

Forum for Collaborative HIV Research
HCV DRAG Meeting #5: Clinical Trial Design
November 2, 2010
Sheraton Boston ~ Boston, MA
Commonwealth meeting room (third floor)

AGENDA

1:00 -2:00 PM		BUFFET LUNCH ~ Fairfax meeting room (third floor)	
2:00pm	10.00	Welcome & Introductions	Nina Mani, Jean-Michel Pawlotsky
2:10pm	10.00	Brief Recap of HCV DRAG & Review of Meeting Goals	Dale Kempf
2:20pm	20.00	Criteria for Liver Biopsy	Moderator: Ira Jacobson Discussants: Jeff Murray; Filip Josephson
2:40pm	20.00	Is it ever advisable to reduce DAA doses in trials? Stopping rules for breakthrough and lack of viral load decline on treatment	Moderator: Jean-Michel Pawlotsky Discussants: Jennifer Kiser, Ann Kwong, Ira Jacobson
3:00pm	10.00	Discussion	
3:10pm	15.00	HCV Viral Load Thresholds	Moderator: Michelle Berrey Discussants: Gaston Picchio, James Thommes
3:25pm	20.00	Discussion	
3:45pm	15.00	Consensus on HCV Clinical Trial Terms and Definitions: The Way Forward (WG?)	Moderator: Heiner Wedemeyer Discussants: Tracy Swan, Stefan Zeuzem
4:00pm	10.00	Discussion	
4:10pm	15.00	COFFEE BREAK	
4:25pm	20.00	FDA and EMA viewpoint: Considerations for Trials with Two or More DAA (Patient population for proof of concept trials: Regulatory perspectives)	Moderator: Stefan Zeuzem Discussants: Jeff Murray and Filip Josephson
4:45pm	20.00	Discussion	
5:05pm	30.00	Trials in Special populations: Amount of data needed for initial approval vs. subsequent approval for decompensated patients and co-infected patients (regulatory and patient perspectives)	Moderator: Stuart Ray Discussants: Jeff Murray, Filip Josephson, Tracy Swan, Mark Antell, Geoff Dusheiko, Xavier Forns, Don Jensen
5:35pm	30.00	Discussion	
6:05pm	20.00	Opportunities for Clinical Studies of Combinations with Multiple Companies	Moderator: Ira Jacobson Discussants: Ken Sherman, Juergen Rockstroh
6:25pm	10.00	Discussion	
6:35pm	5.00	Summary of Meeting	Dale Kempf, Nina Mani
6:40pm	20.00	FDA-FCHR (EMA) Open Public Meeting (Steering Committee)	Veronica Miller, Nina Mani
7:00pm		Adjourn	
7.30 PM		DINNER Grill 23 & Bar 161 Berkeley Street ~ Boston, MA ~ 617-542-2255	