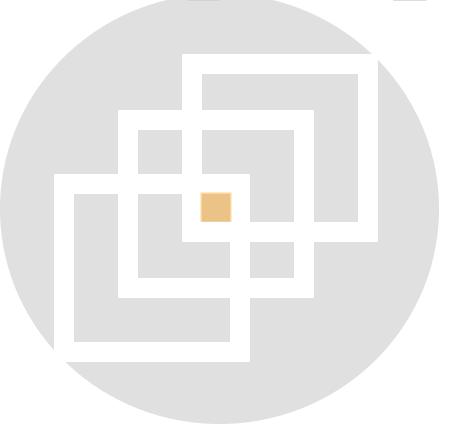


HCV <u>D</u>RUG <u>R</u>ESISTANCE <u>A</u>DVISORY <u>G</u>ROUP/ HCV <u>DR</u>UG DEVELOPMENT <u>A</u>DVISORY <u>G</u>ROUP (HCV DRAG)





HCV DRAG: STEERING COMMITTEE

- Ira Jacobson
- Filip Josephson
- Dale Kempf
- Ann Kwong
- Nina Mani
- Veronica Miller
- Isabel Najera

- Jules O'Rear
- Jean-Michel Pawlotsky
- Stuart Ray
- Jur Strobos
- Kimberly Struble
- Tracy Swan



HISTORY

- 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 and regulatory agencies, patient advocates

Goals:

- Produce consensus recommendations of appropriate methodology for HCV resistance testing for drug development and clinical practice
- Provide scientific guidance to facilitate discussion on clinical trial designs between industry, regulatory agencies, and other parties integral to HCV drug development
- First meeting: May, 2007



HCV DRAG MEETINGS

- DRAG 5: Nov 2, 2010, Boston
 - Issues for clinical development of DAAs
 - Invasive vs. non-invasive dx of liver fibrosis
 - Stopping rules
 - Viral load thresholds
 - Clinical trials terms and definitions: Formation of new WG
 - Combination DAA trials
 - Inclusion of special populations in clinical trials
- DRAG 6: March 30, 2011, Berlin
 - Working group updates
 - SAWG: deep sequencing
 - PWG: HCV DRAG resistance table
 - DWG: clinical trials terms and definitions
 - Issues for clinical development of DAAs
 - Combination DAA trials
 - Special populations and locations

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KEY RECENT ACTIVITIES

- Public Meeting, Dec. 6, 2010, Washington
 - Advancing HCV Drug Development: A Collaborative Approach
 - ~ 200 attended: ~110 on-site and 80 webcast
 - Goal: Obtain comment on future trial designs and endpoints
- Publication: Gastroenterology, 2011;140:755-760
 - Sequence and Phenotypic Analysis for Resistance Monitoring in Hepatitis C Virus Drug Development: Recommendations From the HCV DRAG
 - Combined work of the Sequence Analysis Working Group (SAWG) and Phenotype Working Group (PWG)
- Resistance slide set
 - Available at Forum website as well as at EASL, AASLD, IDSA and ESCMID