

HCV DRAG

Drug Resistance Advisory Group

DRug development Advisory Group

HCV DRAG Meeting #5
November 2, 2010

HCV DRAG: Steering Committee

- Ira Jacobson
- Filip Josephson
- Dale Kempf
- Ann Kwong
- Veronica Miller
- Isabel Najera
- Jules O'Rear
- Jean-Michel Pawlotsky
- Stuart Ray
- Kimberly Struble
- Tracy Swan

Nina Mani
Forum for Collaborative HIV Research

HCV DRAG: Purpose and Goals

- Purpose:
 - Bring together parties interested in and working in HCV drug resistance to discuss issues pertinent to HCV drug development and resistance testing
 - Composition: representatives from industry, academics, government, advocacy and regulatory agencies
- Goals:
 - Produce consensus recommendations of appropriate methodology for HCV resistance testing
 - For drug development
 - For clinical practice
 - Provide scientific guidance to facilitate discussion between industry, regulatory agencies, and other parties integral to HCV drug development and resistance

HCV DRAG: Update of Activities

- Manuscripts
 - Two manuscripts submitted to *Gastroenterology*
 - Sequence Analysis Working Group (SAWG)
 - Phenotype Working Group (PWG)
 - Requested by editors to combine manuscripts
 - Combined manuscript under review
- HCV Resistance Slide Set
- Public meeting
 - Jointly sponsored by HCV DRAG, FDA and EMA
 - Scheduled for Dec 6, 2010, Washington, DC

HCV DRAG: Today's Meeting

- Issues for clinical development of DAAs
 - Liver biopsies
 - Stopping rules
 - Viral load thresholds
 - Terms and definitions
- Combination DAA trials
- Trials in special populations