einhorn
9:15 – 10:00	Protecting People in Research: Group Exercise/Workshop <i>[Grand Ballroom]</i>	Russell-Einhorn
10:00 – 10:15	REFRESHMENT BREAK <i>[Grand Ballroom]</i>	
10:15 – 11:15	Evaluating the Role of Chance in Clinical Trials <i>[Grand Ballroom]</i>	Forrester
11:15 – 12:00PM	Evaluating the Role of Chance in Clinical Trials: Group Exercise/Workshop <i>[Grand Ballroom]</i>	Forrester
12:00 – 1:15	LUNCH <i>[Main Dining Room]</i>	
MODERATOR: Richard I. Shader, M.D.		
1:15 – 2:15	Pharmacogenomics and Drug Development <i>[Grand Ballroom]</i>	Court
2:15 – 2:30	Instant Experience in Clinical Trials <i>[Grand Ballroom]</i>	Shader
2:30 – 5:00	Mock Drug Groups: I <i>[As Assigned to: Arlington, Garden, Back Bay, Commonwealth and Newbury Rooms]</i>	Shader Boucher

Wednesday, February 8th**MODERATOR: Richard I. Shader, M.D.**

7:30 – 8:00AM	Continental Breakfast <i>[Grand Ballroom Foyer]</i>	
8:00 – 10:00	Mock Drug Groups: II <i>[As Assigned to: Arlington, Garden, Back Bay, Commonwealth and Newbury Rooms]</i>	Shader Boucher
10:00 – 10:15	REFRESHMENT BREAK <i>[Grand Ballroom Foyer]</i>	
10:15 – 11:15	Clinical Trial Design to Support Comparative Claims: Building a Successful Marketing Strategy for Drug Development <i>[Grand Ballroom]</i>	Sietsema
11:15 – 12:15PM	Life Sciences and Healthcare Information: Creating Value, Defining Challenges <i>[Grand Ballroom]</i>	Bleicher
12:15 – 1:30	LUNCH <i>[Main Dining Room]</i>	

MODERATOR: Kenneth I. Kaitin, Ph.D.

1:30 – 3:00	Understanding the FDA <i>[Grand Ballroom]</i>	Kweder
3:00 – 3:15	REFRESHMENT BREAK <i>[Grand Ballroom Foyer]</i>	
3:15 – 4:15	Biotechnology Products: The Clinical Challenges <i>[Grand Ballroom]</i>	Taunton- Rigby
4:15 – 5:45	Mock Drug Groups: Presentations <i>[As Assigned to: Grand Ballroom and Taj Room]</i>	Shader Boucher

Thursday, February 9th

MODERATOR: Kenneth I. Kaitin, Ph.D.

8:30 – 9:00AM	Continental Breakfast <i>[Grand Ballroom Foyer]</i>	
9:00 – 10:00	The Role of Epidemiology in Drug Research <i>[Grand Ballroom]</i>	Velentgas
10:00 – 11:00	Patient Adherence and Persistence in Trials & Practice <i>[Grand Ballroom]</i>	Urquhart
11:00 – 11:15	REFRESHMENT BREAK <i>[Grand Ballroom Foyer]</i>	
11:15 – 12:15PM	Development of Drug-Device Combination Products and Regulation <i>[Grand Ballroom]</i>	Richner
12:15 – 1:15	LUNCH <i>[Main Dining Room]</i>	
MODERATOR: Richard I. Shader, M.D.		
1:15 – 2:00	The Evolving Role of Safety in the Drug Development Process <i>[Grand Ballroom]</i>	Beninger
2:00 – 2:45	Postmarketing Surveillance & Risk Management of Drugs <i>[Grand Ballroom]</i>	Jones
2:45 – 3:00	Discussion of Postmarketing/Drug Safety Break Out Groups <i>[Grand Ballroom Foyer] [As Assigned]</i>	Jones
3:00 – 4:45	Breakout Session: An Interactive Discussion on Postmarketing Surprises & Drug Safety <i>[As Assigned to: Arlington, Garden, Back Bay, Commonwealth and Newbury Rooms]</i>	Jones Kaitin Shader
4:45 – 5:45	Postmarketing Presentations <i>[Grand Ballroom]</i>	Jones Kaitin Shader



Friday, February 10th

MODERATOR: Kenneth I. Kaitin, Ph.D.

8:15 – 8:45AM	Continental Breakfast <i>[Grand Ballroom Foyer]</i>	
8:45 – 9:45	Outcomes Research: Measuring the Value of Pharmaceutical Therapies <i>[Grand Ballroom]</i>	Neumann
9:45 – 10:45	How to Select and Work with CRO's <i>[Grand Ballroom]</i>	Halloran
10:45 – 11:45	Opportunities to Leverage Partnerships with Sites and Study Volunteers <i>[Grand Ballroom]</i>	Getz
11:45 – 12:00PM	Course Wrap Up <i>[Grand Ballroom]</i>	Kaitin

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