Forum for Collaborative HIV Research
Rethinking the Design of Clinical Trials for the Development of New ARVs for

Doubletree Hotel
1515 Rhode Island Ave, NW
Washington, DC 20005

AGENDA

January 11, 2008 **Clinical Trials for Treatment Naïve Patients**

7:30 - 8:30	**BREAKFAST**	
8:30 - 9:20	**SESSION 1**	**Moderators:** **Ben Cheng & Bob Huff**
8:35 - 8:55	Overview: Do we need new drug for treatment naïve patients?	Richard Haubrich & Beatriz Grinsztejn
8:55 - 9:05	Community Comments	Robert Camp & Simon Collins
9:05 - 9:15	Industry Comments	Stephen Becker & Andrew Cheng
9:15 - 9:25	NIH Comments	Carl Dieffenbach
9:25 - 12:00	**SESSION 2**	**Moderators:** **Sandra Palleja & Judy Aberg**
9:25 -9:45	EMEA Perspective	Nathalie Morgensztejn
9:45 - 9:55	FDA Comments	Jeff Murray
9:55 - 10:40	**Panel Discussion**	
	What amount and type of data is needed prior to initiating studies in treatment naive patients? When/how is it acceptable to do initiate dose finding studies in treatment naive patients? What is the appropriate study duration to establish safety and efficacy for a treatment naive indication (currently FDA requirement is 48 weeks or longer)	Panelists: Ian Weller David Haerry Martin Delaney Scott McCallister Doug Mayers Victor DeGruttola
10:40 - 11:05	General Discussion	
11:05 - 11:30	**Coffee Break**	
11:30 - 12:00	**SESSION 3** Summing Up and Next Steps	**Moderators:** **Ian Weller, Trip Gulick &** **Veronica Miller**
12:00	**Lunch and Adjorn**	