

GS13 1111: Case Studies in Drug Development (2-Week Crash Course, August 16-27, 2021)

Week 1	Monday, August 16	Tuesday, August 17	Wednesday, August 18	Thursday, August 19	Friday, August 20
	Merck Course Lectures				
	Additional morning lectures				
8:30	No class	Welcome, Intros, and Overview	Coffee and discussion: Takeaways or lingering questions from previous day	Coffee and discussion: Takeaways or lingering questions from previous day	Coffee and discussion: Takeaways or lingering questions from previous day
8:45					
9:00		Target Identification (30+15)	Lead optimization 20+10	Introduction to vaccines (10) and Vaccine classification and Mfg (20) + 15 min designated discussants	Formulation Activities (25+20)
9:15					
9:30			Group discussion		
9:45		Group Discussion		Group discussion	Group discussion
10:00		Break		Break	Break
10:15		Target Validation (30+15)	Biologics (30+15)	Vaccine development and safety monitoring (20+10)	Drug Metabolism and Pharmacokinetics (30+15)
10:30			Group discussion		
10:45			Break	Group discussion	
11:00		Group Discussion			Group discussion
11:15		Lead Identification (20 + 10)	Cell therapies <u>TBD</u>	AI in Drug Discovery; Suman	Nonclinical safety assessment 20 +10
11:30					
11:45		Group Discussion	RNA Therapeutics; John Cooke	DNA Therapeutics <u>TBD</u>	Group discussion
12:00		Lunch	Lunch	Lunch	Lunch
12:15					
12:30					
12:45					
1:00					
1:15			Small molecules <u>TBD</u>	Neurotherapeutics, <u>TBD</u>	
1:30					
1:45		Live lecture - TPP, Jim Liu			Live lecture - Tox studies; Ruiwen Zhang, Jeff Larson
2:00		TPP	Live lecture - IP; Panel from TTO	Live lecture - Needs Assessment &	Case study - or facilitated discussion

2:15			offices	Market Analysis; Rick Silva	
2:30			Case study - or facilitated discussion	Case study - or facilitated discussion	
2:45					
3:00					
3:15					
3:30		Resource Round Table; HTS Cliff Stephan, Imaging Mike Mancini	Resource Round Table; Antibody Zhiqiang An, RNA therapeutics core John Cooke	Resource Round Table; Vaccines or DNA therapies?	Resource Round Table; PK/PD and Formulation Liang, Xie, Chow
3:45					
4:00					
4:15					
4:30					
Week 2	Monday, August 23	Tuesday, August 24	Wednesday, August 25	Thursday, August 26	Friday, August 27
8:30	Coffee and discussion: Takeaways or lingering questions from previous day	Coffee and discussion: Takeaways or lingering questions from previous day	Coffee and discussion: Takeaways or lingering questions from previous day	Coffee and discussion: Takeaways or lingering questions from previous day	Coffee and discussion: Takeaways or lingering questions from previous day
8:45					
9:00	Clinical development plan (10 + 5)	Importance of patient diversity in CTs (50+25)	Who regulates? (15+10)	Phases 3b and 4 (15+15)	
9:15	Phase 1 Trials (50 +25)				
9:30			Group discussion	Group discussion	
9:45			Drug labeling (25 + 10)	Post Market Regulatory Activities (40 +20)	
10:00					
10:15		Group discussion	Group discussion		CTTP Fellows Research Presentations (6@ 10+5)
10:30	Group Discussion	Break	Break		Break
10:45	Break	Patient Engagement in CTs (35 + 10)	Global regulatory strategy (20+10)	Break	
11:00	Phase 2 trials (20 +10)			Group discussion	
11:15			Group discussion		
11:30	Phase 3 trials (40+20)	Group discussion	New drug application and FDA review and approval process (35 + 15) + 10 min for group discussion	Outsourcing vs Insourcing studies; TBD	
11:45					CTTP Fellows Research Presentations (6@ 10+5)
12:00	Lunch	Lunch	Lunch	Lunch	

12:15					Lunch
12:30					
12:45					
1:00					
1:15	Group discussion on P2-3 Trials	Live Lecture - TSU Community Engagement Core: increasing recruitment of URMS in CTs; Veronica Ajewole	Live Lecture - FDA road map Johnny Lau, FDA	Live lecture - Academic Industry Partnerships vs Starting a biotech; ???	Training plan discussion and IDP development
1:30	Live Lecture - CTs; Sujatha Sridhar UTH				
1:45					
2:00		discussion	Case study - or facilitated discussion	Case study - or facilitated discussion	
2:15					
2:30	Case study - or facilitated discussion				Final Thoughts and Motivation: Cancer Therapeutics Landscape- Needs and Opportunities; Phil Jones
2:45					
3:00					
3:15					
3:30	Resource Round Table; CDD Damian and Marty	Resource Round Table; Flow Margie	Resource Round Table; Medicinal Chemistry; Stanton, Amit, Scott	Resource Round Table; ACT, Fannin	Happy Hour Reception???
3:45					
4:00					
4:15					
4:30					