Emerging Issues in Clinical Trials for New ARV Development
September 30, 2010
The Forum for Collaborative HIV Research and Food and Drug Administration
UC Washington Center
1608 Rhode Island Ave, NW
Washington DC 20036

	Topic	Speaker	
7:30 AM	Breakfast		0:30
8:00 AM	Introduction	Veronica Miller	0:05
8:05 AM	Goals and Objectives	Jur Strobos	0:05
8:10 AM	Current and Projected Needs for New Drugs	Bob Huff	0:05
	Panel I General Developments in Clinical Trials. Goal: Introduction to Non-Inferiority and Adaptive Design Moderator: Jur Strobos		
8:15 AM	Non-Inferiority - Statistical Concerns	Victor De Gruttola	0:20
8:35 AM	Non-inferiority from the FDA Perspective: FDA Guidance	Kimberly Struble	0:10
8:45 AM	EMA - New Perspectives	Filip Josephson	0:10
8:55 AM	Practical Implications of Adaptive Design	Michael Rosenblum	0:15
9:10 AM	Adaptive Design - Thoughts Outside the Box	L.J.Wei	0:10
9:20 AM	Panel Discussant	Greg Soon	0:15
	Panel II Recent Clinical Trial Experience Goal: Recent Drug Development Experience Moderators: Trip Gulick and Filip Josephson		
9:35 AM	Vicroviroc/Merck	Wayne Greaves	0:10
9:45 AM	Elvitegravir/Gilead	Brian Kearny	0:10
9:55 AM	GSK Integrase Inhibitor	Sara Hughes	0:10
10:05 AM	ATC (Avexa)/New Concepts	Susan Cox	0:10
10:15 AM	Discussion	All	0:20
10:35 AM	COFFEE BREAK		0:15
	Panel III Trial Designs and Drug Development Issues in Treatment Experienced Patients. Goal: Trial Model Proposals, Issues that Impact Trials and Possible Solutions Moderators: Veronica Miller and Jeff Murray		
10:50 AM	Proposals for Treatment Experienced Patients	Bob Huff	0:05
10:55 AM	Drug Development Proposal for Heavily Treatment Experienced Patients.	Jeff Murray	0:30
11:25 AM	EMA TBD	Filip Josephson	0:10
11:35 AM	Industry Panel Discussion	BMS, TaiMed, Avexa, GSK, Merck	0:15
11:50 AM	Community Proposal	Nelson Vergel	0:10
12:00 PM	Panel Discussion. 1. • Pros and cons of proposals presented by FDA, EMA, Industry and Community, pitfalls and pearls. • Feasibility - investigator and patient acceptance. 2. Management of optimized background regimen: Switches - None, one in class or across class due to toxicity 3. Newer viral load assays, and management of blips. 4. New or different endpoints such as, • Mean change • Proportion < 50 copies/mL • Proportion < 200 copies/mL (ACTG)	All	1:00
1:00 PM	LUNCH		0:30

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	Panel III Continued: More Thoughts After Lunch Moderators: Veronica Miller and Jeff Murray		
1:30 PM	Continued from Before Lunch	All	1:45
	Panel IV Treatment Naive Patients Goal: Rationale for Investigational Agent Use in Treatment Naïve Patients Moderators: Kim Struble, Jur Strobos		
3:15 PM	Criteria for Enrolling Treatment Naive Patients	Bob Huff	0:10
3:25 PM	The Maraviroc Experience and the Future	Jayvant Heera, Hernan Valdez, David Martin	0:20
3:45 PM	Regulatory Considerations for Treatment Naïve Patients	Filip Josephson (EMA), Deborah Birnkrant (FDA)	0:15
4:00 PM	Panel Discussion. 1. Should low CD4 or other criteria exclude treatment-naïve patients from dose finding trials? 2. Should biomarkers (e.g. inflammatory) be evaluated in treatment-naïve trials to permit assessment of correlation with long-term safety? If yes, which biomarkers? 3. Early clinical safety data as criteria for treatment naive studies.	All	0:25
4:25 PM	Summing Up	Jur Strobos	0:05
4:30 PM	Adjournment		