HCV

***D*rug**

***R*esistance**

***A*dvisory**

***G*roup**

HCV DRAG: History

- Outgrowth of proposal at the 1st International Workshop on Hepatitis C: Resistance and New Compounds (October, 2006)
- *Ad hoc* group approached the Forum for Collaborative HIV Research for organizational support

HCV DRAG: Structure

- Participants
  - Scientists responsible for HCV genotypic and phenotypic clinical virology studies required for the conduct of clinical trials
  - Scientists from academia and industry
- Advisors
  - Experts in HIV and HBV resistance studies
- Organizing Committee
  - Ann Kwong, Charles Boucher, Chip Schooley, Dale Kempf, Jules O'Rear, Neil Parkin, Nick Cammack
  - Ben Cheng, Veronica Miller

HCV DRAG: Purpose

- Bring together parties interested in and working in HCV drug resistance to discuss issues pertinent to HCV drug/biologic development and resistance testing

HCV DRAG: Goals

- Produce consensus recommendations of appropriate methodology for HCV resistance testing
  - For drug/biologic development
  - For clinical practice
- Provide scientific guidance to facilitate discussion between industry and regulatory agencies in areas of HCV drug resistance

HCV DRAG: Methods

- Facilitated discussion between representatives from pharmaceutical/biotech companies, academic institutions and regulatory agencies
  - Two meetings per year
  - Teleconference/email
  - Working groups dedicated to specific topics
    - Genotype — Ann Kwong
    - Phenotype — Neil Parkin
    - Clinical — Chip Schooley

HCV DRAG: Measurables

- Presentations/abstracts
  - AASLD, EASL
  - HCV Resistance Workshops
- White papers/manuscripts
  - Consensus guidelines

HCV DRAG: Today's Goals

- Identify the questions:
  - Genotype
  - Phenotype
  - Clinical
- Form working groups
- Define timetables for action items

HCV DRAG: Today's Agenda

HBV/HIV lessons learned	Scott Bowden, Doug Richman
Regulatory perspective	Jules O'Rear
Genotype	Ann Kwong
Clinical	Chip Schooley
Phenotype	Neil Parkin
Group discussion/next steps/timelines	Group