



**HCV DRUG RESISTANCE  
ADVISORY GROUP/  
HCV DRUG DEVELOPMENT  
ADVISORY GROUP (HCV DRAG)**





*enhancing & facilitating HIV research*

# HCV DRAG: STEERING COMMITTEE

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- 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

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- **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

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- **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



# KEY RECENT ACTIVITIES

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- 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