



HCV TRIALS IN THE POST- APPROVAL ERA OF TELAPREVIR AND BOCEPREVIR – THE WAY FORWARD

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**Forum for Collaborative HIV
Research**



MEETING PLANNING COMMITTEE

enhancing & facilitating HIV research

- Michelle Berrey, MD
- Victoria Cargill, MD, MSCE
- Ira Jacobson, MD
- Filip Josephson, MD, PhD
- Dale Kempf, PhD
- Ann Kwong, PhD
- Nina Mani, PhD MPH
- Veronica Miller, PhD
- Isabel Najera, PhD
- Jules O'Rear, PhD
- Jean-Michel Pawlotsky, MD, PhD
- Stuart Ray, MD
- Kimberly Struble, PharmD
- Tracy Swan



MEETING OBJECTIVES

- Approval of two direct acting antivirals (DAAs) led to an era of a new standard of care for chronic HCV treatment
- Objective: Discuss the design and utility of the control arm in trials for investigational HCV agents in Phase 3 trials
- Specifically:
 - Control arms for P/R + DAA trials
 - Control arms for interferon-sparing DAA (+/- RBV) trials
 - Logistical Issues with choice of control arm in International trials



MEETING FORMAT

- Formal presentations
- Followed by moderated panel discussions in Sessions 1-3:
 - Introduction of panelists
 - Discussion of questions posed by moderators
 - Questions from the floor and call-in participants to panelists